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Chronic Pelvic Pain in women

Group-based multimodal physical therapy

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Abbreviations

ACT, acceptance and commitment therapy

ASN, Ane Sigrid Nygaard

CI, confidence interval

CPP, chronic pelvic pain

EAU, European Association of Urology

HSCL-25, Hopkins symptom check list-25

IASP, The International Association for the Study of Pain

IQR, inter quartile range

MFE, Marthe Figenschau Eikedal

NRS, numeric rating scale

PT, physical therapy

RCT, randomized controlled trial

SD, standard deviation

SHC, subjective health complaints

UNN, University Hospital of North Norway

List of papers

I. **Nygaard AS**, Stedenfeldt M, Øian P, Haugstad GK. *Characteristics of women with chronic pelvic pain referred to physiotherapy treatment after multidisciplinary assessment: a cross-sectional study*. Scand J Pain, 2019; 19 (2): 355-364. Doi: 10.1515/sjpain-2018-0308

II. **Nygaard AS**, Rydningen M, Stedenfeldt M, Wojniusz S, Larsen M, Lindsetmo RO, Haugstad GK, Øian P. *Group-based multimodal physical therapy in women with chronic pelvic pain: A randomized controlled trial*. Acta Obstet Gynecol Scand. 2020;00:1–10. Doi: 10.1111/aogs.13896

III. **Nygaard AS**, Haugstad GK, Wilsgaard T, Øian P, Stedenfeldt M. *Baseline pain characteristics predict change in pain intensity after physical therapy treatment in women with chronic pelvic pain. Secondary analysis of data from a randomized controlled trial.* Scand J Pain. Published online: 30 Jun 2020. Doi: 10.1515/sjpain-2020-0026

Abstract

Background and aims: Chronic pelvic pain (CPP) is a common and complex condition, defined as pain perceived in structures related to the pelvis. Clinical guidelines recommend a bio-psycho-social management, with physical therapy included as one of multiple modalities. The ideal content and organization of such a management approach is unknown. The main aims of this PhD-thesis were 1) to describe the characteristics of women with CPP that were referred to physical therapy after evaluation at a tertiary hospital, 2) to compare the change in the mean pain intensity between women randomized to group-based multimodal physical therapy with women randomized to primary care physical therapy, and 3) to explore if selected pre-treatment characteristics were associated with change in pain intensity.
Methods: Cross-sectional data of the participants were collected at baseline, and descriptive statistics applied. For comparison of the two interventions a randomized controlled trial (RCT) was conducted, and primary analyses performed with the Independent Samples T-test. Associations between baseline variables and change in pain intensity were investigated with a multivariable linear regression model.
Results: The baseline data showed that women with CPP are a heterogeneous group with complex symptoms and high scores for both physical and psychological complaints. Women exposed to abuse have high scores related to analgesic use, sick leave, obstructed defecation, anxiety and subjective health complaints. Women with previous pelvic surgery report more analgesic use and sick leave, and lower pain intensity during intercourse, than those without previous surgery. In the RCT 26 women in the intervention group and 25 in the comparator group were available for data analysis. The group-difference in change in the mean pain intensity score was −1.2 (95% confidence interval, −2.3 to −0.2; p=0.027), favoring the intervention group. Pelvic pain for six years or more was associated with less pain reduction, and higher baseline pain intensity was associated with higher pain reduction after physical therapy treatment.
Conclusions: Women with CPP represent a heterogeneous group, many with complex symptoms of both physical and psychological complaints. The reduction in the mean pain intensity from baseline to 12-months was significantly greater in the intervention group than in the comparator group, but the group-difference was small and the clinical relevance is uncertain. We hypothesize that pain duration and pain severity are of distinct importance in terms of treatment outcome. The results in the three papers implicate that further investigation of subgroups within the condition CPP may be useful.

1 Introduction

Chronic pelvic pain (CPP) is a common and debilitating condition that has large individual and societal consequences.[1-3] It is described as a complex condition, and defined as pain perceived in structures related to the pelvis.[4]

Longstanding pain in the pelvic area has probably been a problem through long times, but the amount of research has been sparse, mainly focusing on organic causes of CPP. In 1991, a randomized controlled trial (RCT) showed positive effects of an integrated approach with attention on organic, psychological, dietary and environmental factors.[5] Examination by a physical therapist was included, and the trial from 1991 represents the start of a new perspective on CPP-treatment. In the following decade, two non-randomized studies on psychosomatic physical therapy, a branch that equally addresses the physical and psychological dimensions of health, showed promising results.[6, 7]

The amount of studies on CPP has increased dramatically since the early nineties. There has been a shift in clinical guideline recommendations over the last 10 years, and the current recommendations include physical therapy, patient education and active patient involvement in a bio-psycho-social management.[4, 8] Systematic reviews of physical therapy and other non-invasive treatments for CPP conducted during the last decade conclude that there are promising results for treatments that combine different modalities, but the evidence base is sparse and there is a need of more high quality knowledge both about the condition and about best management.[9-12]

During the years 2008-2014 a group-based multimodal physical therapy program for patients with CPP was developed at the University Hospital of North Norway (UNN), as a cooperation between the Department of Physical Therapy and the Norwegian National Advisory Unit on Incontinence and Pelvic Floor Health. The contents of the multimodal program were largely inspired by studies on CPP showing positive results of integrated care as well as physical therapy treatments that combined bodily and cognitive approaches.[5-7, 13] As the multimodal program at UNN seemed to be a successful treatment option, the need for a systematic evaluation emerged. The purpose of this thesis was to investigate the characteristics of the women that were referred for physical therapy after assessment at a tertiary hospital, to evaluate the effectiveness of a group-based multimodal physical therapy program, and to

explore if selected pre-treatment characteristics were associated with change in pain intensity after treatment. To the best of our knowledge this is the first RCT that evaluates a group-based multimodal intervention that includes physical therapy for women with CPP.

In the following chapter the theoretical and empirical background for the study is presented. First, the condition CPP is described in terms of definition, classification and epidemiology. The anatomy of the female pelvis is briefly reviewed, before the underlying causes and suggested pain mechanisms related to CPP is described. A review of the literature describing characteristics of women with CPP, and the evidence base for multimodal treatment that includes physical therapy is given. Based on this background, the overall aims of the thesis are presented and the methodology that was applied described. The main results are shortly presented, followed by an interpretation of the results and a thorough discussion of methodological aspects of the thesis. Finally, the conclusions based on our findings, clinical implications and suggestions for further research are presented.

2 Background

Chronic pelvic pain

Definitions

The core of the condition CPP is the experience of pain. The International Association for the Study of Pain (IASP) currently states that:

> "**Pain** is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage."[14]

Pain is further described in terms of being acute or chronic. The current definition of chronic pain is:

> "**Chronic pain** is pain that lasts or recurs for longer than three months"[15]

Various definitions have been used for CPP, but publications from the last decade seem to agree that CPP is pain in the pelvic area that has lasted for three to six months.[16-18] In this thesis we apply the definition of CPP published by the European Association of Urology (EAU). This definition is centered on pain instead of being organ-centered, and thus in accordance with the IASP definition of pain as a subjective experience. The EAU states that:

> "**Chronic pelvic pain** is chronic or persistent pain perceived in structures related to the pelvis that has been continuous or recurrent for at least six months (…) and often associated with negative cognitive, behavioral, sexual, and emotional consequences, as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, or gynecological dysfunction".[4]

The term "perceived" indicates that the patient and clinician, to the best of their ability have localized the pain as being perceived in the specified anatomical pelvic area.[4] The definition includes dyspareunia (pain during intercourse) and cyclic pain (eg. dysmenorrhea), if these are associated with negative cognitive, behavioral, sexual, and emotional consequences. Pelvic girdle pain is not included in the term CPP.

Other frequently applied definitions of the condition is by the Royal College of Obstetricians and Gynecologists, that defines CPP as ”intermittent or constant pain in the lower abdomen or pelvis of a woman of at least six months in duration, not occurring exclusively with menstruation or intercourse and not associated with pregnancy”.[18] The American College of Obstetricians and Gynecologists defines CPP as “pain originating from pelvic organs or structures and lasting >6 months”.[17]

Underlying causes and pain mechanisms

It is suggested that the condition CPP is best understood as an end symptom with multiple possible etiologies, each contributing to the result of chronic pain in the pelvic area.[18, 19] The contributory etiologies may be associated with urological, gastrointestinal, musculoskeletal, gynecological, neurological or psychosocial conditions. In the following paragraphs the different pain mechanisms that are described in relation to the development of CPP will be presented based on the **bio-psycho-social model**. This model explain pain and disability, and a person’s perception of and response to it, as a dynamic interaction between multiple factors.[19, 20, 21, 22] Different pain mechanisms may occur simultaneously, and the same presenting symptoms may have different underlying mechanisms.[22] Figure 1 shows a bio-psycho-social model of CPP.

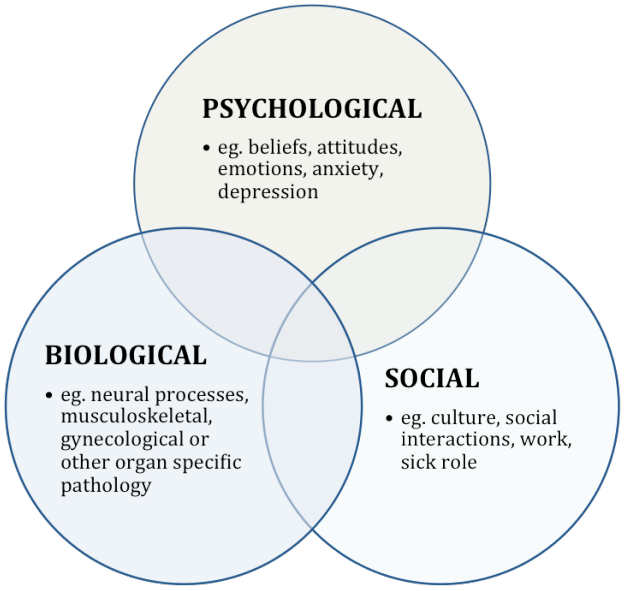

Figure 1 A bio-psycho-social model of chronic pelvic pain.

Adapted from Gatchel et al. 2007, Chimenti et al. 2018 and As-Sanie et al. 2020.

Biological pain mechanisms are closely related to processes in the peripheral and central nervous system, and to brain network activity. Three main categories of neural processes are described.[23, 24, 25] Nociceptive processes are transmission of information of an actual or potentially tissue-damaging event. The information is encoded by nociceptors, which are high-threshold sensory receptors of the peripheral somatosensory nervous system.[25] Neuropathic and nociplastic processes involve the central nervous system and are especially related to chronic pain conditions.[4] The main characteristics of the different mechanisms are described in Table 1.

Table 1 Neural pain processes

	Description		Characteristics	Examples
Nociceptive pain	Transmission of information of an actual or potentially tissue-damaging event, encoded by nociceptors.[25] Associated with a range of musculoskeletal and visceral conditions: Inflammatory, ischemic, infectious, or mechanical injury.[22]	Nociceptive visceral pain:	Diffuse and dull aching pain. Autonomic features (such as nausea and sweating). Associated with referred pain.[25]	Endometriosis. Bladder pain syndrome. Irritable bowel syndrome.
		Nociceptive somatic pain:	Well localized and well recognized.	Chronic urinary tract infection. Pelvic floor myalgia.
Neuropathic pain	Pain caused by a lesion or disease of the central or peripheral somatosensory nervous systems.[25]		Burning, aching or shooting.	Nerve entrapment in scar tissue or nerve injury secondary to surgery.[1] Complex regional pain syndrome
Nociplastic pain	Arises due to alterations of nociceptive processing, such as enhanced central excitability and/or diminished central inhibition, often referred to as central sensitization.		More widespread than nociceptive pain. Chronic. Associated with psychological distress. Alterations of the hypothalamic-pituitary-adrenal axis and the autonomic nervous system.	Pain originating from endometriosis that over time generate myofascial trigger points, and contribute to sensitization.[26] CPP without well-known pathology.

References: Chimenti et al. 2018[22], International Association for the Study of Pain 2020[25]

In chronic pain conditions the different neural mechanisms often overlap, and nociplastic pain appear to play a prominent role.[27] The neural plasticity, described as the possibility for structural changes in living tissues in the body, has been emphasized as a central feature in understanding chronic pain conditions.[28] It has also been shown that the brain network activity in chronic pain is different than in acute pain. The brain activity connected to chronic pain seem to be more related to emotions.[29] However, the exact mechanisms of the transition from acute to chronic pain are yet unknown.

The interaction between psychosocial and biological factors, the mind and the body interaction, is getting more attention in relation to chronic pain conditions. Stress is a core condition of this interaction. The term "stress" applies both to dramatic stressful events, and to the many events of daily life that can elevate and sustain activities of physiological systems. Hormones associated with stress protect the body in the short run and promote adaptation by the process known as allostasis. In the long run allostatic load contributes to the wear and tear on the body and brain, and causes changes in the body that can lead to health-damaging behaviors.[30] Chronic pain can both be a result of other stressors and a factor that contributes to the total physiological burden, and thus to maintain a stress situation.[21, 31]

Psychosocial factors involved in a chronic pain experience can be related both to emotions and cognitions.[21] A persons pain beliefs develop during the lifetime as a result of an individual's learning history and cover all aspects of the pain experience, such as the causes of pain, its prognosis, suitable treatments and possibility to control the pain. The meaning ascribed to pain by an individual can vary according to multiple factors.[28] As shown in Figure 1, social factors also include social network, work situation, exclusion, negative social feedback and cultural beliefs.

The belief that pain means harm has been articulated through the fear avoidance model of chronic pain, and is supported by empirical evidence.[32, 33] Pain catastrophizing can be defined as an exaggerated negative orientation toward actual or anticipated pain experiences, and is closely linked to fear avoidance beliefs. Such negative emotional factors, in addition to depression or anxiety, may contribute to the maintenance of a painful condition, and also influence treatment motivation and compliance with treatment recommendations.[21, 34] For example, individuals experiencing pain avoid activities that they fear can evoke or aggravate

their pain.[34, 35] Patients who are depressed and feel helpless may have little initiative to comply, and patients who are angry at the health care system are not likely to be motivated to respond to recommendations from health care professionals.

The relationship between pain and the movement system has also received attention.[22] It is complex and often highly variable between individuals. Pain can produce increased muscle contraction, tone, or trigger points, and lead to fear-avoidance behaviors resulting in disuse and disability.[22] There is evidence that in most women with CPP the musculoskeletal system is compromised in different manners, either as postural changes or pelvic muscle contractures, or as the primary pain origin.[36]

Classification

A classification system aims to break down broad subjects into smaller, more manageable and specific parts, and thus is important both in research and for clinical management. For women with CPP, getting a diagnosis, or name, for the symptoms they experience, can provide them with a sense of being understood, as well as hope for relief.[4] However, there are challenges connected to such classification as well. The consequence of putting the wrong "nametag" on a condition can be detrimental both in research- and clinical settings, and to implement one consistent classification system throughout the different medical specialties and health authorities is challenging. Trying to overcome this the EAU has developed a comprehensive classification system that incorporates other systems for describing chronic pain and CPP in particular.[37]

In the EAU-classification, conditions where pain is associated with a specific disease or known inflammatory, infectious, ischemic, autoimmune, or neuropathic mechanisms are labeled as CPP with "well defined pathology", or "non-pain syndromes".[4] In the cases where there is no obvious local pathology that may account for the pain, the term "chronic pelvic pain syndrome" is applied. In these cases pain is often the main symptom and pain as a disease process is considered to be the cause of the actual condition.

When the pain can be localized to a specific organ the EAU further suggests that this should be acknowledged in the term used, for example "pelvic floor muscle pain syndrome" or "bladder pain syndrome". However, if the pain is localized in multiple organs and no specific

diagnosis is shown, the term chronic pelvic pain syndrome should be used without adding the name of an end-organ.[4] The EAU also states that in cases of CPP where treatment of well defined pathologies do not lead to expected pain relief, the same management approach as recommended for the chronic pelvic pain syndromes should be applied. Such cases can be when chronic pain develops after surgery, trauma or a known disease.

The many dimensions related to the condition CPP are illustrated in the classification-table below (Table 2). The table is set up according to an axis system developed to assist clinicians in the process of describing and defining the main characteristics of pain syndromes. The axis refers to the body region (Axis I), organ system (Axis II), and end-organs involved (Axis III), the characteristics given in referrals (Axis IV), the temporal characteristics and patterns of occurrence, patients statement of pain intensity and duration (Axis V), pain character (Axis VI), associated somatic (Axis VII) and psychological symptoms (Axis VIII).

Table 2 The European Association of Urology's classification of chronic pelvic pain

Axis I Region		Axis II System	Axis III End-organ as pain syndrome as identified from Hx, Ex and Ix	Axis IV Referral characteristics	Axis V Temporal characteristics	Axis VI Character	Axis VII Associated symptoms	Axis VIII Psychological symptoms
Chronic pelvic pain	Specific disease associated pelvic pain OR Pelvic pain syndrome	Urological	Prostate	Suprapubic Inguinal Urethral Penile/clitoral Perineal Rectal Back Buttocks Thighs	ONSET Acute Chronic ONGOING Sporadic Cyclical Continuous TIME Filling Emptying Immediate post Late post TRIGGER Provoked Spontaneous	Aching Burning Stabbing Electric	UROLOGICAL Frequency Nocturia Hesitance Dysfunctional flow Urgency Incontinence GYNAECOLOGICAL Menstrual Menopause GASTROINTESTINAL Constipation Diarrhoea Bloatedness Urgency Incontinence NEUROLOGICAL Dysaesthesia Hyperaesthesia Allodynia Hyperalegesie SEXUOLOGICAL Satisfaction Female dyspareunia Sexual avoidance Erectile dysfunction Medication MUSCLE Function impairment Fasciculation CUTANEOUS Trophic changes Sensory changes	ANXIETY About pain or putative cause of pain Catastrophic thinking about pain DEPRESSION Attributed to pain or impact of pain Attributed to other causes Unattributed PTSD SYMPTOMS Re-experiencing Avoidance
			Scrotal Testicular Epididymal					
			Penile Urethral					
			Post-vasectomy					
		Gynaecological	Vulvar Vestibular Clitoral					
			Endometriosis associated					
			CPPS with cyclical exacerbations					
			Dysmenorrhoea					
		Gastrointestinal	Irritable bowel					
			Chronic anal					
			Intermittent chronic anal					
		Peripheral nerves	Pudendal pain syndrome					
		Sexological	Dyspareunia					
			Pelvic pain with sexual dysfunction					
		Psychological	Any pelvic organ					
		Musculo-skeletal	Pelvic floor muscle Abdominal muscle Spinal					
			Coccyx					

(Hx = History; Ex = Examination; Ix = Investigation. The European Association of Urology 2019)

Prevalence and characteristics

The reported prevalence of CPP varies largely, probably partly explained by different inclusion criteria and definitions used in studies. In two systematic reviews published in 2006 and 2014 numbers between 2% and 27% were reported.[2, 3] A Danish population study from 2014 reported 15% prevalence, while a study from the United Kingdom in 2017 reported that 11% of the female population had CPP.[38, 39] Studies on other chronic pain conditions show that people often move "in and out" of longstanding pain conditions.[40] This may also be the case for CPP, and thus contribute to unsure numbers of prevalence.

CPP seems to affect women of all ages. Some studies have reported higher prevalence among women in reproductive age than older women, but the results are not consistent.[1, 38] The condition occurs both in men and women, and many of the management approaches are probably relevant for men.[4] However, in this thesis the focus is on females.

Women with CPP report a number of symptoms in addition to pain in the pelvic area. As shown in Table 3 dyspareunia, dysmenorrhea, endometriosis, and psychological problems are frequently reported, and compared to women without CPP the reports of various health complaints are higher.[38, 39, 41, 42] Some of the associated conditions occur as acute pain conditions that commonly are treated surgically, but may later develop to chronic pain, and some of the conditions described are of chronic nature.

It has been shown that women with CPP have a specific pattern of posture, movement, muscle pathology and reduced body awareness compared to healthy controls.[36, 43] Abuse exposure is found to be a factor that may predispose women to CPP,[44] and the prevalence of sexual or physical abuse is reported to be up to 45% in women with CPP.[45, 46] Previous surgeries in the pelvic area is reported by a large proportion, with numbers varying from 50% in a population based study to 90% of women with CPP recruited from a gynecological department.[13, 39, 47]

The presence of pelvic pathology is identified as a factor that may predispose women to CPP.[44] Higher pain intensities and longer pain durations are shown among women with other diagnosis in the pelvic area in addition to CPP.[42]

Table 3 Population based studies on women with chronic pelvic pain

Author	**Study design and setting**	**Participants**	**Pain characteristics**	**Comorbidities and associated symptoms reported** [a]	**Comparison to women without CPP** (CPP versus not CPP)
Zondervan 2001[41, 42] United Kingdom	Cross-sectional Population based	Total: n= 2304 CPP: n = 483 Age: 35.4 Response rate 74%	Duration: <1 year: 19% 1-5 years: 31% >5 years: 33% Unsure: 17% Mean VAS-score 4.2 (SD = 2.6)	Irritable bowel syndrome: 38.5% Stress, ovarian cysts, endometriosis, cystitis, pelvic inflammatory disease, constipation, back pain, adhesions, appendicitis.	Dysmenorrhea: 80% versus 60% Dyspareunia: 41% versus 14% Work absence last 12 months: 18% versus 10%
Ayorinde 2017[38] United Kingdom	Cross-sectional Population based	Total n = 2088 CPP: n= 309 Ages: ≤51: 66% >51: 34% Response rate 45%	NRS-score: 4 (IQR 3-6) Constant pain: 10 % Recurrent pain: 90 %	Fatigue, depression, sleep problems were reported. Dyspareunia: 6.1% Dysmenorrhea: 13.7% Two clusters identified: 1) little/no psychosocial distress, 2) high psychosocial distress.	Multiple non-pain somatic symptoms: 40% versus 17% Significantly poorer scores for physical health and mental health Sleep problems: 29% versus 19% Fatigue: 56% versus 35% Depression: 23% versus 11%
Loving 2014[39] Denmark	Cross-sectional Population based	Total n = 1179 CPP: n = 130 Age: 46.3 Response rate 48%	Mean NRS: 4 (IQR 2-6)	48.5% had diagnosis of pelvic diseases. Irritable bowel syndrome (20%), vulvodynia (9%), endometriosis (8%).	Dyspareunia: 7-35% versus 2-10% Diagnosis related to bowel, irritable bowel syndrome, bladder pain syndrome, vulvodynia and endometriosis significantly more prevalent in CPP. Previous pelvic surgery: 49% versus 31%

CPP; chronic pelvic pain, IQR; inter quartile range, NRS; numeric rating scale, SD; standard deviation, VAS; visual analogue scale.

The female pelvis – anatomy and functions

The female pelvis contains a number of structures, and serves important functions such as micturition, defecation, sexual function, reproduction, and mobility. The bones of the pelvic girdle serve as attachment points for trunk and lower limb muscles, as well as the internal pelvic muscles. The bony structures also protect the internal pelvic organs and support the weight of the upper body when sitting and transfer weight to lower extremities when standing and walking. The pelvic floor supports the pelvic organs, and together with the urethral and anal sphincter muscles it maintains continence, permit urination, defecation, intercourse and vaginal birth.[48] The pelvic floor is arranged into overlapping layers of muscles and connective tissues, and consists of the perineal muscles (ischiocavernosus, bulbospongiosus and transversus perinea superficialis) and the levator ani muscle (iliococcygeus, the puborectalis and the pubococcygeus). The anal sphincter complex involving the internal and external anal sphincter muscles surrounds the anal canal (Figure 2).

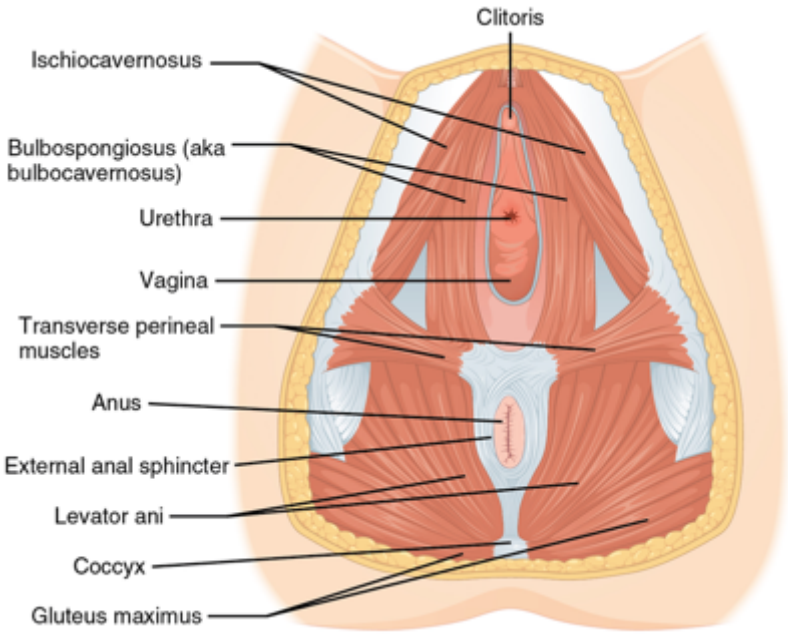

Figure 2 Muscles of the female pelvis
(from the Textbook OpenStax Anatomy and Physiology May 2016[49])

The visceral (intraperitoneal) organs in the female pelvis are the bladder, uterus, fallopian tubes and ovaries, intestines and rectum. The cervix, vagina and anus and pelvic floor muscles are extraperitoneal.

Pelvic structures are innervated by the somatic (T12-S5) and visceral (T10-S5) nervous systems, which are organized in complex anatomical and neurobiological networks. The primary nerves of the pelvis are the obturator nerve, the femoral nerve, the sciatic nerve and the pundenal nerve. The autonomic neuronal center of the pelvis is the hypogastric plexus, while the pudendal nerve is the major somatic nerve. An overview of the structures of the female pelvis is given in Figure 3.

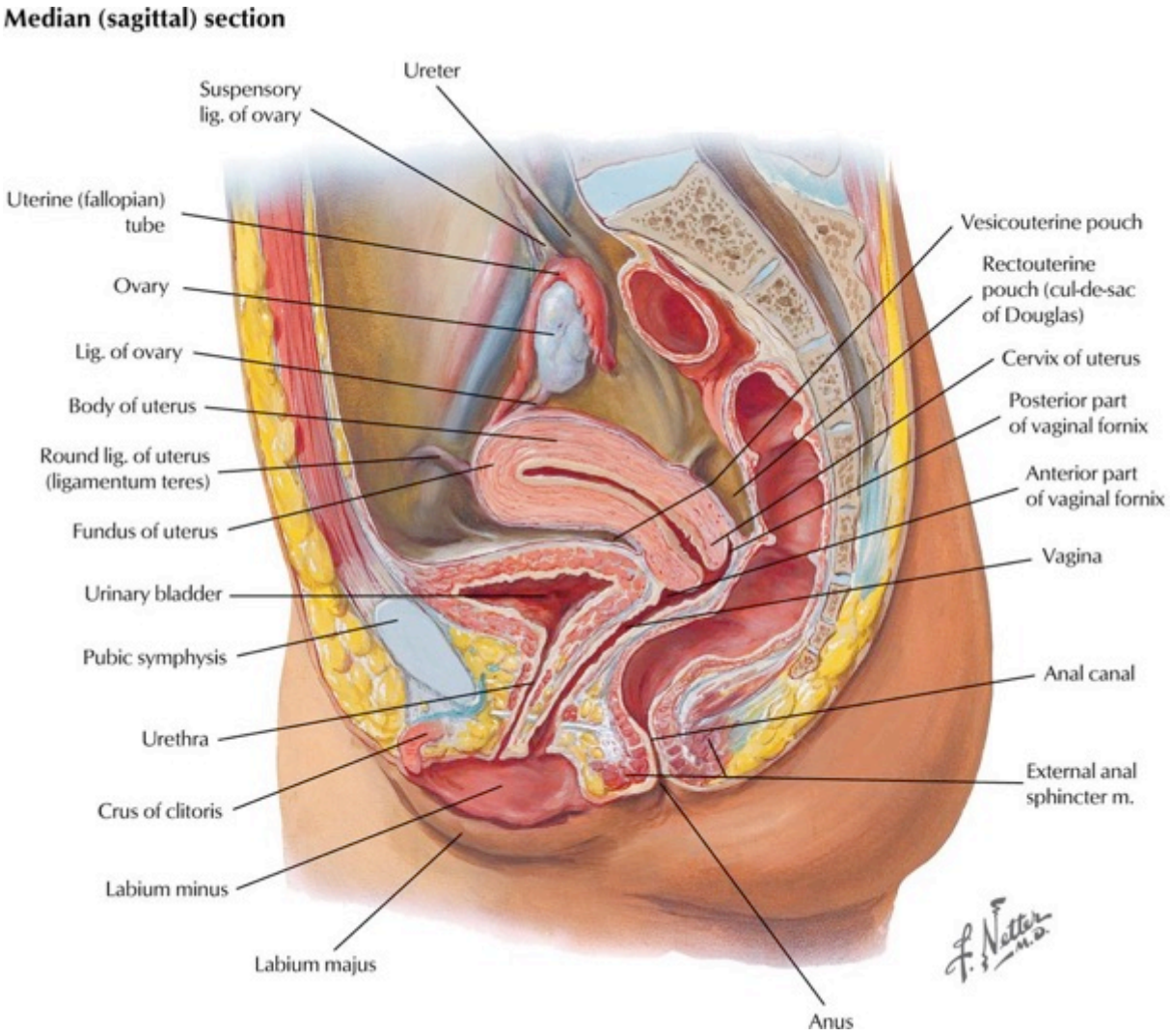

Figure 3 The female pelvis, sagittal view.
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Treatment of chronic pelvic pain

When assessing women with signs of chronic pain in the pelvic area it is recommended to identify pathology that may cause ongoing tissue trauma, inflammation or infection in the early stages of investigations. If such conditions are excluded it is not recommended to perform further investigations for such causes.[8, 17, 18] Aiming for precise classification, avoiding unnecessary investigations and starting effective management as soon as possible is emphasized as important.[18]

Systematic reviews of non-surgical treatment of CPP in women show that a number of modalities are applied, such as pharmacological, psychological and complementary treatments, and physical therapy including electrotherapy, manual treatment, exercises or different forms for movement therapies. Some effect has been shown by several single treatment modalities, but the common conclusion in systematic reviews is that most studies had small samples, the modalities have not been tested in multiple studies, and the quality of the evidence is generally low.[9-12, 50] Pharmacological modalities can be appropriate in some cases of long lasting pelvic pain, for instance to allow or improve compliance with other treatment modalities. Surgical and pharmacological modalities will, however, not be described further in this thesis.

In this thesis the focus is on CPP-conditions with no well-recognized pathology, or CPP with well-recognized pathology that has not responded as expected to the recommended treatment. For these cases, the clinical guidelines of the EAU recommend a "holistic" approach, which is described as an approach that enhances biological, psychological, social and sexual factors, active patient involvement and provision of information that is responsive to the patient's problems.[8] Physical therapy is recommended as one component in a multimodal management, together with patient education.[4] The EAU further recommends that management preferably should be undertaken in a multi-specialty and multi-disciplinary environment, and that those involved must have knowledge of peripheral and central pain mechanisms.[4] The corresponding clinical guidelines from the Royal College of Obstetricians and Gynaecologists and the American College of Obstetricians also recommend a bio-psycho-social management based on principles from chronic pain in general.[17, 18]

In the following paragraphs the treatment modalities physical therapy, patient education and psychological or cognitive therapies will be shortly described as applied in treatment of

chronic pain conditions. Further, the evidence base multimodal interventions for women with CPP combining physical therapy with one or several other modalities will be reviewed.

Physical therapy

Physical therapy is described as "services that develop, maintain and restore people's maximum movement and functional ability, and help people improve their quality of life, looking at physical, psychological, emotional and social wellbeing".[51] Multiple techniques are available within physical therapy, such as exercises aiming to influence strength, endurance, flexibility, balance, posture or awareness, manual treatment of soft tissue or joints, patient-related instruction, education or counseling, environmental interventions, and electro-therapy.[52] The rich "toolkit" gives physical therapists a good basis for practicing bio-psycho-social treatment, and there exist a number of specialties within physical therapy.[53]

Psychosomatic physical therapy is often applied in the management of patients with widespread or long lasting pain conditions.[54, 55] The basic perspective in that specialty is that the mind and body is indivisible, and that a person total health is influenced both by biological, psychological and social strains.[54, 56] The terms "body awareness"- and "mind and body interventions" are also applied for this kind of interventions, which is appropriate, as a key goal is to explore and experience how thoughts, emotions, attitude, movement and respiration are integrated and affect each other, and to integrate this new awareness into daily activities.[13 54, 56 57] Psychosomatic interventions include a combination of treatment modalities, such as education, relaxation, massage, mindfulness, cognitive approaches and graded activity.[55] Several branches are grounded on this theory. Examples relevant for this thesis are the "Norwegian psychomotor physical therapy",[54] "Mensendieck somatocognitive therapy",[13, 58] and "learning oriented physical therapy".[59, 60] Clinical trials on chronic pain conditions support the value of body awareness both in terms of pain-related and psychological benefits.[61]

Manual techniques are commonly applied in the treatment of CPP; in the form of trigger point treatment, pelvic floor muscle exercises with or without biofeedback, myofascial release techniques, deep intra-vaginal massages, and electrotherapeutic modalities. Such techniques are suggested to increase the woman's awareness of her pelvic floor muscles, in addition to strengthen, lengthen or normalize muscle activity.[36]

Patient education

Patient education is described as the process of giving information to patients that will alter their health behaviors or improve their health status.[62] This can be done through a range of teaching techniques, as well as through the use of psychosocial and behavioral theories.

The educational intervention "explain pain" was launched by Moseley and Butler in 2003, and has become a recognized and widely used approach.[63, 64] The core objective of the intervention is to explain the key bio-psycho-social mechanisms that underpin pain, and to integrate the new understanding into pain- and function related beliefs, attitudes, behaviors, treatment, and lifestyle choices. Based on knowledge of neuroplasticity it is specifically emphasized that pain is a modifiable experience.[64]

Current evidence supports the use of pain education for chronic musculoskeletal disorders in reducing pain and improving patient knowledge of pain.[65]

Psychological treatments

Psychological treatments applied in chronic pain aim to reduce disability and distress despite continuing pain.[66] Such treatments focus on helping people to change behavior that maintains or worsens pain, disability, distress and catastrophic thinking. Cognitive behavioral therapy also directly addresses the thoughts and feelings that can be challenging for people with persistent pain. Evidence shows that addressing maladaptive psychosocial factors can maximize therapy effectiveness.[22]

Acceptance and commitment therapy is one cognitive approach that focuses on behavior change rather than symptom reduction, and is often applied as a tool to help people accept present situations, set goals and commit to use available resources despite the challenges.[67-69]

A systematic review of RCTs with psychological interventions for women with CPP that included only three studies, found that type of psychological intervention varied greatly. The most promising of the reviewed approaches was the Mensendieck somatocognitive therapy,

which combines a cognitive approach that includes working with dysfunctional thoughts, with physical therapy targeting awareness of posture, movement- and respiration patterns.[50, 70]

Group-based versus individual treatment

Physical therapy, and chronic pain management in general, can be organized as individual treatment or group-based interventions, or a combination of the two.[51] Group therapy has been recommended as part of a multimodal treatment program, as it appears to have a positive effect on psychosocial outcomes.[71] Benefits of participating in a group are related to the feeling of having similar problems as others, the feeling of belonging to the group, communication about the condition between group members, and the feeling of helping and supporting others.[72] Group-based treatment can be time saving and cost efficient, and for physical therapy it has been shown that group treatment can be as effective in reducing pain as individual treatment.[73]

Evidence base for multimodal treatment

A literature search was conducted to identify trials on multimodal interventions that include physical therapy. The study population was limited to women aged 18 or more, diagnosed with CPP according to the EAU-definition, and studies published before 2005 were not included. Two RCTs, with rather small sample sizes, and three non-randomized trials were identified (Tables 4 and 5).[13, 74-77] No RCTs that apply a multimodal intervention including physical therapy in a group setting were identified.

As shown in Table 4 significant pain reduction and improved motor functions were shown after treatment with Mensendieck somatocognitive therapy combined with standard gynecological care, compared to gynecological care alone.[13] Mensendieck somatocognitive therapy is a physical therapy treatment that combines exercises, manual treatment and cognitive techniques, focusing on exploration of movements and enhancement of body awareness.[13, 78] In the study by Ariza-Mateos et al. (2018) a combination of patient education, graded exposure therapy and manual therapy was superior to manual therapy alone, and to none treatment, in terms of reducing fear-avoidance beliefs and improving pain interference. However, the combined intervention did not reduce pain intensity more than manual therapy alone.[74]

The results of the non-randomized studies indicate that positive changes can be obtained with multimodal treatment that includes physical therapy. However, the lack of control group makes it impossible to conclude whether the applied interventions are superior to any other intervention or not. Also, there seem to be some degree of spontaneous improvement in CPP, which also is a plausible explanation of the observed improvements.[79] In the non-randomized trials the interventions are not clearly described, and it appears as if treatment modalities have been selected for each individual woman in a non-standardized manner. This might well be a reasonable procedure in a real-world clinical setting, but it makes it impossible to evaluate the effect of the single modalities.

In studies that have investigated factors associated with treatment outcome in terms of change in pain intensity after treatment for CPP, psychological factors, pain characteristics, general health status and age have been identified as predictors.[32, 76, 80] The same predictors are described for other chronic pain conditions,[81] in addition to number of pain sites and pain duration.[40, 82] However, both for CPP and other chronic pain conditions the strength and direction of the associations vary.

Table 4 Randomized controlled trials of multimodal interventions including physical therapy for women with chronic pelvic pain

Author	Participants	Design	Intervention and comparator	Adherence	Main results
Haugstad et al. 2006 and 2008 [13, 78] Norway	n = 40 Age: 33.3	RCT	IG: Mensendieck somatocognitive therapy (1hour/week) for 10 weeks + standard gynecological treatment (2 sessions) CG: Standard gynecological treatment alone (2 sessions)	92.5 % after 12 weeks 90 % after 12 months	Performance of functional tasks, SMT[b] (0-7[a]): *12 weeks:* Significant improvements in posture, active movements, gait, sitting and respiration in the IG, versus no significant improvements in the CG. *12 months:* Significant improvements from 12 weeks to 12 months for active movements, gait and respiration in the IG, versus no significant improvements in the CG. Pain intensity - visual analogue scale (0-10[a]): *12 weeks:* IG 2.9 versus CG 6.2, significantly reduced from baseline in the IG only. *12 months:* IG 2.0 versus CG 6.0, significantly reduced from baseline in the IG only.
Ariza-Mateos et al. 2019[83] Spain	n = 49 Age: 41.8	RCT, three groups	IG_1: Pain education and graded exposure to fearful tasks selected by each woman (1x45 minutes/week) + manual therapy (2x45 minutes/week) for 6 weeks IG_2: Manual therapy 2x45 minutes/week for 6 weeks CG: Booklet with CPP-information	100 %	Fear-avoidance beliefs – physical activity (0-24[a]): *6 weeks:* IG_1 significantly lower score than IG_2 and CG (10.5 versus 14.8 versus 17.3). *12 weeks:* IG_1 significantly lower score than IG_2 and CG (6.4 versus 13.4 versus 19.6), and IG_2 significantly lower scores than CG (13.4 versus 19.6). Brief pain inventory – interference (0-10[a]): *12 weeks:* IG_1 significantly lower score than IG_2 and CG (2.6 versus 5.7 versus 5.1) Brief pain inventory - severity (0-10[a]): *12 weeks:* IG_1 significantly lower score than CG (3.3 versus 6.0). IG_2 significantly lower score than CG (4.1 versus 6.0).

[a]Lower score indicate less bothers. [b]Standardized Mensendieck test, described in chapter four.

RCT, randomized controlled trial; IG, intervention group; CG, comparator group

Table 5 Non-randomized studies of multimodal interventions including physical therapy for women with chronic pelvic pain

Author	Study design	Participants	Intervention	Adherence	Main result
Lamvu et al. 2006[75]	Prospective cohort, 12 months follow-up	n = 370	Pharmacotherapy, psychotherapy, physical therapy, or combinations of the three (n = 181 women), or surgical treatment (n = 189)	62% non-responders	Pain: 46% improved, equal in the two groups. Depression: 32% improved. Modest improvements in both groups.
Allaire 2018[76]	Prospective cohort, 12 months follow-up	n = 525 Age: 34.3	Interdisciplinary treatment at a specialist center. Patients chose between minimally invasive surgery, medical management and/or a pain program (pain education, physiotherapy and counseling).	57% followed-up at 1 year	Pain severity (0-10): Baseline 6/10, 1 year 4/10, p<0.001 Functional quality of life (0-100[a]): Baseline 42, 1 year 29, p<0.001 Physician or emergency visits (%): Baseline 96, 1 year 47, p<0.001
Aboussan et al. 2020[77]	Retrospective cohort, 3-4 weeks follow-up	58 cases + 58 matched women with other chronic pain	Medication management, weaning from habituating medications, physical/occupational therapy and individual, group and family psychotherapy		Pain severity, pain-related sexual impairment and emotional symptoms improved significantly both in cases and controls. Greater sexual impairments in women with CPP both pre- and post-treatment.

[a]Lower score indicate improvement.

CPP; chronic pelvic pain

3 Aims of the study

The overall aim of this thesis was to describe the characteristics of women with CPP that were referred to physical therapy after evaluation by specialist doctors at the tertiary hospital UNN, and to compare the change in mean pain intensity between women randomized to group-based multimodal physical therapy with women randomized to primary care physical therapy.

The specific aims were:

1) To describe the characteristics of women with CPP evaluated at the University Hospital of North Norway, and further referred to physical therapy (**Paper I**).
2) To investigate if suggested risk factors such as history of abuse and previous surgeries in the pelvic area are frequently reported, and if women with and without these experiences report different subjective health status (**Paper I**).
3) To compare changes in mean pain intensity between women randomized to group-based multimodal physical therapy (intervention group) versus primary care physical therapy (comparator group) (**Paper II**).
4) To explore if selected characteristics were associated with treatment outcome in terms of change in pain intensity at 12 months (**Paper III**).
5) To explore baseline differences between women that dropped out of the study and those who did not (**Paper III**).

4 Materials and methods

Literature search

The literature presented in this thesis was collected through searches in PubMed, Medline, PEDro and Cochrane Databases during the project period from 2015 to 2020. Searches were also made in the reference lists of relevant papers. Systematic searches were not performed, but the keywords of the thesis were included in the searches. Languages included were English and Norwegian.

Key words applied were: pelvic pain, chronic pain, characteristics, women, multimodal treatment, physical therapy, women's health, patient education, subjective health outcomes.

Study design

To address the multiple aims of the thesis, different study designs were applied. In Paper I a cross-sectional design was used, analyzing baseline data for all included women regardless of treatment group. In Paper II a parallel RCT design was applied to investigate group-differences in change after an intervention period. In Paper III secondary analysis of the data collected in the RCT was performed for the whole group as one cohort.

We chose to do a pragmatic RCT in Paper II. With this approach we aimed to test an intervention within a whole-spectrum clinical setting as seen in real-life clinical practice. This is in contrast to explanatory RCTs that seek to investigate how an intervention works, but then typically in well-defined and controlled settings with strict inclusion- and exclusion criteria.[84, 85] An explanatory trial design is not suitable in a complex condition as CPP and with a complex intervention as in our study.[86]

As a theoretical framework the bio-psycho-social model is applied. This is a widely accepted and practical applicable theory that meets the requirements of understanding pain as a highly subjective experience that is influenced by biological, psychological and social factors.[20, 21, 22]

Participants

The participants of all three papers were recruited from outpatient clinics at UNN. The main inclusion criterion was CPP with no well-known pathology identified, or CPP that could be

explained by a well-known pathology but had not responded as expected to the recommended treatment (Figure 4). Women referred to physical therapy following assessment and diagnosis by a gynecologist, urologist, and/or colorectal surgeon, with pain for a minimum of six months, aged 20-65 years, motivated to participate in a randomized trial, and able to speak and understand a Scandinavian language, were eligible. If malignancy or conditions requiring special medical attention were discovered, the women were referred to relevant follow-up, and not considered for study participation.

The exclusion criteria were pregnancy, childbirth during the last year, drug addiction, serious psychiatric diagnosis, and previous treatment by the physical therapists at the intervention program. Women with intra-abdominal or pelvic surgery within the previous six months or Botolinum toxin injections in the pelvic area in the last four months were not eligible.

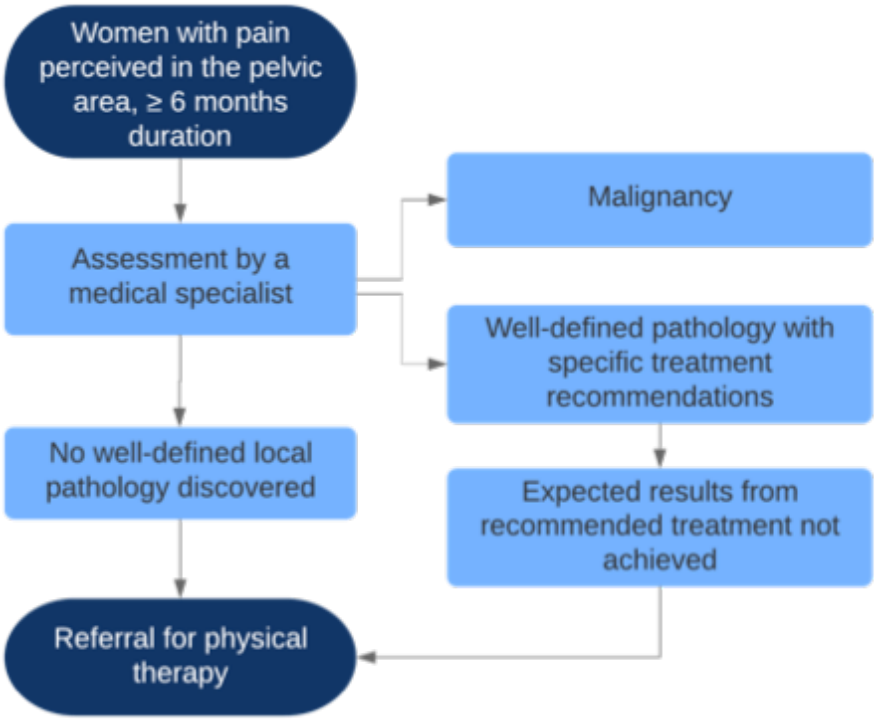

Figure 4 Algorithm for eligible participants

Study intervention

The protocol for the study intervention was based on the EAU clinical guideline for CPP, taking a broad approach enhancing biological, psychological and social factors.[4] The term multimodal was applied because of the concurrent application of therapeutic modalities with different mechanisms of action;[25] including patient education,[63, 65] explorative movement and body awareness therapy,[54, 61] and the cognitive approach ACT.[68] The overall aim was to facilitate change in terms of reduced pain and improved daily function, and this was sought through increasing knowledge of pain and its effect on body and mind, challenge habits of avoidance related to fear of pain, and to give new positive movement experiences.

The study intervention consisted of a total of 16 treatment-days during one year. The first session lasted for 10-days, and was followed by two-day sessions after three, six and 12 months (Figure 5). The rationale for the long duration was based on theories of behavioral change, emphasizing that it takes time to integrate new experiences into daily routines and to obtain lasting changes.[65] The intervention was run in the city of Tromsø, and participants from other places stayed in a hotel or other suitable accommodation during the sessions.

The intervention was group-based with between five and 10 women in each group. Each participant had an individual physical therapy assessment at the start and the end of the program (Figure 5). The structure of the intervention was predetermined with a detailed schedule for all sessions (Appendix 1), but small adjustments could be done according to the specific group's needs. Every day lasted from 8.30 to 15.00 with a combination of movement and body awareness therapy, patient education, group discussions and reflections. The participants were provided with a workbook that included both short informative notes and reflection tasks to work with both during and between the sessions.

The study intervention was run by three physical therapists with competence in psychosomatic physical therapy, women’s health and chronic pain management. A gynecologist and a nutritionist contributed on one lecture each.

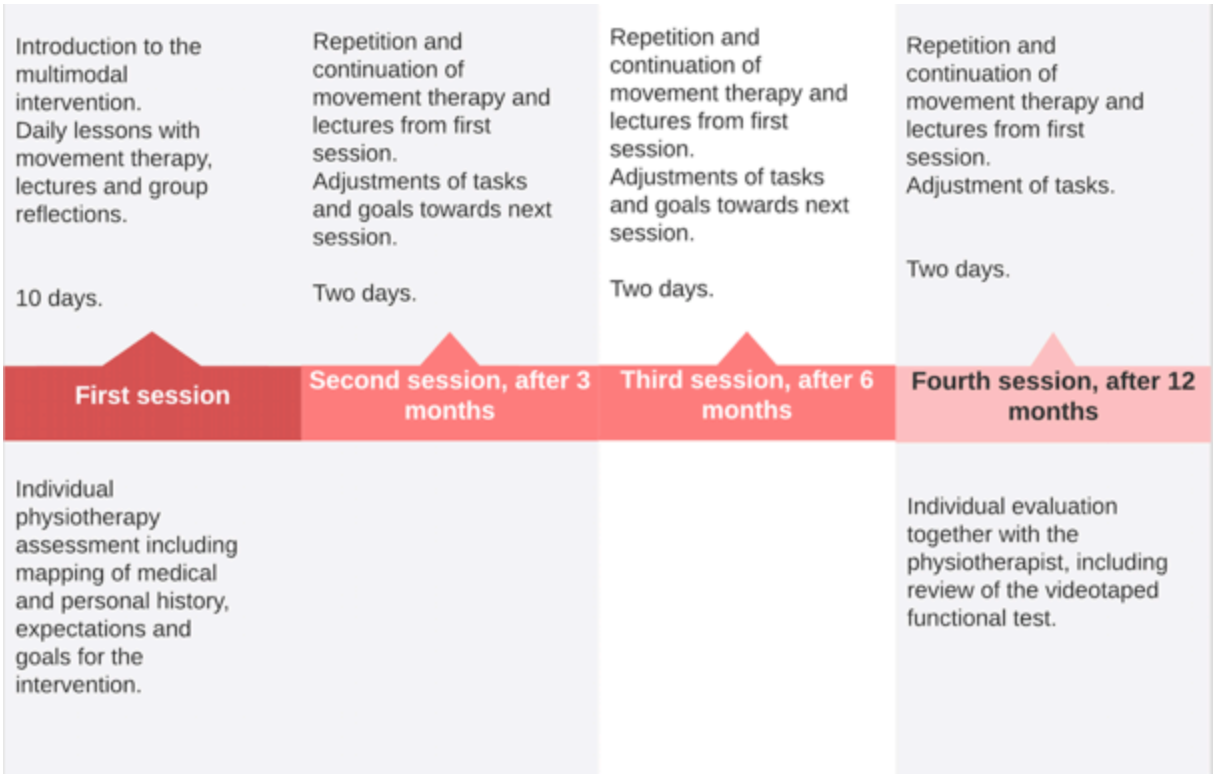

Figure 5 Timeline of the multimodal intervention

Movement and body awareness therapy

The explorative movement and body awareness therapy combined elements from the Norwegian psychomotor physical therapy,[54] learning oriented physical therapy[59, 60] and Mensendieck somatocognitive therapy, three different branches within the concept of body awareness therapy.[13, 58] The purpose was to enhance the body and mind interaction and to increase the women's awareness about own body reactions and resources.[7, 54, 61] Through functional movement tasks the women were challenged to explore flexibility, balance, respiration, postural stability, muscle tension and relaxation, and to reflect about how these functions are influenced by each other and by physical, emotional or social strain.[78] Individual guidance in adjusted movement tasks aimed to provide positive movement experiences, in order to gradually reduce the expectation of pain with movements.[33] There was shifting focus between tasks involving the whole body and exercises focusing specifically on the pelvic area, such as practicing to stand firmly on both legs, being aware of how the abdomen move during respiration or recognition of tension versus relaxation when performing pelvic floor muscle exercises. Two daily lessons of movement therapy were held in a small gym, and one in a heated pool.[87]

A Standardized Mensendieck Test of functional movements was integrated in the program, and conducted both at the start and end of the 12-month intervention.[88] The test was videotaped in order for the participants to review their performances at the last day of the program. The purpose of this is to facilitate reflection and awareness of the changes that have or have not occurred during treatment. In this study the test was also included as one of the outcome measures and therefore videotaped by the data collector both at inclusion and at posttests. The women that were randomized to the intervention group watched the video together with the physical therapist at the last session of the treatment.

Patient education

Lectures on topics related to living with CPP, both focusing on biological and psychosocial factors, were given in twice daily during the first 10-days session. Largely based on the theory of "Explain pain" that was described in chapter 2, the purpose was to improve the participants understanding of pain mechanisms, with special focus on why pain can persist despite lack of objective findings and after the expected time for tissue healing.[63, 65] Further, the lectures aimed to influence the women's pain beliefs, introduce new perspectives about possibilities to control the pain, for changing focus and setting realistic goals for changes. Group discussions and individual tasks related to the topics were part of the educational sessions. The exact topics that were discussed are shown in the intervention schedule (Appendix 1).

Acceptance and Commitment Therapy

ACT was included in the multimodal intervention as a tool to help the women to accept that the pain is present, set goals and commit to use available resources despite the pain.[67-69] ACT was introduced in the lectures and incorporated both in the practical and theoretical sessions. The reflection tasks in the workbook were based on techniques applied in ACT.

A detailed description of the study intervention is provided in the enclosed TidiER Checklist (Appendix 2).

Comparator group

Women randomized to the comparator group were referred for physical therapy in primary health care, which is the usual procedure when a medical specialist recommends physical

therapy. The participants were given information about physical therapists near their home with competence in women's health, and alongside the referral they received an information letter for the therapist (Appendix 3). There was no standardization of the contents of the comparator treatment, other than that the therapists were asked to provide treatment according to own academic competence and in consultation with the woman. The deductibles of physical therapy treatment were refunded, and women that still needed treatment were offered participation in the group-based intervention after study completion.

For participants in both groups, a website with information about CPP was available. All participants could at any time to contact the researcher (ASN) or project coordinator if they had questions.

Data collection

The trial was conducted at the Norwegian National Advisory Unit on Incontinence and Pelvic Floor Health at UNN. Baseline data were collected at the Physiotherapy Outpatient Clinic at the time of inclusion, before randomization. Baseline data collection took place between March 2015 and November 2016. All outcomes were registered again 12 months after start of the study intervention or after being referred to primary care physical therapy. Women who did not manage to travel to the hospital for the post-test due to practical reasons were contacted by phone and mail. Two physical therapists (ASN and MFE) performed all the baseline and follow-up tests.

Outcome measures

Demographic information and information about medical history were collected at baseline using a semi-structured interview. This included information about age, body mass index, smoking, number of children, civil status, education, work status, pain duration, main pain site, use of analgesics, previous treatment, previous surgeries, other diagnosis and abuse exposure (physical, psychological, or sexual). Appendix 4 shows the interview guide that was applied at baseline.

After 12 months a modified interview guide were used to collect information about changes in demographic or medical information during the study period. In addition, information

about number of consultations and type of treatment were registered. Appendix 5 show the interview guide applied at 12 months.

Pelvic pain intensity (Papers I, II and III)

Information about baseline pain intensity was collected and presented in **Paper I**. Change in mean pain intensity from baseline to 12 months follow-up was the primary outcome measure in **Papers II and III**.

Pelvic pain intensity was assessed using a numerical rating scale (NRS), an eleven point box scale in which zero represents no pain and 10 represents pain as bad as it can be.[89] The participants were asked to rate their mean, worst and least pain intensity during the last seven days. There was also a rubric for the participants to state if pain in the last week was worse, better, or unchanged compared to the previous month. Information about pain intensities was registered by mail at three and six months, in addition to the registrations at baseline and 12 months. The NRS has shown good sensitivity and validity.[89, 90] According to Williamson and Hoggart (2003) the NRS is as a measure that provides parametric data.[89]

Movement patterns (Paper II)

Movement patterns were assessed with the Standardized Mensendieck test, which evaluates performance of standing and sitting posture, active movements, gait and respiration patterns, according to criteria based on functional anatomy.[88] The test was video recorded before a blinded physical therapist scored the five domains on a scale from zero to seven (0=least optimal, 7=optimal). The Standardized Mensendieck test has been validated in a sample of Norwegian women with chronic pelvic pain.[88]

As described above the test was included as a part of the study intervention in addition to being applied as an outcome measure.

Sexual function (Papers I and II)

Information about sexual function was recorded using a modified self-reported questionnaire originally developed by Træen et al.[91] The questionnaire comprised four questions. First the women were asked whether they were sexually active, with answers reported as “yes” or

"no". If they answered affirmatively they were asked if they had experienced lack of sexual desire or dyspareunia over the past 12 months. Answers were reported as "Yes" ("all the time," "almost all the time," and "quite often") or "No" ("quite rarely" or "never"). In addition the women were asked to register the intensity of dyspareunia on a NRS (0-10). The questionnaire, which has not been validated, is enclosed in Appendix 6.

Subjective health complaints (Papers I and II)

The Subjective Health Complaints (SHC) questionnaire was used to register common somatic and psychological health complaints during the last 30 days.[92] The 29-item list consists of complaints in the categories musculoskeletal pain, pseudoneurology, gastrointestinal problems, allergy, and flu. Severity of each complaint is rated on a 4-point Likert scale (0=none, 1=some, 2=much, 3=severe). The SHC questionnaire is known to be a reliable measure of SHC.[92]

In **Paper I** the proportion of women who reported any complaints (score 1–3) within each of the five categories was calculated. In addition, the proportion of women reporting each of the 29 single complaints (score 1–3) and the proportion of women reporting severe complaints within the 29 items (score 3), were calculated.[92]

In **Paper II** the total score of SHC was reported on a continuous scale from 0-87 (higher scores indicate more complaints).[92]

Symptoms of anxiety and depression (Papers I, II and III)

Common symptoms of anxiety and depression were measured using the Hopkins Symptom Checklist (HSCL-25).[93, 94] The respondents indicated the extent to which they had experienced any of 25 different symptoms of anxiety and depression over the last 14 days using a four-point Likert scale ranging from 1-4 (1=not at all, 2=a little, 3=quite a bit, 4=extremely). The HSCL-25 is known to be a reliable measure among Norwegian women, and its validity has been shown in a Swedish population.[95, 96]

In **Paper I** separate mean scores for anxiety and depression items were calculated. A cut off point of 1.75 was used to distinguish women with and without psychiatric symptoms, and the

dichotomized data were presented.[95]

In **Papers II and III** the total score was reported on a continuous scale with possible scores ranging from 1-4 (higher score indicating more severe symptoms).

Urinary incontinence (Papers I and II)

Urinary incontinence was defined as "the complaint of involuntary leakage of urine" and documented by the self-administered questionnaire ICIQ-UI SF.[97] Scores range from 0 to 21, and values of one or higher indicate urinary incontinence. The questionnaire is validated and the Norwegian version is found adequate for use after linguistic validation.[98, 99]

In **Paper I** the dichotomized scores were used to differentiate between women reporting and not reporting UI, and in **Paper II** both the dichotomized and continuous scores were reported.

Anal incontinence (Papers I and II)

Information about anal incontinence, defined as involuntary passage of fecal material and/or flatus[100], was collected using the validated St. Marks interview score.[101] The score gives information about type (gas, liquid, solid) and frequency of anal incontinence, its impact on daily life, the need to wear a pad or plug, the use of constipating medication, and the lack of ability to defer defecation for 15 minutes.[101] Scores range from 0 to 24, and scores zero to three indicate no anal incontinence while scores between four and 24 indicate anal incontinence.[102, 103]

In **Paper I** the dichotomized scores were reported to differentiate between women reporting and not reporting anal incontinence, and in **Paper II** both the dichotomized and continuous scores were reported.

Obstructed defecation

To record information about obstructed defecation symptoms a five-item score developed and validated by Renzi et al. was used.[104] Each item is graded from zero to five with a maximum total score of 25, and the optimal cutoff point to discriminate between healthy participants and

patients with and without obstructed defecation symptoms is found to be a score of nine (≤8=no obstructed defecation symptoms and ≥9= obstructed defecation symptoms).[104]

In **Paper I** the dichotomized scores were reported to differentiate between women reporting and not reporting obstructed defecation symptoms, and in **Paper II** both the dichotomized and continuous scores were reported.

Sample size calculation

The sample size was calculated based on the results from an RCT conducted on women with CPP that applied an intervention similar to the one in this study, though it was individually delivered. The aforementioned study showed a change of 2.2 on the NRS for mean pain intensity between the groups after three months[13] which indicated a difference of one standard deviation (SD) in the change. Based on these assumptions, the effect size was estimated as "1". With a significance level of 0.05, a power of 90%, and an estimated dropout rate of 30%, 33 women should be included in each group.

Randomization and blinding

The randomization database was administered by the Clinical Research Department at the hospital, and available only for the primary researcher and the project leader. Randomization with alternating block sizes of four and six were applied. A nurse at the Pelvic Floor Center administered referrals to treatment groups.

Because of the nature of the intervention and comparator group, the participants and physical therapists involved could not be blinded. The person that scored the videos of the Standardized Mensendieck Test was blinded to group assignment and to time of data collection (baseline or 12 months).

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics for Macintosh, versions 25 and 26.[105] The level of statistical significance was set to $p<0.05$.

In all three papers descriptive statistics were presented with mean and SD or median and

interquartile range (IQR) for the continuous variables, and frequencies and percentages for the categorical variables.

Paper I: To investigate differences in current subjective health status between women with and without a history of abuse and with and without pelvic surgery, the variables "sick leave ≥12 weeks last year," "use of analgesics weekly in the last month," "pelvic pain intensity," "dyspareunia", "urinary incontinence", "anal incontinence", "obstructed defecation syndrome", "number of any SHC," "number of severe SHC," and "HSCL-25 score above 1.75" (included subscales for anxiety and depression) were tested separately with bivariate tests. For continuous variables the independent samples t-tests or Mann Whiney U-tests were used as appropriate, and for categorical variables the Pearson Chi-square test for independence was used.

Paper II: For continuous data, the independent samples t-test or Mann-Whitney U-test was used for primary analyses of group-differences in the change in the groups from baseline to 12 months. The assumptions for parametric tests of normal distribution of residuals and equality of variances were checked before analyzing the data.[106, 107] For the categorical variables changes in the number of women reporting problems were described. Sensitivity analysis of the primary outcome was performed with a linear regression model adjusted for the baseline value. The statistical analyses followed the intention-to-treat approach.
In case of missing data on sub-items of the secondary outcome measures, averages of the available responses were used.[108] Outcome measures with more than 10% of missing items were not included in analyses.

Paper III: The potential associations between the selected pretreatment characteristics and change in mean pain intensity were first assessed one by one in a linear regression model, adjusted for age and treatment group. The variables with strongest association ($p<0.10$) with the primary outcome were further included in a multivariable linear regression model with backward selection, adjusted for age and treatment group. The normality and homoscedasticity assumptions for the multivariable linear regression model were assessed by visual inspection of the residuals. Estimates of association were presented as regression coefficients with 95% confidence intervals (CI). For continuous variables, the regression coefficients were presented per SD.

Ethical considerations, trial registration and funding

This study was conducted in accordance with the principles of the Declaration of Helsinki. Written and oral study information was provided to the participants, and the informed consent forms were signed. The study was approved by the Regional Committee for Medical and Health Research Ethics North (18.09.2014 2014/1398, Appendix 7) and by the Institutional Review Board at the University Hospital of North Norway (0444 / 24.02.2015). The trial was registered at clinicaltrials.gov (NCT02356796, February 5, 2015) and reported in accordance with the CONSORT statement.[109]

The Norwegian Fund for Post-Graduate Training in Physical Therapy (ID: 62559) and Northern Norway Regional Health Authority (SFP1228-15) funded this study. The funding sources had no involvement in any stages of the study.

5 Results

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

Participant flow, dropouts and adherence

A total of 108 women were considered for study participation. Sixty-two (57%) of these women gave consent to participate in the study and were included, 31 (29%) declined to participate, and 15 (14%) did not meet the inclusion criteria. Excluded participants were offered a referral to regular physical therapy treatment. The participant flow through the papers is shown in Figure 6.

Among the 62 randomized women, six in the intervention group and five in the comparator group, dropped out of the study before the 12-months analysis. Reasons for dropping out were withdrawal (n=5), lost to follow-up (n=4) and missing data on the primary outcome at 12 months (n=2).

The majority of the women in the intervention group attended all the four sessions. One woman attended only for the first 10-days session, and seven attended 12-14 days of the total 16 treatment days (median 16, IQR 2). In the comparator group the median number of physical therapy consultations was 14 (IQR 29). One woman did not receive any physical therapy during the 12 months from baseline data collection to post-test.

Table 6 shows the main baseline characteristics regarding demography, pain status and medical history of the participants in each of the three papers. Detailed descriptions of the samples are given in each paper.

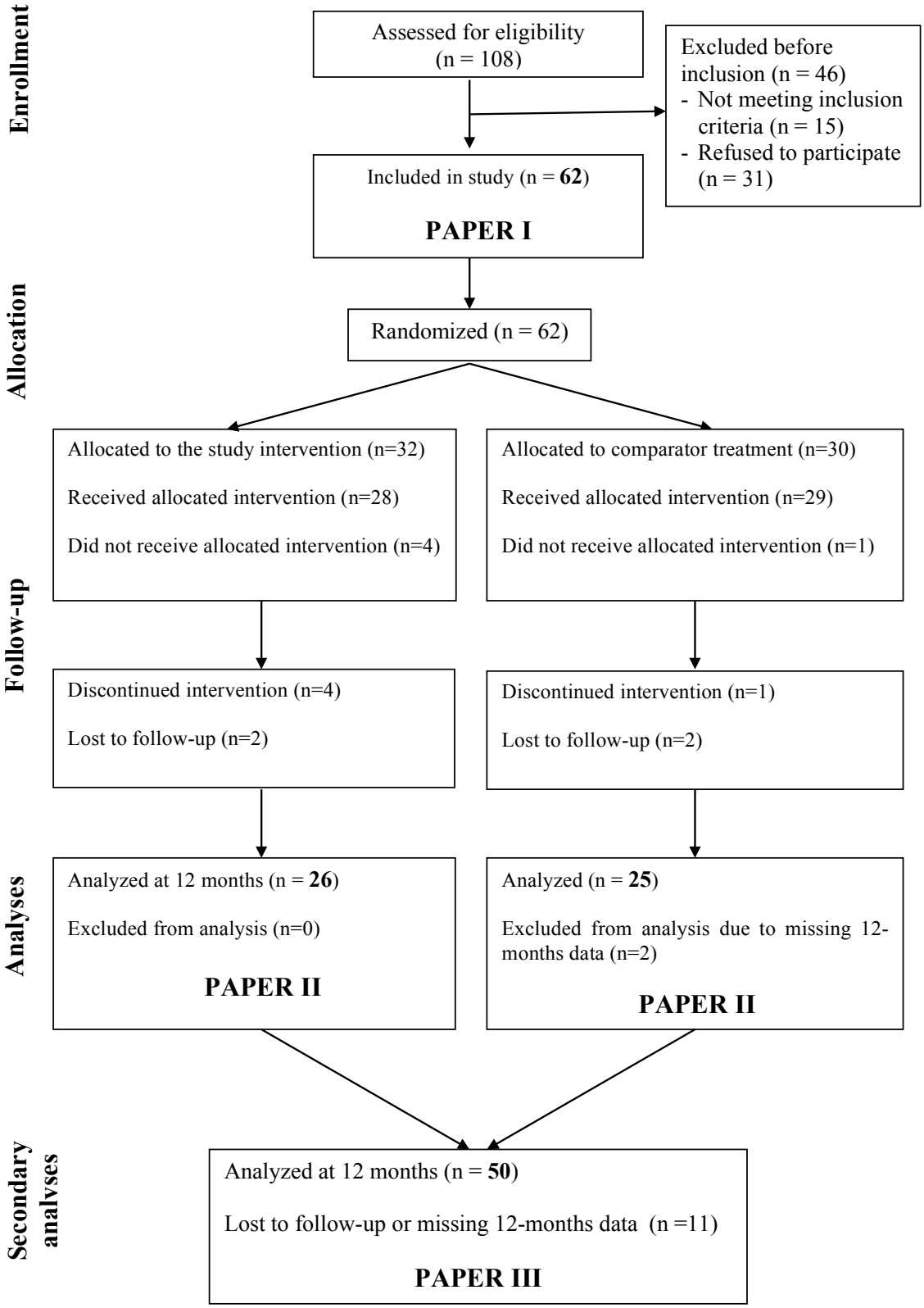

Figure 6 Participant flow through the study

Table 6 The main baseline characteristics of the participants in Papers I, II and III

	Paper I	**Paper II**		**Paper III**	
	Included (n=62)	Intervention group (n = 26)	Comparator group (n = 25)	Received PT treatment (n=50)	Drop-outs (n=11)
Age, years (SD)	38.0 (12.4)	39.4 (10.3)	36.5 (13.8)	38.1 (12.2)	38.3 (14.4)
Children, number (SD)	1.6 (1.4)	2.0 (1.5)	1.3 (1.2)	1.6 (1.4)	1.6 (1.4)
Higher education[a], n (%)	28 (45.2)	11 (42.3)	14 (56.0)	25 (50.0)	3 (25.0)
Active in work of studies, n (%)	34 (54.8)	13 (50.0)	15 (60.0)	28 (56.0)	
Sick leave >12 weeks last year, n (%)	18 (32.0)[b]	9 (36.0)	6 (27.3)	15 (32.6)	3 (30.0)
Pelvic pain intensity last week (NRS 0-10), mean (SD)	4.5 (2.4)	4.7 (2.0)	4.5 (2.8)	4.6 (2.4)	3.8 (2.5)
Duration of pelvic pain, n (%):					
1 - 4 years	19 (30.6)	9 (34.6)	7 (28.0)	16 (32.0)	3 (27.3)
4-10 years	17 (27.5)	8 (30.8)	7 (28.0)	15 (30.0)	2 (18.2)
> 10 years	26 (41.9)	9 (34.6)	11 (44.0)	19 (38.0)	6 (54-5)
Previous abdominal or pelvic surgery, n (%)	44 (71.0)	18 (72.0)	15 (60.0)	32 (65.3)	9 (81.8)
History of abuse, n (%)	31 (50.0)	12 (46.2)	15 (60.0)	26 (52.0)	4 (36.4)

[a]Completed ≥1 year of University College or University. [b]Five missing at baseline.
SD, standard deviation; PT, physical therapy; NRS, numeric rating scale.

Paper I

The results showed that women with CPP have complex symptoms and high scores for both physical and psychological complaints, including reduced sexual desire and pain during intercourse. The mean pain intensity at baseline was reported to be approximately the same as that experienced over the last four weeks by 49 women (79%). The majority (n = 47, 76%) also reported that they had experienced constant pain during the last week.

Thirty-one (50%) of the women reported events perceived as abuse of a physical, psychological or sexual nature. Compared to women not exposed to abuse, a significantly larger proportion of the women exposed to abuse reported use of analgesics (61% versus 35%, p = 0.04), sick leave >12 weeks (56% versus 14%, p = 0.005), anxiety scores above cut-off (56% versus 21%, p = 0.009) and obstructed defecation syndrome score above cut-off (48% versus 19%, p = 0.02). They also reported a higher median number of total subjective health complaints (14 versus 11, p = 0.02), than women not exposed to abuse (Table 2 in Paper I).

Forty-four (71%) women reported a previous intra-abdominal, vaginal or anal surgery, with a range from 1 to 10 surgeries for each of these women. Women reporting previous surgery used more analgesics (p=0.04), reported more sick leave (p=0.02), and less dyspareunia (p=0.008) than those not reporting surgery (Table 3, Paper I).

Paper II

The results of the RCT showed that the mean change in the primary outcome was -1.8 (-2.6 to -1.0) in the intervention group and -0.5 (95% CI -1.3 to 0.3) in the comparator group. Among the women in the intervention group, 19 reported improvement whereas four reported no change and three reported worsening in mean pain intensity. In the comparator group 17 reported improvement, three reported no change and five reported worsening. The group-difference in mean pain intensity was 1.2 (95% confidence interval; -2.3 to - 0.2, p = 0.027) (Figure 7).

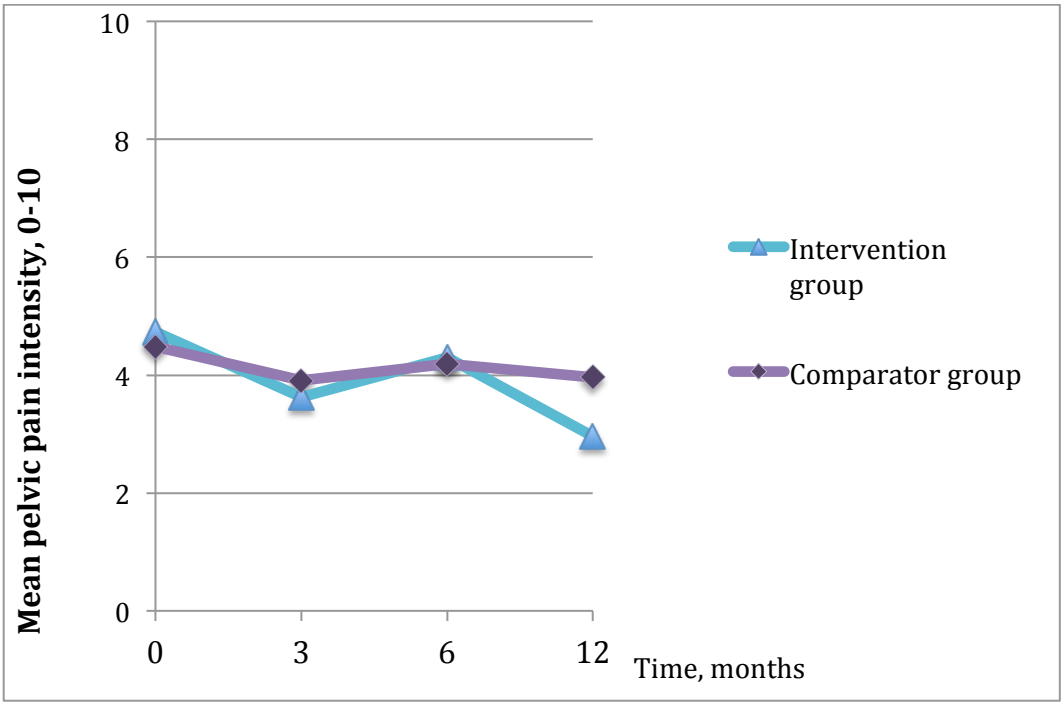

Figure 7 Mean pelvic pain intensity at different time points for the two groups

The intervention group showed greater improvements for respiratory patterns assessed with the Standardized Mensendieck test (mean difference 0.9, 95% confidence interval 0.2-1.6, p = 0.015) and for pain-related fear of movements assessed with the Tampa Scale of kinesiophobia (mean difference 2.9, 95% confidence interval -5.5 to -0.3, p = 0.032). There were no significant group-differences for the remaining secondary outcomes (Table 5, Paper II).

Paper III

Among the four baseline variables that were included in the multivariable regression analysis the variables duration of pain ≥6 years and mean pain intensity at baseline were identified as significant predictors of change in pain intensity after PT-treatment. The regression coefficient for duration of six years or more was 1.3 (95% CI 0.3 to 2.4), meaning that compared to the group with shorter duration than six years the mean change in pain intensity was 1.3 points higher (=worse) in the group with longest duration after PT treatment. For pain intensity the regression coefficient was -0.6 (95% CI -1.1 to -0.1), meaning that for every standard deviation (SD = 2.4) increase of baseline pain intensity the changes in pain after 12 months decreased by 0.6 points on the NRS.

The variable main pain site in the pelvic area (yes/no) was not included in the regression analysis due to few participants in one of the categories (n=5), but we observed that none of these five women reported pain reduction after physical therapy treatment.

Observations of the baseline data for the women that dropped out of the study showed that they were more likely to have a body mass index of 25 or higher. A larger proportion had lower education, and 55% (n=6) were on sick leave at the time of data collection compared to 12 % (n=6) of the women that did not drop out. A larger proportion of the women that dropped out had used analgesics weekly the last month, reported main pain other sites than in the pelvis or had a higher number of previous surgeries. They also had a higher mean score on the HSCL-25 for symptoms of anxiety and depression.

6 Discussion

Summary of main findings

The aims of this thesis were to obtain knowledge of the characteristics of women with CPP referred to physical therapy after being cleared for non-malignancy or other specific therapy at a tertiary hospital, and to compare the effectiveness of a group-based multimodal treatment with primary care physical therapy. Additionally, we aimed to investigate if selected baseline characteristics were associated with treatment.

We found that the study population represented a heterogeneous group of women with a range of different histories and health statuses. The reduction of the mean pain intensity from baseline to 12-months was significantly greater in the intervention group than in the comparator group, but the difference in the change between the groups was less than expected and the clinical relevance of the results is uncertain. Further, women with the longest pain durations were less likely to obtain reduced pain intensity after physical therapy treatment, and higher baseline pain intensity was associated with larger reduction in pain after treatment.

In the following chapter these results will be discussed more thoroughly. The results of the single papers will be seen in relation to each other, and be discussed in light of the theory and evidence presented in the background chapter.

Interpretation of the results

Paper I

The analysis of the baseline data of the 62 women included in this study confirmed previous descriptions of women with CPP in terms of long pain duration, multiple associated health complaints and multiple treatment alternatives tested.[1, 41, 42, 44, 110] The health histories and the magnitude of current health complaints varied among the women. This heterogeneity is considered to be an essential characteristic of the group, and important both for the interpretation of the treatment results in the present study, for clinical practice and in planning of future research.

The mean pelvic pain intensity reported at baseline was 4.7 on the NRS-scale. This is in accordance with the pain intensities previously reported in population-based studies of

women with CPP,[38, 39, 41] and slightly lower than reported in studies conducted in clinical settings.[43, 46] An important observation is that the standard deviation of the mean pain intensity was 2.4, reflecting large variations in baseline pain between the women in the group. The majority of women reported unchanged mean pain intensity during the last month, indicating that the numbers reported are representative for their "usual" pain.

The prevalence of sexual dysfunction, urinary incontinence, anal incontinence and obstipation were higher among the women in our study than reported in the general population.[111, 112, 113] The majority of the participants were sexually active, and about two thirds of these women reported reduced desire and dyspareunia. These numbers are in the upper tier compared to previous reports of dyspareunia among women with CPP, where the prevalence of dyspareunia vary between 6% and 75%.[4, 42, 38, 43] The severity of incontinences and obstipation was low for most women, but for the few women with severe problems such dysfunctions are important to reveal. No comparable numbers have been found for other chronic pain patients, but it is likely that these pelvic dysfunctions are more prominent in women with CPP and thus especially important to address during assessment and treatment.

Surgery in the abdominal or pelvic area was reported by almost three quarters of the women in the present study, with a total of 116 surgeries reported among those. Compared to previous studies on CPP this number appears higher, although direct comparison is not possible due to differing reporting methods and inclusion criteria.[13, 47] Women with previous surgery had been more on sick leave and used significantly more analgesics than those without. Notably, they also reported lower mean pain intensity during intercourse than women without previous surgery. This may be due to more analgesic use, or indicate that in some cases surgery have alleviated pain from local pathologies and thereby also led to less dyspareunia. In contrast to other reports, we did not find associations between having had a surgery and scores of anxiety, depression, or other health complaints.[1, 44] The heterogeneity among the women in the study sample both regarding history and present health status may be an explanation of the lack of associations shown.

Abuse has been identified as a potential risk factor for CPP.[44] Fifty percent of the women reported that they had been exposed to physical, psychological or sexual abuse. The high number is in line with the findings in a survey of 713 women with CPP recruited from an American pelvic pain clinic, with 46% reporting abuse exposure.[45] Studies that report only

sexual abuse show a prevalence of 15-25% among women with CPP, equivalent to other patient groups.[114-116] The reports of abuse appear to be high compared to the general female population, but cannot be directly compared as different definitions and data collection methods have been used. Women with a history of bullying or abuse have been shown to have poorer scores on both somatic and psychological health measures,[117] and several reports indicate that exposure to abuse of any kind can lead to a higher risk of poor health later in life.[45, 115, 116, 118] This was supported by our study, as the women reporting abuse also reported significantly poorer scores of other health outcomes such as anxiety, obstructed defecation and total subjective health complaints.

Paper II

To our knowledge, the RCT conducted here is the first that compares a group-based treatment consisting of body awareness therapy, patient education, and cognitive techniques with primary care physical therapy for women with CPP. The study intervention had not previously been evaluated systematically and never been compared to other treatments, hence, we did not know which treatment approach would give the best result for the participants. The results of the RCT showed larger improvements in pain intensity, respiratory patterns and pain-related fear of movements among the participants in the multimodal group based intervention than among those referred to primary care physical therapy.

The differences in changes between the two study groups were small, possibly explained by the heterogeneity described in Paper I. The varying results of both study groups may indicate that women with CPP benefit from different interventions, supporting further investigations of subgroups within the condition.[4, 12] This is supported by the findings in a recently published study of Norwegian patients with a range of chronic pain conditions, concluding that investigation of subgroups are necessary to improve treatment outcome.[119] The varying change in pain intensity in the intervention group contrasts with the results by Haugstad et al., where only one of the 19 women in the somatocognitive therapy group reported unchanged pain, and the rest of the group improved.[13] This can be due to differences between the samples in the two studies, but it can also reflect different interventions and study designs. The intervention in Haugstad et al. was individually delivered, and contained manual soft-tissue treatment in addition to body awareness exercises and cognitive strategies. Group-based interventions can provide a feeling of belonging to a group, exchange of valuable experiences

with others with a similar condition, and depending on the setting and organization it can be time saving and cost efficient.[71, 72, 73] However, a group-setting may be challenging for some patients as well,[73] and for those an individual approach can be more suited. Also, manual techniques are shown effective for pain reduction in CPP, and may provide extra benefits for some women.[12]

In our study we found a group-difference in change of pain of 1.2, while in Haugstad et al. it was 2.2. In the latter study the intervention was compared to two consultations with standard gynecological care consisting of advice and medication, while in our study the comparator group received physical therapy consisting of pelvic floor muscle training, general exercises, relaxation exercises and soft tissue treatment alone or in combination. Half of the women in our study also reported dialogue with the therapist as a part of the treatment. This shows that physical therapy as administered in primary care in many cases also addresses the multiple factors of CPP. In the RCT published in 2019 by Ariza-Mateos et al. the comparator group received physical therapy, and the results showed a difference in pain reduction of 1.1. This is similar to what we found, and confirms the explanation of smaller group-differences when both groups receive physical therapy.[83]

The multimodal treatment aimed to give new positive movement experiences, to increase the knowledge of pain and its effect on body and mind as well as challenge habits of avoidance related to fear of pain. We argue that although the group differences were smaller than expected, the statistically significant greater improvements in pain, respiratory patterns and pain-related fear of movements in the intervention group support the hypothesis that a group-based multimodal approach is suitable for women with the multifaceted condition CPP. The complex characteristics described in Paper I and the multiple pain mechanisms are also arguments for the application of a broad management that addresses the multiple mechanisms assumed to be involved.[4] The perspectives provided in ACT may be especially helpful in dealing with a complex condition like CPP. In many cases the women may feel insecure regarding the condition and the prognosis, and a structured method to accept not only the pain, but also to accept the insecurity related to the pain condition, can be central in a process of change.[67, 69]

Respiration patterns are described as closely linked to the ability to relax and to body awareness, and the findings of improved respiration patterns can thus be related to the

relaxation techniques and body awareness in the study intervention.[120] New experiences through the movement therapy combined with pain education can enhance the feeling of control of the pain, and thus reduce the fear of pain related to movements or activities.[28, 35, 32] The greater improvements in respiratory patterns and pain-related fear of movement shown in the intervention group corroborate with the previous results presented by Haugstad et al.[13] and Ariza-Mateos et al.[83]

Surprisingly, we found no statistically significant changes in the other outcome measures that were included in the RCT. Both groups obtained an improvement in health related quality of life equivalent to estimated minimal important change.[121] However, there were no group differences in the change. For symptoms of anxiety and depression, dyspareunia, reduced sexual desire and obstructed defecation the improvements were not statistically significant. The proportions reporting problems with urinary or anal incontinence remained almost unchanged during the intervention period. However, the numbers were small and this study was not powered to detect differences in improvement in the multiple secondary outcomes.

The greatest reduction in mean pain intensity in the intervention group was observed between six and 12 months. In the comparator group the pain reduction did not change after the first three months. The continued pain reduction might reflect that a pre-planned program designed to last for 12 months entails positive factors such as the feeling of being in a system and predictability. Considering the theory that chronic pain also is sustained by some types of behaviors, these results are in line with behavioral change research stating that sustainable behavioral change is considered to take six to eight months.[122] This suggests that the long duration of the intervention is important for many women with CPP.

Paper III

The secondary analysis of possible associations between baseline characteristics and treatment outcome showed that long pain duration was a negative predictor, while higher baseline pain intensity was associated with more pain reduction. Only four baseline variables were included in the analyses, thus the results have limitations and can only be used for generation of hypothesis for future studies.

The significant association between duration and treatment outcome has not previously been

shown in women with CPP,[76, 123] but is supported by studies on other chronic pain conditions showing that lasting pain becomes more complex and the prognosis of recovery becomes poorer.[40, 124] In a prospective study by Allaire et al. the variable "re-referral" was identified as a predictor of poorer outcome. This may indirectly indicate failure of previous treatment efforts or prolonged pain, both leading to re-referrals, and thus support the importance of early and effective treatments. The finding of long pain duration as a negative predictor for pain reduction emphasize that early intervention is important.[32, 40]

Our finding of higher baseline pain as associated with larger pain reduction during treatment contrasts with the results of two previous studies on CPP, where the opposite association was found.[32, 76] The literature on other chronic pain conditions is conflicting regarding the direction of the association between baseline pain intensity and treatment outcome.[125] This can have several explanations, such as different study populations, treatments and outcome measures.[126] Additionally, the experience of pain is highly subjective and influenced by multiple factors, including sensory, emotional, cognitive and social dimensions.[127] The association between high baseline pain and larger pain reduction might also be explained by the methodological effect of regression to the mean. Due to normal fluctuations participants with high baseline pain may report lower pain intensity at posttest.[81, 125]

The presence of pain at multiple sites has received increasing attention in pain research, and the phenomenon has been described both as a predictor of pain outcome, and as a result of chronic pain.[128, 82, 76] In CPP, a greater number of pain sites has been shown to be associated with more negative outcomes, such as anxiety, depression and worse quality of life.[80, 128] In this study five women had worse pain in other areas of the body than in the pelvis. None of these women reported reduced pain after the intervention period, which may indicate that they were in need of some other type of intervention prior to receiving treatment focused on CPP. Due to the small group of women these observations are highly unsure.

We did not detect the expected associations between anxiety and depression and treatment outcome.[32, 126, 129, 40] One possible explanation of this is that the participants in our study reported mild or moderate scores for anxiety and depression, which was also the case in two former studies on CPP that also did not show such associations.[76, 123] In a large population based study Ayorinde et al. (2017) identified two distinct clusters among their sample of

women with CPP, characterized by the absence or presence of psychosocial distress.[38] It has been suggested that associations between patient characteristics and outcome predictors must be investigated in each individual patient, and may not be detectable at a group level.[130] The role of psychological factors upon treatment outcome is definitely multifaceted and warrants further subgroup investigations. The women that dropped out of the trial showed some distinctly different characteristics, and these observations can serve as a reminder that patients with a more "vulnerable" profile need closer follow-up, and possibly different interventions.

These secondary analyses were performed for the whole sample as one group, regardless which intervention they had received. Treatment group was included as a confounding variable, but the variables pain duration and baseline pain intensity came out as stronger predictors of change in pain intensity. The claim that physical therapy may provide valuable therapeutic effects for subgroups of women with CPP seem to be valid, whether it is delivered in primary care or in a group in a specialist health care setting.

Discussion of methodological aspects

In this chapter the strengths and limitations of the different methodological aspects of the thesis will be discussed. All the three papers were based on the same sample of participants, outcome measures and study setting, and a common discussion of the methodological aspects in the thesis follows.

Internal and external validity are central terms in clinical research. Internal validity concerns the degree to which the correct conclusions are drawn about what actually happened in the study. External validity, or generalizability, concerns the degree to which the results or conclusions can be applied to people and events outside the study.[131]

Study design

In Paper I, a cross-sectional design was applied, as it is appropriate for describing characteristics of a sample. A limitation of this design is that no causality can be established between the historical variables. This means that the observed health status of women with a history of abuse exposure or surgery cannot be determined a consequence of these experiences.

In Paper II the RCT-design was applied, which is the gold standard for establishing causality between an applied treatment and outcome and for comparison of different interventions. The pragmatic RCT-design was chosen due to the real world clinical setting, complex study intervention and lack of standardization of comparator group. This design strengthens the external validity as it is considered to be both applicable and generalizable to real world clinical settings.[86] A limitation of the pragmatic RCT design is that the heterogeneity of practitioners, participants and delivery of treatment can make comparison to other trials challenging.[86] The conduction of a pilot study prior to the full scale RCT could have sorted out some of the practical challenges that were discovered during the study period.[132]

The secondary analysis in Paper III emerged based on the results from the RCT, and the results are presented as hypothesis generating for further studies. In order to increase the strength of a predictor analysis, the study should be designed with this purpose from the start, meaning larger sample size and pre-planned hypothesis of associations between baseline characteristics and treatment outcome.[133]

Study sample

The study sample was a selected group of women referred to physical therapy after assessment by a medical specialist in a tertiary hospital, meaning that the results cannot be generalized to others than women with CPP who fulfill the same inclusion criteria as used in this study. Although wide, the inclusion criteria were clearly defined, which is a strength. A limitation to the generalizability of the results is that among the eligible women only 57 % gave consent to participate. Reasons for this were economic concerns, long travel distance and inability to stay away from home for 10 days. This means that the women that gave consent are an even more selected group than described in the inclusion criteria.

The sample size that was needed to detect clinical meaningful differences in change of pain intensity was calculated based on a previous study, and the necessary number of participants were retained through the final analyses. The relatively small sample size allowed us to perform thorough interviews with each of the 62 women. The small sample size can be regarded a limitation, though, especially related to analyses and interpretation of changes in the multiple secondary outcomes and small subgroups detected. However, no previously conducted RCTs applying a multimodal intervention on women with CPP have included a

higher number of participants,[13, 83] and despite great efforts it took 18 months to include the 62 women. To be able to include a higher number of participants a multi-center study would be necessary, and hence more economic and personnel resource demanding.

Although we conducted a pragmatic RCT and the comparator group was referred to the usual treatment in primary care, these women were offered closer follow-up than in a non-research-setting as they were provided with information about recommended physical therapists, they could contact the nurse associated to the project if they had queries, and they got their deductibles refunded. This may have lead to better adherence to the primary care physical therapy than in a non-research setting.

The 18% dropouts are a threat to the internal validity. Some of the dropouts seem difficult to prevent, as the women withdraw or stopped replying. Data on four of the women that ended up as missing at 12 months could possibly have been collected and included in the intention to treat analysis. One of these women received a botox injection after two weeks of physical therapy in primary care, and the other three did not want to continue in the intervention group after the first session due to "to much else going on" or because they did not experience the desired improvements.

Blinding

Except for during the baseline tests and the person that scored the videos of the movement test, we were unable to blind participants, therapists and assessors for group allocation. The main cause for this was the impossibility to conceal whether the participants were referred to a group-based intervention organized by the hospital or to primary care physical therapy. However, prior to randomization both the participants and the therapists were informed that it was unknown which treatment that was more effective.

Of practical reasons, the baseline assessors contacted the research department for randomization after inclusion of a new participant. The same person administered the three and six-months data collections, and conducted the 12-months tests. This complicated the concealment of treatment group allocation throughout the study. Involving another person had been more resource demanding but not impossible, and should be endeavored in future studies.

Outcome measures and data collection

The primary objective of the RCT was to register changes in the women's pain intensity from baseline to post-intervention at 12 months. The choice of primary outcome was based on several factors. First, pain intensity is a core aspect of the condition CPP. Secondly, the study intervention aimed to reduce pain in addition to improve daily function. Third, mean pain intensity is a commonly applied primary outcome measure and application of this ensures comparability with previous studies. The NRS is a recommended and frequently applied tool in clinical trials on chronic pain conditions.[134]

As pain intensity in most cases varies both during the day and from day to day, we chose to record the mean pain during the last seven days. This also allowed direct comparison with the results of the previous RCT by Haugstad et al.[13] To ensure registrations from all participants, the questionnaires were filled out when the women attended the outpatient clinic for testing. However, when retrospective questions are applied there is a risk of recall bias. Alternatives could have been to shorten the time period for registrations to for example four days, or to apply the more time consuming variant of daily registrations for a week and then calculate the average score. Using a smart phone with real time registrations could have been a good solution, and can be considered in future trials.

CPP is a complex experience, and pain intensity is one among many dimensions.[134] According to the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT), selection of outcome measures should be based on "the domains of interest for the participants, the characteristics of the treatment and its putative effects".[134] With a complex condition and an intervention aiming to improve both pain and function, an outcome measure that embrace more dimensions of the condition could have been an alternative.[135] One example of such a measure is the "Patient Global Impression of Change scale", which is described as suited for detecting clinically relevant changes in overall health status in chronic pain patients.[136, 137]

A number of secondary outcome measures were applied in this study. In Paper I this allowed reporting of several aspects of the women's situations. In retrospect, the number of secondary outcomes was too extensive in Papers II and III. The sample size calculation was not based on the secondary outcomes, thus these results must be interpreted with caution. A strength is that

all of the secondary outcome measures were validated, except from the scheme that recorded sexual function. Self-reported questionnaires were applied for all outcome measures except the Standardized Mensendieck test. A limitation of self-reported questionnaires is that they always involve a risk that respondents either underestimate or overestimate their symptoms.

Several of the outcome measures were dichotomized, which gives a more imprecise estimate of the measures reported. This is particularly obvious in Paper III, where the duration variable was dichotomized at under or above six years – a rather rough measure. With a larger sample, the possibility to split in more categories could have given a more precise report of the association between duration and treatment outcome.

The Standardized Mensendieck Test is validated for application on the patient group that are studied in this thesis. However, only one reliability-study has been performed and the application of the test is rather limited.[88] Thus, further studies to ensure the reliability of the test is warranted.

In our study, we did not include any manual testing of muscle quality, strength, flexibility, or other specific tests. The importance of the pelvic floor muscles is advocated in numerous reports on CPP, and myofascial pain and trigger points are likely to be present.[138] However, as a holistic approach was emphasized here, the local pathology was not considered the main focus. Also, the fact that we did not record physical activity can be considered a limitation. In many chronic pain conditions, physical activity is limited due to pain and a response to decreased pain may be increased activity and improved functioning.[139] The EQ5D-5L questionnaire includes questions about daily functions, and thus covers part of this aspect. Additionally, as stated above, the number of secondary outcomes was high. In this study it was necessary to limit the total number of outcome measures both considering how much you can demand from the participants, and to obtain the power of the study.

The lack of active engagement of women with CPP in the planning and conduction of the study is a weakness. This could have brought other perspectives, provided important tips regarding outcome measures, and thus led to better quality.[140, 141]

Study intervention and comparator group

The study intervention was based on clinical guidelines and developed by experienced clinicians. This multimodal intervention was as standardized as feasible. However, the multifaceted nature of the intervention make it difficult to evaluate the effectiveness of each of its components.[86] The EAU-guidelines does not specify how the exact organization, contents, or necessary contributions from multiple disciplines should be. In our study three different disciplines were involved, but the physical therapists made the main contributions. It is not known what is best in terms of involving multiple health professionals with specialized but narrow competence, or involving fewer disciplines with broader competence. The question of what is optimal versus what is sufficient is also relevant. An intervention that involves fewer disciplines, as the study intervention in this thesis, is less resource demanding both regarding organization and economy.

Both the study intervention and the comparator were carried out in the ordinary clinical settings, which strengthens the external validity. The study intervention was designed with a specific combination of practitioners and in a certain setting, making the effect unsure when adapted by other therapists in different settings.

The lack of standardization of the comparator group can be considered a limitation because of the heterogeneous treatment. In the pragmatic RCT the aim was to compare the study intervention with the physical therapy usually offered to women wit CPP in North-Norway. The concern of the unstandardized comparator group was thoroughly discussed in our research group when planning the study. As there is no consensus on a standardized physical therapy approach in CPP,[12] comparing the intervention to treatment different from what is usually offered could be criticized as well. It would probably be challenging to make the primary care physical therapists provide a pre-designed treatment, as the knowledge of evidence based pain treatment; focus on individualization and patient involvement is among the therapist. Another solution could have been a multiple-arm design similar to that applied in the RCT by Ariza-Mateos et al. (2019),[83] where the comparator groups received single modality treatment in the same setting as the intervention group. However, such a design would require more resources and a larger sample size. Finally, a wait-list comparator was discussed, but regarded unethical, as the women would have to wait for 12 months after assessment.

Statistical considerations

Statistical validity refers to the extent to which the statistical analyses are appropriate. In Paper II the Students T-test for independent samples was applied to compare changes between pre- and post-treatment scores, and linear regression performed as sensitivity analyses to adjust for baseline values. These are appropriate analyses, although it is claimed that reporting group differences as actual scores at 12 months including baseline values as covariates are the analysis of choice.[142] This method is termed analysis of covariance, often referred to as ANCOVA, and is known to produce unbiased estimates of treatment effect in the presence of baseline imbalance when groups are randomized. In our data material the results turned out the same either we applied the predetermined tests or ANCOVA, but for future studies the recommended analysis should be chosen.[142]

The statistical power of the RCT was determined for the primary outcome, and it can therefore be expected that inadequate power may sometimes explain unexpected findings or lack of expected results for secondary outcome measures.

Making a statistical analysis plan prior to data collection could possibly have avoided some of the challenges met during the data analysis.

7 Conclusions

The cross-sectional study showed that women with CPP are a heterogeneous group, with complex symptoms of both physical and psychological complaints. The heterogeneity indicates that there are several subgroups with different characteristics within the wide group. Women exposed to abuse have especially high scores related to analgesic use, sick leave, and they report more physical and psychological health complaints. Women with previous surgery report more analgesic use and sick leave, and lower pain intensity during intercourse, than those without previous surgery.

The RCT showed a smaller than expected difference between the groups with respect to reduction in mean pelvic pain intensity after 12 months, but the difference was statistically significant. The intervention group showed additional improvements in the respiratory patterns and in pain-related fear of movements.

Based on the secondary analysis we hypothesize that pain duration and pain severity is of distinct importance in terms of treatment outcome. The results in all the three papers strengthen the suggestions of existence of subgroups within the wide condition CPP, and there is a need for further tailoring of interventions.

The conduction of this study provided valuable experiences regarding performing a RCT with a complex intervention and a heterogeneous group of participants, which will be helpful in planning of future studies on CPP.

8 Clinical implications and future research

Treatment of CPP is challenging, and there does not seem to be a "quick fix" for the condition. In a bio-psycho-social perspective multiple factors influence a treatment process, and contribute to the results.[143] The complexity of the participant's health history and -status shown in this thesis highlights the need for health professionals to have specialized knowledge of chronic pain mechanisms. In order to tailor interventions to the individual women's needs, thorough baseline assessments, preferably in a multidisciplinary setting, should be performed.[76] Specific issues related to the pelvic area distinguish these women from other chronic pain patients. Sexual function, incontinence and constipation should be paid attention. In addition, it is important to be aware of the high prevalence of abuse exposure. Although not shown in our data, psychiatric symptoms are known to be poor prognostic indicators for treatment success, and thus essential to take into account in the assessment and treatment of CPP.[144-146]

The finding of long pain duration as associated with poorer treatment outcome emphasize that early interventions should be sought. Many participants reported pelvic surgeries or other treatments without satisfactory results prior to referral for physical therapy. In many cases, consideration for a non-invasive intervention such as physical therapy may be appropriate at an earlier stage.[147] Increased knowledge about which women that are at risk of developing long lasting and more complex CPP-condition is needed, as well as knowledge of factors that may be predictive for treatment outcome. This information can be applied when making treatment plans. Also, evaluations during treatment can identify women with worsening of symptoms that may be in need of other types of management.

Overall, we argue that the results in this thesis support the recommendation for taking a broad bio-psycho-social approach and that a multimodal intervention including physical therapy should be further developed.[46] The physical therapy component adds the expertise about the movement system with the other pain mechanisms.[22] A discussion of alternative forms for multimodal approaches would be interesting to include in future works, as it seem difficult to integrate multidisciplinary and multimodal assessment and management in all stages of the health care systems. Single discipline treatment with multimodal approach may then be a good alternative.[148] An even more tangible strategy can be to focus on increased knowledge of CPP, and to inform general practitioners and others about where to access useful information and practical tips about how to deal with CPP.

There is a need of studies investigating which components of a multimodal intervention that are more beneficial for different women with CPP, as well as studies to evaluate group-based versus individually tailored interventions. The challenges regarding the contents of a comparator group must also be solved as discussed earlier. The fact that a large proportion of the eligible women in this study did not agree to participate should be considered when planning future studies, as well as the observations of the women that dropped out. Another subject for future studies would be to perform another follow-up 12 months after the end of treatment.

To provide the desired knowledge, studies with clear descriptions of the participants and of the treatments investigated, are needed. Due to the limited evidence base on multimodal treatment for women with CPP, and the complex nature of the study intervention, a prospective cohort study could have been considered prior to an RCT. Allaire et al. (2019) performed such a cohort study in a interdisciplinary clinical setting, and their model can be an example of how to gain more knowledge about patient characteristics, development of the condition over time, prognostic factors and outcome predictors.[1, 76] It would also be useful to evaluate the quality and applicability of available evaluation tools for women with CPP.

It has been suggested that combining the quantitative and qualitative outcome measures is particularly relevant in complex conditions, such as CPP. A mixed model design could have been considered here, in order to include information about the meaning the women ascribe to the pain, and how they experience the interventions given and the treatment process.[28]

In the process of determining which treatment offers that should be continued and which should not, the cost-effectiveness of implementing a treatment should be evaluated in addition to the clinical effect. This can involve examining the effect on other healthcare use and societal costs. Additionally, a consideration of the practicability of scaling up the intervention for application in other hospitals should be performed.

Works cited

1. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in women: an epidemiological perspective. Womens Health (Lond). 2015;11(6):851-864.
2. Latthe P, Latthe M, Say L, Gulmezoglu M, Khan KS. WHO systematic review of prevalence of chronic pelvic pain: a neglected reproductive health morbidity. BMC Public Health. 2006;6:177.
3. Ahangari A. Prevalence of chronic pelvic pain among women: an updated review. Pain Physician. 2014;17(2):E141-147.
4. Engeler D, Baranowski AP, Berghmans B, et al. EAU Guidelines. Edn. presented at the EAU Annual Congress Barcelona 2019. Arnhem, The Netherlands: EAU Guidelines Office 2019.
5. Peters AA, van Dorst E, Jellis B, van Zuuren E, Hermans J, Trimbos JB. A randomized clinical trial to compare two different approaches in women with chronic pelvic pain. Obstetrics & Gynecology. 1991;77(5):740-744.
6. Albert H. Psychosomatic group treatment helps women with chronic pelvic pain. J Psychosom Obstet Gynaecol. 1999;20(4):216-225.
7. Mattsson M, Wikman M, Dahlgren L, Mattsson B. Physiotherapy as Empowerment - Treating Women with Chronic Pelvic Pain. Adv Physiother. 2000;2:125-143.
8. Engeler DS, Baranowski AP, Borovicka J, et al. EAU Guidelines on Chronic Pelvic Pain2017.
9. Cheong YC, Smotra G, Williams AC. Non-surgical interventions for the management of chronic pelvic pain (Review). Cochrane Database of Systematic Reviews. 2014(3).
10. Yunker A, Sathe NA, Reynolds WS, Likis FE, Andrews J. Systematic review of therapies for noncyclic chronic pelvic pain in women. Obstetrical & gynecological survey. 2012;67(7):417-425.
11. Loving S, Nordling J, Jaszczak P, Thomsen T. Does evidence support physiotherapy management of adult female chronic pelvic pain? A systematic review. Scand J Pain. 2012;3(2):70-81.
12. Klotz SGR, Schön M, Ketels G, Löwe B, Brünahl CA. Physiotherapy management of patients with chronic pelvic pain (CPP): A systematic review. Physiother Theory Pract. 2018;28:1-17.
13. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. American journal of obstetrics and gynecology. 2006;194(5):1303-1310.
14. IASP. Pain terms: a list with definitions and notes on usage: recommended by the IASP Subcommittee on Taxonomy. PAIN. 1979;6(249).
15. Treede R-D, Winfried Rief W, Barke A, et al. A classification of chronic pain for ICD-11. Pain. 2015;156(6):1003–1007.
16. Tu FF, As-Sanie S. Evaluation of chronic pelvic pain in females UpToDate2019 [updated Jul 22, 2019. Available from: https://www.uptodate.com/contents/evaluation-of-chronic-pelvic-pain-in-females?search=chronic pelvic pain&source=search_result&selectedTitle=1~120&usage_type=default&display_rank=1.
17. ACOG. Chronic Pelvic Pain. ACOG Practice Bulletin, Number 218. Obstet Gynecol. 2020;135(3):e98-e109.
18. Green-top Guideline The Initial Management of Chronic Pelvic Pain. Royal College of Obstetricians & Gynaecologists; 2012 May. Contract No.: 41.

19. As-Sanie S. Causes of chronic pelvic pain in nonpregnant women. *UpToDate* [Internet]. 2020 January 26 [cited 2020 March 10]. Available from: https://www.uptodate.com/contents/causes-of-chronic-pelvic-pain-in-nonpregnant-women?search=chronic pelvic pain&topicRef=5467&source=see_link.
20. Edwards RR, Dworkin RH, Sullivan MD, Turk DC, Wasan AD. The Role of Psychosocial Processes in the Development and Maintenance of Chronic Pain. The Journal of Pain. 2016;17(9, Supplement):T70-T92.
21. Gatchel RJ, Peng YB, Peters ML, Fuchs PN, Turk DC. The Biopsychosocial Approach to Chronic Pain: Scientific Advances and Future Directions. Psychological Bulletin. 2007;133(4):581-624.
22. Chimenti RL, Frey-Law LA, Sluka KA. A Mechanism-Based Approach to Physical Therapist Management of Pain. Phys Ther. 2018;98(5):302-314.
23. Nicholas M, Vlaeyen JWS, Rief W, et al. The IASP classification of chronic pain for ICD-11: chronic primary pain. Pain. 2019;160(1):28-37.
24. Treede R-D. The International Association for the Study of Pain definition of pain: as valid in 2018 as in 1979, but in need of regularly updated footnotes. Pain Rep. 2018;3(2):e643.
25. International Association for the Study of Pain I. IASP Terminology www.iasp-pain.org: IASP; [cited 2020 March 24th]. Available from: https://www.iasp-pain.org/terminology.
26. Aredo JV, Heyrana KJ, Karp BI, Shah JP, Stratton P. Relating Chronic Pelvic Pain and Endometriosis to Signs of Sensitization and Myofascial Pain and Dysfunction. Semin Reprod Med. 2017;35(1):88-97.
27. Steege JF, Siedhoff MT. Chronic pelvic pain. Obstet Gynecol. 2014;124(3):616.
28. Brodal P. A neurobiologist's attempt to understand persistent pain. Scand J Pain. 2017;15:140-147.
29. Ng SK, Urquhart DM, Fitzgerald PB, Cicuttini FM, Hussain S, Fitzgibbon B. The relationship between structural and functional brain changes and altered emotion and cognition in chronic low back pain brain changes: a systematic review of MRI and fMRI studies. Clin J Pain. 2018;34:237-261.
30. McEwen BS. Protective and damaging effects of stress mediators: central role of the brain. Dialogues Clin Neurosci. 2006;8(4):367-381.
31. McEwen BS. Stressed or stressed out: what is the difference? J Psychiatry Neurosci. 2005;30(5):315-318.
32. Dybowski C, Löwe B, Brünahl CA. Predictors of pain, urinary symptoms and quality of life in patients with chronic pelvic pain syndrome (CPPS): A prospective 12-month follow-up study. J Psychosom Res. 2018;112:99-106.
33. Granan L-P. Pain revised - learning from anomalies? Scand J Pain. 2020;20(1).
34. Vlaeyen JWS, S.J. L. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. Pain. 2000;85:317-332.
35. Alappattu MJ, Bishop MD. Psychological factors in chronic pelvic pain in women: relevance and application of the fear-avoidance model of pain. Phys Ther. 2011;91(10):1542-1550.
36. Montenegro ML, Vasconcelos EC, Candido Dos Reis FJ, Nogueira AA, Poli-Neto OB. Physical therapy in the management of women with chronic pelvic pain. Int J Clin Pract. 2008;62(2):263-269.
37. Nickel JC, Shoskes D. Phenotypic approach to the management of chronic prostatitis/chronic pelvic pain syndrome. Curr Urol Rep. 2009;10(4):307-312.

38. Ayorinde AA, Bhattacharya S, Druce KL, Jones GT, Macfarlane GJ. Chronic pelvic pain in women of reproductive and post-reproductive age: a population-based study. Eur J Pain. 2017;21(3):445-455.
39. Loving S, Thomsen T, Jaszczak P, Nordling J. Female chronic pelvic pain is highly prevalent in Denmark. A cross-sectional population based study with randomly selected participants. Scand J Pain. 2014;5(2):93-101.
40. Landmark T, Dale O, Romundstad P, Woodhouse A, Kaasa S, Borchgrevink P. Development and course of chronic pain over 4 years in the general population: The HUNT pain study. Eur J Pain. 2018;22:1606-1616.
41. Zondervan KT, Yudkin PL, Vessey MP, et al. Chronic pelvic pain in the community - Symptoms, investigations and diagnosis. American journal of obstetrics and gynecology. 2001;184(6):1149-1155.
42. Zondervan KT, Yudkin PL, Vessey MP, et al. The community prevalence of chronic pelvic pain in women and associated illness behaviour. Br J Gen Pract. 2001;51:541-547.
43. Haugstad GK, Haugstad T, Kirste U, et al. Posture, movement patterns, and body awareness in women with chronic pelvic pain. J Psychosom Res. 2006;61:637-644.
44. Latthe P, Mignini L, Gray R, Hills R, Khan K. Factors predisposing women to chronic pelvic pain: systematic review. BMJ. 2006;332(7544):749-755.
45. Meltzer-Brody S, Leserman J, Solnoun D, Steege J, Green E, Teich A. Trauma and posttraumatic stress disorder in women with chronic pelvic pain. Obstet Gynecol. 2007;109(4):902908.
46. Miller-Matero LR, Saulino C, Clark S, Bugenski M, Eshelman A, Eisenstein D. When treating the pain is not enough: a multidisciplinary approach for chronic pelvic pain. Arch Womens Ment Health. 2016;19(2):349-354.
47. Whitaker LH, Reid J, Choa A, et al. An Exploratory Study into Objective and Reported Characteristics of Neuropathic Pain in Women with Chronic Pelvic Pain. PLoS One. 2016;11(4):e0151950.
48. Healey C, Borley N, Mundy A. True pelvis, pelvic floor and perineum. Grays´s Anatomy: The anatomical Basis of Clinical Practice. 39 ed. Edinburgh: Elsevier Churchill Livingstone; 2005. p. 1357-1371.
49. The perineum muscles Textbook OpenStax Anatomy and Physiology 2016 [Version 8.25:[Available from: https://cnx.org/contents/FPtK1zmh@8.108:b3YG6PIp@6/Axial-Muscles-of-the-Abdominal.
50. Champaneria R, Daniels JP, Raza A, Pattison HM, Khan KS. Psychological therapies for chronic pelvic pain: systematic review of randomized controlled trials. Acta Obstet Gynecol Scand. 2012;91(3):281-286.
51. WCPT. Description of physical therapy London: World Confederation for Physical Therapy.; 2011 [Available from: http://www.wcpt.org/policy/ps-descriptionPT. .
52. Geneen LJ, Moore RA, Clarke C, Martin D, Colvin LA, Smith BH. Physical activity and exercise for chronic pain in adults: an overview of Cochrane Reviews. Cochrane Database Syst Rev. 2017;1(1):Cd011279.
53. Till SR, Wahl HN, As-Sanie S. The role of nonpharmacologic therapies in management of chronic pelvic pain: what to do when surgery fails? Curr Opin Obstet Gynecol. 2017;29:231–239.
54. Bergland A, Fromholt Olsen C, Ekerholt K. The effect of psychomotor physical therapy on health‐related quality of life, pain, coping, self‐esteem, and social support. Physiother Res Int. 2018;23(4).
55. Wortman MSH, van der Wouden JC, Grutters JPC, et al. Psychosomatic therapy for patients frequently attending primary care with medically unexplained symptoms, the CORPUS trial: study protocol for a randomised controlled trial. Trials. 2019;20(1):697.

56. Kvåle A. Body Awareness Therapies. In: Gebhart G, Schmidt R, editors. Encyclopedia of Pain. Berlin, Heidelberg: Springer 2013.
57. Skjaerven LH, Mattsson M, Catalan-Matamoros D, Parker A, Gard G, Gyllensten AL. Consensus on core phenomena and statements describing Basic Body Awareness Therapy within the movement awareness domain in physiotherapy. Physiotherapy theory and practice. 2018.
58. Haugstad GK, Kirste U, Leganger S, Haakonsen E, Haugstad TS. Somatocognitive therapy in the management of chronic gynaecological pain. A review of the historical background and results of a current approach. Scandinavian Journal of Pain. 2011;2(3):124-129.
59. Bratberg G, Leira K, Granan LP, et al. Learning oriented physiotherapy (LOP) in anxiety and depression: an 18 months multicentre randomised controlled trial. Eur J Physiother. 2020.
60. Fadnes B LK, Brodal P. Learning-oriented physiotherapy. Theory and practice.: University Press; 2013.
61. Mehling WE, Gopisetty V, Daubenmier J, Price CJ, Hecht FM, Stewart A. Body Awareness: Construct and Self-Report Measures. PLoS ONE. 2009;4(5):e5614.
62. Patient education Wikipedia: Wikipedi - The free encyclopedia; [cited 2020 28th of July]. Available from: https://en.wikipedia.org/wiki/Patient_education.
63. Butler D, Moseley L. Explain pain. 2. ed. Adelaide, Australia: Noigroup Publications; 2013.
64. Moseley L, Butler DS. Fifteen Years of Explaining Pain: The past, Present, and Future. J Pain. 2015;16(9):807-813.
65. Louw A, Zimney K, Puentedura EJ, Diener I. The efficacy of pain neuroscience education on musculoskeletal pain: A systematic review of the literature. Physiother Theor Pract. 2016;32(5):332-355.
66. Williams ACdC, Eccleston C, Morley S. Psychological therapies for the management of chronic pain (excluding headache) in adults. Cochrane Database of Systematic Reviews 2012. Contract No.: 11.
67. Hann KEJ, McCracken LM. A systematic review of randomized controlled trials of acceptance and commitment therapy for adults with chronic pain: outcome domains, design quality, and efficacy. J Context Behav Sci. 2014;3:217–227.
68. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: model, processes and outcomes. Behav Res Ther. 2006;44(1):1-25.
69. Veehof MM. Acceptance- and mindfulness-based interventions for the treatment of chronic pain: a meta-analytic review. Cogn Behav Ther. 2016;45(1):5-31.
70. Danielsen KG, Dahl-Michelsen T, Håkonsen E, Haugstad GK. Recovering from provoked vestibulodynia: Experiences from encounters with somatocognitive therapy. Physiother Theory Pract. 2018.
71. Rosenquist RW, Benzon HT, Connis RT, Leon-Casasola OA. Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine. Practice Guidelines. 2010. Contract No.: 4.
72. Yalom ID, Leszcz Mc. The theory and practice of group psychotherapy. 5th ed. New York: Basic Books; 2005. 688 p.
73. O´Keeffe M, Hayes A, McCreesh K, Purtill H, O'Sullivan K. Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis. Br J Sports Med. 2017;51:126-132.
74. Ariza-Mateos MJ, Cabrera-Martos I, Ortiz-Rubio A, Torres-Sanchez I, Rodriguez-Torres J, Valenza MC. Effects of a Patient-Centered Graded Exposure Intervention Added to

Manual Therapy for Women With Chronic Pelvic Pain: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2018;09:09.
75. Lamvu G, Williams R, Zolnoun D, et al. Long-term outcomes after surgical and nonsurgical management of chronic pelvic pain: One year after evaluation in a pelvic pain specialty clinic. Am J Obstet Gynecol. 2006;195(2):591-600.
76. Allaire C, Williams C, Bodmer-Roy S, et al. Chronic pelvic pain in an interdisciplinary setting: 1-year prospective cohort Am J Obstet Gynecol. 2018;218(114):e1-12.
77. Aboussouan AB, Mandell D, Johnson J, Thompson N, Huffman KL. An interdisciplinary chronic pain rehabilitation program effectively treats impairment in sexual function, depression, alexithymia, and pain in women with chronic pelvic pain. J Psychosom Obstet Gynaecol. 2020:1-11.
78. Haugstad GK, Haugstad TS, Kirste UM, et al. Continuing improvement of chronic pelvic pain in women after short-term Mensendieck somatocognitive therapy: results of a 1-year follow-up study. American journal of obstetrics and gynecology. 2008;199(6):615.e611-618.
79. Weijenborg PTM GA, Dekker FW, Peters AAW, Kuile MMt. Clinical course of chronic pelvic pain in women. Pain. 2007;132:S117-S123.
80. Naliboff BD, Stephens AJ, Lai HH, et al. Clinical and Psychosocial Predictors of Urologic Chronic Pelvic Pain Symptom Change Over One Year: A Prospective Study from the MAPP Research Network. J Urol. 2017;198(4):848-857.
81. Rooij AD, Van Der Leeden M, Roorda LD, Steultjens MP, Dekker J. Predictors of outcome of multidisciplinary treatment in chronic widespread pain: an observational study. BMC Musculoskeletal Disorders. 2013;14(1).
82. Nordstoga AL, Nilsen TIL, Vasseljen O, Unsgaard-Tøndel M, Mork PJ. The influence of multisite pain and psychological comorbidity on prognosis of chronic low back pain: longitudinal data from the Norwegian HUNT Study. BMJ Open. 2017;7(5).
83. Ariza-Mateos MJ, Cabrera-Martos I, Ortiz-Rubio A, Torres-Sanchez I, Rodriguez-Torres J, Valenza MC. Effects of a Patient-Centered Graded Exposure Intervention Added to Manual Therapy for Women With Chronic Pelvic Pain: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2019;100(1):9-16.
84. Patsopoulos NA. A pragmatic view on pragmatic trials. Dialogues Clin Neurosci. 2011;13(2):217-224.
85. Ford I, Norrie J. Pragmatic Trials. N Engl J Med. 2016;375(5):454-463.
86. Minary L, Trompette J, Kivits J, Cambon L, Tarquinio C, Alla F. Which design to evaluate complex interventions? Toward a methodological framework through a systematic review. BMC Medical Research Methodology. 2019;19(1):92.
87. Barker AL, Talevski J, Morello RT, Brand CA, Rahmann AE, Urquhart DM. Effectiveness of Aquatic Exercise for Musculoskeletal Conditions: A Meta-Analysis. Arch Phys Med Rehabil. 2014;95(9):1776-1786.
88. Haugstad GK, Haugstad T, Kirste U, et al. Reliability and validity of a standardized Mensendieck physiotherapy test. Physiother Theory Pract. 2006;22(4):189-205.
89. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs. 2003;14:798-804.
90. Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain. 2011;152(10):2399-2404.
91. Træen B, Stigum H. Sexual problems in 18-67-year-old Norwegians. Scand J Public Health. 2010;38(5):445-456.
92. Eriksen HR, Ihlebæk C, Ursin H. A scoring system for subjective health complaints (SHC). Scand J Public Health. 1999(27):63-72.

93. Sandanger I, Moum T IG, Dalgard OS, Sørensen T et al. Concordance between symptom screening and diagnostic procedure: the Hopkins Symptom Checklist-25 and the Composite International Diagnostic Interview I. Social Psychiatry and Psychiatric Epidemiology. 1998;33(7):345-354.
94. Derogatis LR, Lipman R, Rickels K, Uhlenhuth E, L. C. The Hopkins Symptom Checklist (HSCL): A self-report symptom inventory. Behav Sci. 1974;19.
95. Strand BH, Dalgard OS, Tambs K, Rognerud M. Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). Nord J Psychiatry. 2003;57(2):113-118.
96. Nettelbladt P, Hansson L, Stefansson CG, Borgquist L, Nordström G. Test characteristics of the Hopkins Symptom Check List-25 (HSCL-25) in Sweden, using the Present State Examination (PSE-9) as a caseness criterion. Soc Psychiatry Psychiatr Epidemiol. 1993;28:130-133.
97. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurology and Urodynamics. 2004;23(4):322-330.
98. ICIQ Structure Short Form [Available from: http://www.iciq.net/ICIQ-UIshortform.html.
99. Abrams P, Avery K, Gardener N, Donovan J. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol. 2006;175(3 Pt 1):1063-1066.
100. Macmillan AK, Merrie AEH, Marshall RJ, Parry BR. The Prevalence of Fecal Incontinence in Community-Dwelling Adults: A Systematic Review of the Literature. Dis Colon Rectum. 2004;47:1341-1349.
101. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. Gut. 1999;44(1):77-80.
102. Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. Anal incontinence, urinary incontinence and sexual problems in primiparous women - a comparison between women with episiotomy only and women with episiotomy and obstetric anal sphincter injury. BMC Womens Health. 2014;14(157).
103. Roos A-M, Sultan AH, Thakar R. St. Mark's incontinence score for assessment of anal incontinence following obstetric anal sphincter injuries (OASIS). Int Urogynecol J. 2009;20:407-410.
104. Renzi A, Brillantino A, Di Sarno G, d'Aniello F. Five-Item Score for Obstructed Defecation Syndrome: Study of Validation. Surgical Innovation. 2012;20(2):119-125.
105. IBM. IBM SPSS Statistics for Macintosh, Version 25.0. Armonk, NY: IBM Corp.; 2017.
106. Altman DG, Bland JM. Statistics notes: the normal distribution. BMJ. 1995;310(6975):298.
107. Ghasemi A, Zahediasl S. Normality Tests for Statistical Analysis: A Guide for Non-Statisticians. Int J Endocrinol Metab. 2012;10(2):486-489.
108. Parent M. Handling Item-Level Missing Data: Simpler is Just as Good. Couns Psychol. 2016;41(4):568-600.
109. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. BMJ. 2012;10(1):28-55.
110. Piontek K, Ketels G, Albrecht R, et al. Somatic and psychosocial determinants of symptom severity and quality of life in male and female patients with chronic pelvic pain syndrome. J Psychosom Res. 2019;120(May 2019):1-7.
111. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study.

Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol. 2000;53(11):1150-1157.
112. Rømmen K, Schei B, Rydning A, Sultan A, Mørkved S. Prevalence of anal incontinence among Norwegian women: a cross-sectional study. BMJ Open. 2012;2(4):1-9.
113. Schmidt FM, Santos VL. Prevalence of Constipation in the General Adult Population: An Integrative Review. J Wound Ostomy Continence Nurs. 2014;41(1):70-76.
114. Lampe A, Doering S, Rumpold G, et al. Chronic pain syndromes and their relation to shildhood abuse and stressful life events. J Psychosom Res. 2003;54:361-367.
115. Hilden M, Schei B, Swahnberg K, et al. A history of sexual abuse and health: a Nordic multicentre study. BJOG. 2004;111:1121-1127.
116. As-Sanie S, Clevenger LA, Geissner ME, Williams DA, Roth RS. History of abuse and its relationship to pain experiences and depression in women with chronic pelvic pain. American journal of obstetrics and gynecology. 2014;210(4):317.e317 - 317.e318.
117. Nault T, Gupta P, Ehlert M, et al. Does a history of bullying and abuse predict lower urinary tract symptoms, chronic pain, and sexual dysfunction? Int Urol Nephrol. 2016;48:1783-1788.
118. Paras ML, Murad MH, Chen LP, et al. Sexual abuse and lifetime diagnosis of somatic disorders. JAMA. 2009;302(5):550-561.
119. Meisingset I, Vasseljen O, Vøllestad N, et al. Novel approach towards musculoskeletal phenotypes. Eur J Pain. 2020;24:921-932.
120. Ekerholt K, Bergland A. Breathing: a sign of life and a unique area for reflection and action. Phys Ther 2008;88(832-840).
121. McClure N, Al Sayad F, Xie F, Luo N, Johnson JA. Instrument-Defined Estimates of the Minimally Important Difference for EQ-5D-5L Index Scores. Value Health. 2017;20(4):644-650.
122. Prochaska JO, Velicer WF. The Transtheoretical Model of Health Behavior Change. Am J Health Promot. 1997;12(1):38–48.
123. Weijenborg PTM, Ter Kuile MM, Gopie JP, Spinhoven P. Predictors of outcome in a cohort of women with chronic pelvic pain - a follow-up study. Eur J Pain. 2009;13(7):769-775.
124. Fine PG. Long-Term Consequences of Chronic Pain: Mounting Evidence for Pain as a Neurological Disease and Parallels with Other Chronic Disease States. Pain Med. 2011;12:996-1004.
125. Boonstra AM, Reneman MF, Waaksma BR, Schiphorst Preuper HR, Stewart RE. Predictors of multidisciplinary treatment outcome in patients with chronic musculoskeletal pain. Disabil Rehabil. 2015;37(14):1242-1250.
126. Gerdle B, Molander P, Stenberg G, Stålnacke B-M, Enthoven P. Weak outcome predictors of multimodal rehabilitation at one-year follow-up in patients with chronic pain — a practice based evidence study from two SQRP centres. BMC Musc Dis. 2016;17(490).
127. Williams ACdC, Craig K. Updating the definition of pain. Pain. 2016;157(11):2420-2423.
128. Lai HH, Jemielita T, Sutcliffe S, et al. Characterization of Whole Body Pain in Urological Chronic Pelvic Pain Syndrome at Baseline: A MAPP Research Network Study. J Urol. 2017;198(3):622-631.
129. Rooij Ad, Roorda LD, Otten RHJ, Van Der Leeden M, Dekker J, Steultjens MP. Predictors of multidisciplinary treatment outcome in fibromyalgia: a systematic review Disabil Rehabil. 2013;35(6):437-449.
130. Gerdle B, Åkerblom S, Brodda Jansen G, et al. Who benefits from multimodal rehabilitation – an exploration of pain, psychological distress, and life impacts in over 35,000

chronic pain patients identified in the Swedish Quality Registry for Pain Rehabilitation. J Pain Res. 2019;12:891-908.
131. Hulley SB, Cummings SR, Browner WS, Grady DG, Newman TB. Designing clinical research. Philadelphia, USA: Lippincott Williams & Wilkins; 2013.
132. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355(i5239).
133. Riley RD, Hayden JA, Steyerberg EW, et al. Prognosis Research Strategy (PROGRESS) 2: Prognostic Factor Research. PLoS Med. 2013;10(2).
134. Dworkin RH, Turk DC, Farrar JT, et al. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005;113:9-19.
135. Passavanti MB, Pota V, Sansone P, Aurilio C, De Nardis L, Pace MC. Chronic Pelvic Pain: Assessment, Evaluation, and Objectivation. Pain Res Treat. 2017;2017.
136. Rampakakis E, Ste-Marie PA, Sampalis JS, Karellis A, Shir Y, Fitzcharles MA. Real-life assessment of the validity of patient global impression of change in fibromyalgia. RMD Open. 2015;1(1):e000146.
137. Gagnon CM, Scholten P, Atchison J. Multidimensional Patient Impression of Change Following Interdisciplinary Pain Management. Pain Practice. 2018;18(8):997-1010.
138. Berghmans B. Physiotherapy for pelvic pain and female sexual dysfunction: an untapped resource Int Urogynecol J. 2018;29:631-638.
139. Taylor AM, Phillips K, Patel KV, et al. Assessment of physical function and participation in chronic pain clinical trials: IMMPACT/OMERACT recommendations. Pain. 2016;157:1836-1850.
140. Wright D, Foster C, Amir Z, Elliott J, Wilson R. Critical appraisal guidelines for assessing the quality and impact of user involvement in research. Health Expect. 2010;13(4):359-368.
141. Staniszewska S, Brett J, Mockford C, Barber R. The GRIPP checklist: strengthening the quality of patient and public involvement reporting in research. Int J Technol Assess Health Care. 2011;27(4):391-399.
142. Egbewale BE, Lewis M, Sim J. Bias, precision and statistical power of analysis of covariance in the analysis of randomized trials with baseline imbalance: a simulation study. BMC Med Res Methodol. 2014;14:49.
143. Flink IK, Reme S, Jacobsen HB, et al. Pain psychology in the 21st century: lessons learned and moving forward. Scand J Pain. 2020;20(2):229-238.
144. Bryant C, Cockburn R, Plante AF, Chia A. The psychological profile of women presenting to a multidisciplinary clinic for CPP: high levels of psychological dysfunction J Pain Res. 2016;16(9):1049-1056.
145. Doggweiler R, Whitmore KE, Meijlink JM, et al. A standard for terminology in chronic pelvic pain syndromes: A report from the chronic pelvic pain working group of the international continence society.; 2017. Contract No.: 4.
146. Engeler DS, Baranowski AP, Borovicka J, et al. EAU Guidelines on Chronic Pelvic Pain 2017 [Pocket version:[Available from: https://uroweb.org/wp-content/uploads/Chronic-pelvic-pain-2017-pocket.pdf.
147. Nygaard AS, Stedenfeldt M, Øian P, Haugstad GK. Characteristics of women with chronic pelvic pain referred to physiotherapy treatment after multidisciplinary assessment: a cross-sectional study. Scand J Pain. 2019;19(2):355-364.
148. Pearce C, Curtis M. A multidisciplinary approach to self care in chronic pelvic pain. Br J Nurs. 2007;16(2):82-85.

Papers I-III

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Observational study

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Characteristics of women with chronic pelvic pain referred to physiotherapy treatment after multidisciplinary assessment: a cross-sectional study

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Abstract

Background and aims: Chronic pelvic pain (CPP) in women is a complex condition that can seriously impact health and quality of life. Clinical guidelines for CPP place great demands on healthcare professionals, as they require both specialized knowledge about the pelvic area and knowledge of the mechanisms of chronic pain. To ensure best possible assessment and treatment of these women it is important to bring about more knowledge of the special CPP features. The purpose of this paper is to describe the characteristics of women with CPP evaluated at the University Hospital of North Norway, and further referred to physiotherapy. The frequency of having a history of abuse or previous pelvic surgery will also be reported, and analyses performed to investigate if subjective health status differs between women with and without these experiences.

Methods: We collected cross-sectional data from 62 women with CPP aged 20–65 (mean age 38.0), referred to physiotherapy after assessment by medical specialists. Data were collected by semi-structured interviews for demographic variables and medical history, and self-administered questionnaires on pain intensity, sexual function, urinary incontinence (UI), anal incontinence (AI), obstructed defecation syndrome (ODS), subjective health complaints (SHC) and symptoms of anxiety and depression.

Results: Pain duration of more than 10 years was reported by 42%, mean pain score was 4.7/10, and analgesics were used weekly by 48%. Previous pelvic or abdominal surgery was reported by 71%, and sick leave >12 weeks the last year by 34%. Reduced sexual desire was reported by 78%, dyspareunia by 73%, UI by 54%, AI by 23%, and obstructed defecation syndrome (ODS) by 34%. More than 90% reported musculoskeletal or pseudoneurologic complaints. Anxiety and depression scores defined as requiring treatment were reported by 40%. Abuse was reported by 50%, and associated with significantly more reports of ODS ($p = 0.02$), more SHC ($p = 0.02$) and higher anxiety scores ($p = 0.009$). Analgesic use and sick leave were significantly higher both among women with a history of abuse ($p = 0.04$ and $p = 0.005$) and among those with previous surgery ($p = 0.04$ and $p = 0.02$). Women with previous surgery reported significantly lower pain intensity during intercourse than those without previous surgery ($p = 0.008$).

Conclusions: Women with CPP have complex symptoms and high scores for both physical and psychological complaints. Women exposed to abuse have especially high scores related to analgesic use, sick leave, ODS, anxiety and SHC. Women with previous surgery report more analgesic use and sick leave, and lower pain intensity during intercourse, than those without previous surgery.

Implications: This study illustrates the complexity of CPP and highlights the need for health professionals to have specialized knowledge of the possible features of the condition. Previous abuse seems to be more associated with poor scores on several health outcomes than surgery, but this needs to be investigated further.

Keywords: pelvic pain; chronic pain; women's health; subjective health outcomes.

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1 Introduction

Chronic pelvic pain (CPP) is a common and debilitating condition, and population-based studies suggest a prevalence of 11–25% in Western European women [1, 2]. The European Association of Urology has defined CPP as "chronic or persistent pain perceived in structures related to the pelvis that has been continuous or recurrent for at least 6 months". They additionally describe CPP as "often associated with negative cognitive, behavioral, sexual, and emotional consequences, as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, or gynecological dysfunction" [3].

This rather broad definition reflects the complexity of CPP. Relative to the general female population both physical and psychological health scores are poorer in this group [2, 4]. Repeated surgical procedures in the pelvic area, co-existing conditions, and traumatic experiences such as physical, sexual, or psychological abuse are suggested as possible risk factors for CPP [4]. Multiple referrals, investigations and treatments in different medical specialties are common [2], but in many cases no physical cause of the pain is identified or new interventions not possible, leaving a significant number of women with long-term pain [2, 5]. Concerning the correct extent of the condition it is also important to mention that it is recognized that many women with CPP do not seek help or are not referred to secondary care [2].

Clinical guidelines for CPP recommend that early assessment should involve investigations aimed at specific disease-associated pelvic pain and assessment of functional, emotional, behavioral, sexual and other quality of life issues. They further recommend a multi-specialty and multi-disciplinary management with consideration of all symptoms [3, 6]. These recommendations place great demands on healthcare professionals, requiring both specialized knowledge about the pelvic area and peripheral pain mechanisms, and knowledge of prolonged pain and central pain mechanisms.

Women with CPP might be referred to a pain center with assessment and treatment within the scope of a biopsychological perspective, however without focus on specific challenges in the pelvic region. On the other hand they can also be referred to different specialists such as gynecologists, urologists or colorectal surgeons that not necessarily have specialized skills in chronic pain management. After medical assessment many of these women are referred to a physiotherapist, a profession also with varying knowledge of CPP. Thus, it is important to bring about more knowledge of the special CPP features to enable early recognition of the condition and to ensure precise assessment and treatment.

The purpose of this paper is to describe the characteristics of women with CPP evaluated at the University Hospital of North Norway, and further referred to physiotherapy. We also want to investigate if suggested risk factors such as history of abuse and previous surgical operations in the pelvic area are frequently reported, and if women with and without these experiences report different subjective health status.

2 Materials and methods

This study was based on cross-sectional data of 62 women who participated in a randomized controlled trial comparing two different physiotherapy treatments. The trial was conducted at the Norwegian National Advisory Unit on Incontinence and Pelvic Floor Health, University Hospital of North Norway. All data was collected at the time of inclusion at the hospital's Physiotherapy Outpatient Clinic by two trained physiotherapists, between March 2015 and November 2016. The data presented in this paper was collected before randomization and start of treatment.

Participants were women referred to physiotherapy treatment following CPP diagnosis by a gynecologist, urologist, and/or colorectal surgeon. Women with pain defined as gynecologic, urologic, or gastroenterological and/or pain in the pelvic floor muscles for a minimum of 6 months, aged 20–65 years, motivated to participate in the randomized trial, and able to speak and understand a Scandinavian language were included. If malignancy or conditions requiring special medical attention were discovered the women were referred to relevant follow-up, and not considered for study participation.

The exclusion criteria were pregnancy, childbirth during the last year, drug addiction, serious psychiatric diagnosis, and previous treatment by the physiotherapists at the intervention program. Women with intraabdominal or pelvic surgery within the previous 6 months or Botolinum toxin injections in the pelvic area in the last 4 months were also not eligible.

Demographic data and data on health-related history were obtained during a semi-structured interview. This included information about duration of CPP, use of analgesics, previous treatment, other diagnosis, sick leave and previous abuse exposure (physical, psychological, or sexual). Questions on abuse exposure were asked at the end of the semi-structured interview, with the same phrasing for all women. For detailed information about the content of the interview see Appendix 1.

Pelvic pain intensity was assessed using a Numerical Rating Scale (NRS), an 11 point box scale in which zero represents no pain and 10 represents pain as bad as it could be [7]. The women were asked to rate their mean pain intensity during the last 7 days, and to state if pain in

the last week was worse, better, or unchanged compared to the previous month. The NRS has shown good sensitivity and validity [7, 8].

For information about sexual function a modified self-reported questionnaire originally developed by Træen et al. was used [9]. The questionnaire comprised four questions. First the women were asked whether they were sexually active, with answers reported as "yes" or "no". If they answered affirmatively they were asked if they had experienced lack of sexual desire or dyspareunia over the past 12 months. Answers were reported as "Yes" ("all the time", "almost all the time", and "quite often") or "No" ("quite rarely" or "never"). In the last point the women were asked to register the intensity of dyspareunia on a NRS.

The subjective health complaints (SHC) questionnaire was used to register common somatic and psychological health complaints during the last 30 days [10]. The 29-item list consists of complaints in the categories musculoskeletal pain, pseudoneurology, gastrointestinal problems, allergy, and flu. The respondents provided a score for each of the complaints on a Likert scale ranging from 0 to 3. We calculated the proportion of women who reported complaints within each category and the number of single items, classified as absent (score 0) or present (score 1–3), and we also calculated the proportion of "severe complaints" (score 3) [10]. The SHC questionnaire is known to be a reliable measure of SHC [10].

Common symptoms of anxiety and depression were measured using Hopkins Symptom Checklist (HSCL-25) [11]. The respondents indicated the extent to which they had experienced any of 25 different symptoms of anxiety and depression over the last 14 days using a four-point Likert scale ranging from 1 to 4. Separate mean scores for anxiety and depression items were calculated. A cut off point of 1.75 was used to distinguish women with and without psychiatric symptoms, and the dichotomized data are presented in the results section [11]. The HSCL-25 is known to be a reliable measure among Norwegian women, and its validity has been shown in a Swedish population [11, 12].

Urinary incontinence (UI) was defined as "the complaint of involuntary leakage of urine" and documented by the self-administered questionnaire ICIQ-UI SF [13]. Scores range from 0 to 21, and in this study we used the dichotomized values to indicate no UI (score = 0) or UI (score ≥ 1) [14]. The questionnaire is validated [13] and the Norwegian version is found adequate for use after linguistic validation [15, 16].

Information about anal incontinence (AI), defined as involuntary passage of fecal material and/or flatus [17], was collected using the validated St Marks interview score [18]. The score gives information about type and frequency of AI (gas, liquid, solid) and its impact on daily life, the need to wear a pad or plug, the use of constipating medication, and the lack of ability to defer defecation for 15 min [18]. Scores range from 0 to 24, and we used the dichotomized scores so that 0–3 = "no AI" and 4–24 = "AI" [19, 20].

To record information about obstructed defecation symptoms (ODS) a five-item score developed and validated by Renzi et al. [21] was used. Each item is graded from 0 to 5 with a maximum total score of 25, and the optimal cutoff point to discriminate between healthy participants and patients with ODS is found to be ≥9 [21]. We used the dichotomized values so that ≤8 = no ODS and ≥9 = ODS.

2.1 Statistical analyses

Descriptive statistics for continuous variables are presented with mean and standard deviation (SD) or median and interquartile range (IQR) as appropriate, and categorical variables are presented as percentages and frequencies (n).

To investigate differences in current subjective health status between women with and without a history of abuse and with and without pelvic surgery, the variables "sick leave ≥12 weeks last year", "use of analgesics weekly in the last month", "pelvic pain intensity", "dyspareunia", "UI", "AI", "ODS", "number of any SHC", "number of severe SHC", and "HSCL-25 score above 1.75" (included subscales for anxiety and depression) were tested separately with bivariate tests. Independent samples t-tests or Mann-Whiney U-tests were used for continuous variables as appropriate, and the Pearson χ^2-test for independence were used for categorical variables.

We used the total score for non-missing items when calculating means for outcome measures with missing values. Outcome measures with more than 10% of missing items were not included in analyses. All tests were two-tailed and a p-value < 0.05 was considered statistically significant. Statistical analyses were conducted using SPSS version 25 [22].

3 Results

A total of 108 women were referred for study participation. Fifty percent ($n = 62$) of the referred women were included and gave consent, 29% ($n = 31$) declined to participate, and 14% ($n = 15$) did not meet the inclusion criteria. Excluded participants were offered a referral to regular physiotherapy treatment.

Characteristics of the included women are summarized in Table 1. Current pain intensity was reported to be approximately the same as that experienced over the last 4 weeks by 79% ($n = 49$), and 76% ($n = 47$) reported constant pain during the last week. There was no significant

Table 1: Characteristics of women with chronic pelvic pain, $n = 62$.

	Mean (SD) or percentage (n)
Age (years)	38.0 (12.4, range 20–65)
BMI[a]	26.6 (5.6)
Smoking	23% (14)
Cohabiting (with partner)	77% (48)
Children	1.6 (1.4)
Among parous women ($n = 43$)	
Children	2.4 (1.0)
Vaginal delivery only	70% (30)
Cesarean section only	12% (5)
Both vaginal delivery and cesarean section	19% (8)
Higher education[b]	45% (28)
Working or student (not receiving social benefits)	61% (38)
Currently on sick leave	32% (12)
Sick leave >12 weeks last year	47% (18)
Duration of pelvic pain	
1–4 years	31% (19)
4–10 years	27% (17)
> 10 years	42% (26)
Mean pelvic pain intensity last 7 days (NRS[c] 0–10)	4.7 (2.4)
Use of analgesics weekly in the last month	48% (30)
Urinary incontinence (ICIQ-UI-SF)	54% ($n = 33$)
Anal incontinence (St. Marks interview score ≥4)	23% ($n = 14$)
Obstructed defecation (ODS-score ≥9)	34% ($n = 21$)
Previous diagnosis in the abdomen/pelvic area	79% (48)
– Ovarian cysts	– 35% (22)
– Urinary tract infections, repeated	– 26% (16)
– Endometriosis	– 15% (9)
Previous abdominal or pelvic surgery	71% (44)
Intraabdominal surgery	
– Gastrointestinal intraabdominal (excl. C-section)	– 34% (21)
– Cesarean section (≥1)	– 21% (13)
– Hysterectomy	– 15% (9)
– Ovarian resection/extirpation	– 6% (4)
Vaginal or anal surgery	
Repair of OASIS[d] among women with vaginal deliveries ($n = 38$)	21% (8)
Hemorrhoidectomy or ligation	6% (4)
Tried non-surgical treatment prior to current referral	55% ($n = 35$)

[a]BMI = body mass index. [b]Completed ≥1 year of University College or University. [c]NRS = numeric rating scale. [d]OASIS = obstetric anal sphincter injuries grade 3 or 4.

group difference in pain intensity among women reporting and not reporting analgesics use weekly the last month (mean pain 4.2/10 vs. 4.8/10, $p > 0.05$). The total number of surgeries among the 44 women (71%) who reported previous abdominal or pelvic surgery was 116 (range 1–10) (Table 1).

Fifty percent ($n = 31$) of the women reported events perceived as abuse of a physical, psychological or sexual nature. Of these, 42% ($n = 13$) had been exposed to abuse as a child (≤16 years of age), 39% ($n = 12$) as an adult, and 19% ($n = 6$) had been exposed to abuse both as a child and as an adult. We do not have complete information about type of abuse, as giving this information was optional.

Of the 62 women 79% ($n = 49$) reported being sexually active. Reasons for not being sexually active were dyspareunia (15%, $n = 9$) and no partner (6%, $n = 4$). Lack of or reduced sexual desire was reported by 78% ($n = 38$) of the sexually active women, and dyspareunia was reported by 73% ($n = 36$). The median pain intensity during intercourse among the sexually active women was 5.5/10 (IQR = 4.5) on the NRS.

Ninety-eight percent ($n = 61$) of the women reported at least one musculoskeletal complaint on the SHC questionnaire. Pseudoneurological complaints, including sleep problems, tiredness, anxiety, depression, and sadness, were reported by 92% ($n = 57$). Information on the most

reported complaints is presented in Fig. 1, including both the proportion reporting any complaints and proportion reporting severe complaints. The most commonly reported complaints in the "other complaints" category were leg pain, gas discomfort, shoulder pain, upper back pain and sadness/depression.

Forty-five percent ($n=24$) of the women scored above the cut off point for psychiatric symptoms on the HSCL-25, with a total mean score of 1.83 (SD = 0.5, $n=53$) (data from nine women missing, five did not receive the questionnaire at baseline and four did not fill inn sufficient number of items to be included in the analyses). Forty-six percent ($n=25$) scored above the cut off point for symptoms of depression, with a mean score of 1.88 (SD = 0.5, $n=53$), and 36% ($n=19$) scored above the cut off point for anxiety, with a mean score of 1.76 (SD = 0.5, $n=53$).

Table 2 shows the results of bivariate tests for differences in subjective health status among women exposed and not exposed to abuse. The same variables were tested for women with previous pelvic or intra-abdominal surgery, and the results are presented in Table 3.

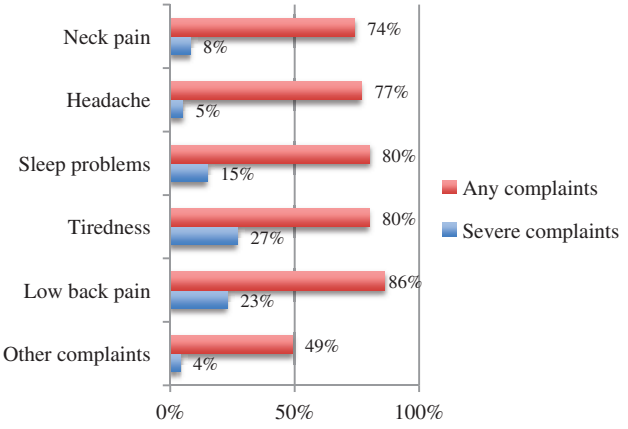

Fig. 1: The most reported subjective health complaints among women with chronic pelvic pain, $n=62$. The red bar indicates the proportion of the sample reporting any complaints at all; the blue bar represents the proportion of the total sample reporting severe complaints.

4 Discussion

Our results show high rates of sick leave, sexual complaints, musculoskeletal SHC, UI, AI, constipation and abuse exposure compared to previous reports of women with CPP [23, 24]. CPP characteristics including long duration of pain, previous pelvic or abdominal surgery, psychiatric symptoms, and a large number of co-existing conditions or complaints were also confirmed in this study [2, 4]. Women exposed to abuse reported higher use of analgesics, more sick leave, more SHC, higher anxiety scores and ODS than women not exposed to abuse. Women reporting previous surgery used more analgesics, and they reported more sick leave and less dyspareunia than those not reporting surgery.

The relatively small sample size of this study is a limitation. However, the low number of participants allowed us to perform thorough interviews with all of the women, which we believe provided more in-depth information. The included women represent a selected group, and the results cannot be generalized to others than women

Table 2: Subjective health status of women reporting abuse exposure versus not reporting abuse exposure, $n=62$.

	Percentage (n), mean (SD) or median (IQR)		
	Exposed to abuse ($n=31$)	Not exposed to abuse ($n=31$)	Between group difference (p-value)
Mean pelvic pain intensity, last 7 days (NRS[a] 0–10) ($n=62$)	5.0 (SD 2.6)	3.9 (SD 2.02)	0.063[f]
Use of analgesics weekly in the last month ($n=62$)	61% (19)	35% (11)	0.04[d,g]
Sick leave more than 12 weeks in the last year (of those working, $n=38$)	56% (9)	14% (3)	0.005[g,e]
Dyspareunia (NRS[a] 0–10) (among those sexually active, $n=49$)	5.5 (IQR 4.3)	5.5 (IQR 5.3)	0.61[h]
Number of SHC[b] (any) ($n=62$)	14 (IQR 12)	11 (IQR 6)	0.02[h,e]
Number of SHC[b] (severe) ($n=62$)	1.0 (IQR 3)	0.0 (IQR 1.0)	0.043[h,d]
Total score HSCL-25[c] ≥1.75 ($n=55$)	62% (18)	31% (8)	0.003[g,d]
Anxiety subscale HSCL-25[c] ≥1.75 ($n=55$)	56% (15)	21% (6)	0.009[g,d]
Depression subscale HSCL-25[c] ≥1.75 ($n=55$)	59% (16)	36% (10)	0.08[g]
Urinary incontinence ICIQ-UI-SF, score >0 ($n=61$)	63% (19)	45% (14)	0.15[g]
Anal incontinence (St. Marks interview score ≥4) ($n=61$)	32% (10)	13% (4)	0.08[g]
Obstructed defecation (ODS-score ≥9) ($n=62$)	48% (15)	19% (6)	0.02[g,e]

[a]NRS = numeric rating scale. [b]SHC = subjective health complaints. [c]HSCL-25 = Hopkins Symptom Check List 25. [d]$p<0.01$. [e]$p<0.05$.
[f]Independent samples t-test. [g]Pearson χ^2-test. [h]Wilcoxon-Mann-Whitney test.

Table 3: Subjective health status of women with previous pelvic or intraabdominal surgery versus women not reporting surgery, $n = 62$.

	Percentage (n), mean (SD) or median (IQR)		
	Previous surgery ($n = 44$)	**No previous surgery ($n = 18$)**	**Between group difference (p-value)**
Mean pelvic pain intensity, last 7 days (NRS[a] 0–10) ($n = 62$)	4.7 (2.1)	4.0 (3.0)	0.4[f]
Use of analgesics weekly, the last month ($n = 62$)	57% (25)	28% (5)	0.04[g,e]
Sick leave more than 12 weeks the last year (of those working, $n = 39$)	41% (16)	11% (2)	0.02[g,e]
Dyspareunia (NRS 0–10) (among those sexually active, $n = 49$)	4.5 (IQR 4.8)	7.5 (IQR 4.8)	0.008[h,d]
Number of SHC[b] (any) ($n = 62$)	11.5 (IQR 7.5)	13.5 (IQR 8.0)	0.2[h]
Number of SHC[b] (severe) ($n = 62$)	1.0 (IQR 1.75)	1.0 (IQR 2.25)	0.7[h]
Total score HSCL-25[c] ≥1.75 ($n = 55$)	47% (17)	41% (7)	0.7[g]
Anxiety subscale HSCL-25[c] ≥1.75 ($n = 55$)	33% (12)	41% (7)	0.6[g]
Depression subscale HSCL-25[c] ≥1.75 ($n = 55$)	44% (16)	47% (8)	0.9[g]
Urinary incontinence (ICIQ-UI-SF score >0) ($n = 61$)	56% (24)	50% (9)	0.7[g]
Anal incontinence (St. Marks interview score ≥4) ($n = 61$)	28% (12)	11% (2)	0.1[g]
Obstructed defecation (ODS-score ≥9) ($n = 62$)	34% (15)	33% (6)	0.9[g]

[a]NRS = numeric rating scale. [b]SHC = subjective health complaints. [c]HSCL-25 = Hopkins Symptom Check List 25. [d]$p < 0.01$. [e]$p < 0.05$.
[f]Independent samples t-test. [g]Pearson χ^2-test. [h]Wilcoxon-Mann-Whitney test.

with CPP who fulfill the same inclusion criteria as used in this study. Among the women that were referred after assessment by a specialist doctor, 31 refused to participate. Although not reported systematically, we are aware that economic reasons, long travel distance, the necessity to stay away from home for 10 days, to much bothers and possibility of being randomized to a group treatment were reasons given by some of the women. This may have influenced the group characteristics. The cross-sectional design itself implies that data cannot be used to infer any temporal associations between exposure and outcome, and there may be recall bias [25]. All questionnaires used in this study were validated except the one related to sexual function, because we were unable to find an appropriate and not to time consuming sexual function questionnaire that was validated in Norway.

The mean pelvic pain intensity of 4.7/10 is classified as "moderate to severe" [24] and most of the women reported constant pain, yet only half had used analgesics weekly in the last month. This is in agreement with the use of analgesics reported in a Danish study on women with CPP [24], but lower than the 60% reported among women with chronic pain in a large Norwegian population [26]. There may be several reasons why the women in our study report less analgesic use than the general chronic pain patient population, including the observation that CPP patients appear to report lower mean pain intensity [27, 28]. Different methods of measuring analgesic usage may also give different results.

Twenty percent of the women in our study reported that they were currently on sick leave, and one third of the working women reported a minimum of 12 weeks sick leave in the last year. The same result was documented in a CPP-study from New Zealand [29], and 35% of women in a previous Norwegian randomized controlled trial on women with CPP were on sick leave at the time of data collection [23]. This is considerably higher than found in general among Norwegian women [30], and suggests that CPP may be a significant factor in work absence.

Half of the women in our study reported that they had been exposed to abuse. A survey of more than 700 women diagnosed with CPP reported that 46% had been exposed to abuse, indicating the magnitude of this problem among women with CPP [31]. Information about the total number of Norwegian women with CPP reporting physical, psychological or sexual abuse does not exist, but the numbers of sexual abuse alone has been reported to be 15–20% [23]. The overall abuse rate including violence, threats of violence, or sexual assault in the general female population in Norway has been estimated to be 36% [32]. Although it appears that the numbers reported among women in our study are higher than compared to the general female population, we cannot directly compare these numbers as different phrasing, definitions and data collection methods and periods have been used.

Sexual function is affected by pain during intercourse and reduced sexual desire [3], and the majority of the women in our study were sexually active despite these symptoms. Previous studies on women with dyspareunia have shown that reasons for this can be a prioritization of the partner's enjoyment before their own or expectations from the partner or the community [33], but this was not explored in our study. Desrochers et al. suggested that the psychosocial

burden of genital pain is heavier due to feelings of shame, inadequacy, and low self-esteem [34]. Our results emphasize that sexual function, dyspareunia and desire are important to address during assessment and treatment.

We found higher prevalence of UI, AI and ODS among the women in our study than are reported in studies of the general population [35–37]. These findings reflect some of the special characteristics of women with CPP, and illustrates how they differ from other chronic pain patients and need more specialized competence.

To our knowledge, there are no comparable data on the occurrence of SHC in women with CPP. We found considerably higher scores on all parameters of the SHC questionnaire in our sample than in the general female population in Norway. The highest reports were on low back and neck pain the last month, which was reported by about 80% of our sample compared to 45% in the general population [38]. In our study 78% of the women reported headache, compared to 58% in the general female population [38]. This confirms that women with CPP have health concerns beyond the pelvic and abdominal area.

Abuse is identified as a potential risk factor for CPP [4], but only a few previous studies have provided information on the occurrence of abuse and associations with health status in women with CPP [31, 39, 40]. Women with a history of bullying or abuse have been shown to have poorer scores on both somatic and psychological health measures [39], and several reports indicate that exposure to abuse of any kind can lead to a higher risk of poor health later in life [31, 40–42]. This is in agreement with our findings showing more symptoms of anxiety or depression and more SHCs among women exposed to abuse. We also found that those exposed to abuse had significantly more sick leave and used more analgesics, suggesting that abuse exposure may have significant impacts on both on the complexity and the severity of the CPP condition. Significantly higher numbers were shown for ODS among women who reported exposure to abuse, and although not statistically significant these women also had more complaints of UI and AI than women not exposed to abuse. We did not find a statistically significant association between abuse and pain intensity, which is in line with the findings in As-Sanie et al. [40] although reported by others [4]. Women exposed to abuse did report higher mean pain intensity the last 7 days though.

We found that women with previous surgery had been more on sick leave and used significantly more analgesics than those without. Notably, they also reported lower pain intensity during intercourse than women without previous surgery. We have no explanation of this finding. In some cases, surgery may have alleviated pain originating from local pathologies and thereby also led to less dyspareunia. The women with previous surgery also had higher scores of UI, AI and ODS than those without surgery, although not statistically significant. In contrast to other reports, we did not find associations between having had a surgery and scores of anxiety, depression, or SHC [2, 4]. The lack of a control group without CPP may explain the absence of significant associations, and our study sample was too small to run subgroup analysis of those who had received different types of surgeries. Further studies investigating possible associations between number and types of surgeries and the different health outcomes are warranted.

5 Conclusions and implications

Our study contributes to the understanding of the complexity seen in this group of women, and thus supports the recommendation for taking a broad biopsychosocial and multidisciplinary approach [43]. However, this kind of approach may be more resource demanding and not always possible to implement, and single discipline treatment with multimodal approach may then be a good alternative [5]. Long duration of pain and high levels of psychiatric symptoms such as anxiety and depression are known to be poor prognostic indicators for treatment success. It is essential for clinicians to take this into account in the assessment and treatment of CPP [3, 6, 44]. Specific issues related to the pelvic area, as sexual function/dysfunction, incontinence and constipation should also be paid attention. In addition, the high prevalence of abuse exposure is of great importance.

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Informed consent: Informed consent was obtained from all individuals included in this study.

Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration. The Regional Committee for Medical and Health Research Ethics North approved the study (18.09.2014 2014/1398).

Appendix

Appendix 1: Interview-guide for data on demographics and health-related history.

	Actual numbers/ answers recorded	Pre-defined response categories
Age	X	
Year of birth	X	
Height	X	
Weight	X	
Do you smoke?		Yes/No
Civil status		Married or cohabiting Living alone or with children
What is your highest level of completed education?		Completed <1 year, or ≥1 year of University College or University
What is your work status?		Answers were dichotomized into: (1) Working or student (2) Receiving social benefits (including unemployment)
Have you been on sick leave because of the pelvic pain the last 3 years?		Yes/No
If yes approximately how many weeks the last year and the last 3 years	X	
Number of children	X	
When did your pelvic pain start?		6 months, 7–12 months, 1–2 years, 2–4 years, 4–6 years, 6–10 years, more than 10 years ago
Have you ever had any surgery in the pelvic or abdominal area?		Yes/No
If yes, how long ago? how many surgeries in total?	X	
What type of surgery/-ies?		Anorectal Uro- or gynecological Intraabdominal Other
Have you had other diagnosis/diseases related to the pelvic area than the pelvic pain?		Obstetric injury incl. OASIS[a] Fistula Infections Adhesions Neurologic condition/injury, Repeated urinary tract infections the last 2 years Endometriosis Ovarian cysts Other None
Have you had any previous treatment of your pelvic pain (other than surgical)?		Yes/No
If yes, what kind of treatment?	X	
Have you used any pain medicines/analgesics because of your pelvic pain the last 4 weeks?		Less than weekly Every week but not daily Daily Not used
Have you been exposed to events that you experienced as abusive – either physical, psychological or sexual?		Yes/No
If yes, when did the abuse happen? optional to add more information about the abuse?		Child (under 16) Adult (16 or older)

[a]OASIS = obstetric anal sphincter injuries.

References

[1] Ahangari A. Prevalence of chronic pelvic pain among women: an updated review. Pain Physician 2014;17:E141–7.

[2] Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in women: an epidemiological perspective. Womens Health (Lond) 2015;11:851–64.

[3] Engeler DS, Baranowski AP, Borovicka J, Cottrell AM, Dinis-Oliveira P, Elneil S, Hughes J, Messelink EJ, de C. Williams AC. EAU Guidelines on Chronic Pelvic Pain 2017 [Pocket version: Available from: https://uroweb.org/wp-content/uploads/Chronic-pelvic-pain-2017-pocket.pdf].

[4] Latthe P, Mignini L, Gray R, Hills R, Khan K. Factors predisposing women to chronic pelvic pain: systematic review. BMJ 2006;332:749–55.

[5] Pearce C, Curtis M. A multidisciplinary approach to self care in chronic pelvic pain. Br J Nurs 2007;16:82–5.

[6] Doggweiler R, Whitmore KE, Meijlink JM, Drake MJ, Frawley H, Nordling J, Hanno P, Fraser MO, Homma Y, Garrido G, Gomes MJ, Elneil S, van de Merwe JP, Lin ATL, Tomoe H. A standard for terminology in chronic pelvic pain syndromes: a report from the chronic pelvic pain working group of the international continence society; 2017. Contract No.: 4.

[7] Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs 2003;14:798–804.

[8] Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. Pain 2011;152:2399–404.

[9] Træen B, Stigum H. Sexual problems in 18–67-year-old Norwegians. Scand J Public Health 2010;38:445–56.

[10] Eriksen HR, Ihlebæk C, Ursin H. A scoring system for subjective health complaints (SHC). Scand J Public Health 1999;27:63–72.

[11] Strand BH, Dalgard OS, Tambs K, Rognerud M. Measuring the mental health status of the Norwegian population: a comparison of the instruments SCL-25, SCL-10, SCL-5 and MHI-5 (SF-36). Nord J Psychiatry 2003;57:113–8.

[12] Nettelbladt P, Hansson L, Stefansson CG, Borgquist L, Nordström G. Test characteristics of the Hopkins Symptom Check List-25 (HSCL-25) in Sweden, using the Present State Examination (PSE-9) as a caseness criterion. Soc Psychiatry Psychiatr Epidemiol 1993;28:130–3.

[13] Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurol Urodyn 2004;23:322–30.

[14] Klovning A, Avery K, Sandvik H, Hunskaar S. Comparison of two questionnaires for assessing the severity of urinary incontinence: the ICIQ-UI SF versus the incontinence severity index. Neurourol Urodyn 2009;28:411–5.

[15] ICIQ Structure Short Form [Available from: http://www.iciq.net/ICIQ-UIshortform.html.

[16] Abrams P, Avery K, Gardener N, Donovan J. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. J Urol 2006;175(3 Pt 1):1063–6.

[17] Macmillan AK, Merrie AEH, Marshall RJ, Parry BR. The prevalence of fecal incontinence in community-dwelling adults: a systematic review of the literature. Dis Colon Rectum 2004;47:1341–9.

[18] Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. Gut 1999;44:77–80.

[19] Stedenfeldt M, Pirhonen J, Blix E, Wilsgaard T, Vonen B, Øian P. Anal incontinence, urinary incontinence and sexual problems in primiparous women – a comparison between women with episiotomy only and women with episiotomy and obstetric anal sphincter injury. BMC Womens Health 2014;14:157.

[20] Roos A-M, Sultan AH, Thakar R. St. Mark's incontinence score for assessment of anal incontinence following obstetric anal sphincter injuries (OASIS). Int Urogynecol J 2009;20:407–10.

[21] Renzi A, Brillantino A, Di Sarno G, d'Aniello F. Five-item score for obstructed defecation syndrome: study of validation. Surg Innov 2012;20:119–25.

[22] IBM. IBM SPSS Statistics for Macintosh, Version 25.0. NY: IBM Corp, 2017.

[23] Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. Am J Obstet Gynecol 2006;194:1303–10.

[24] Loving S, Thomsen T, Jaszczak P, Nordling J. Female chronic pelvic pain is highly prevalent in Denmark. A cross-sectional population based study with randomly selected participants. Scand J Pain 2014;5:93–101.

[25] Sedgwick P. Cross sectional studies: advantages and disadvantages. BMJ 2014:g2276.

[26] Dale O, Borchgrevink P, Fredheim O, Mahic M, Romundstad P, Skurtveit S. Prevalence of use of non-prescription analgesics in the Norwegian HUNT3 population: impact of gender, age, exercise and prescription of opioids. BMC Public Health 2015;15:461.

[27] Sturgeon JA, Dixon EA, Darnall BD, Mackey SC. Contributions of physical function and satisfaction with social roles to emotional distress in chronic pain: a Collaborative Health Outcomes Information Registry (CHOIR) Study. Pain 2015;156:2627–33.

[28] Becker N, Thomsen AB, Olsen AK, Sjøgren P, Bech P, Eriksen J. Pain epidemiology and health related quality of life in chronic non-malignant pain patients referred to a Danish multidisciplinary pain center. Pain 1997;73:393–400.

[29] Zondervan KT, Yudkin PL, Vessey MP, Jenkinson CP, Dawes MG, Barlow DH, Kenney SH. The community prevalence of chronic pelvic pain in women and associated illness behaviour. Br J Gen Pract 2001;51:541–7.

[30] SSB. Sykefravær ssb.no: Statistisk sentralbyrå; [Available from: https://www.ssb.no/sykefratot/]. Accessed: Dec 2018.

[31] Meltzer-Brody S, Leserman J, Solnoun D, Steege J, Green E, Teich A. Trauma and posttraumatic stress disorder in women with chronic pelvic pain. Obstet Gynecol 2007;109:902–8.

[32] Hjemdal OK, Sogn H, Schau L. Vold, negative livshendelser og helse En gjennomgang av data fra to regionale helseundersøkelser (Norwegian). Norwegian centre for violence and traumatic stress studies; 2012. Contract No.: 1.

[33] Elmerstig E, Wijma B, Swahnberg K. Prioritizing the partner's enjoyment: a population-based study on young Swedish women with experience of pain during vaginal intercourse. J Psychosom Obstet Gynaecol 2013;34:82–9.

[34] Desrochers G, Bergeron S, Landry T, Jodoin M. Do psychosexual factors play a role in the etiology of provoked vestibulodynia? A critical review. J Sex Marital Ther 2008;34:98–226.

[35] Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incon-

tinence: the Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol 2000;53:1150–7.
[36] Rømmen K, Schei B, Rydning A, Sultan A, Mørkved S. Prevalence of anal incontinence among Norwegian women: a cross-sectional study. BMJ Open 2012;2:1–9.
[37] Schmidt FM, Santos VL. Prevalence of constipation in the general adult population: an integrative review. J Wound Ostomy Continence Nurs 2014;41:70–6.
[38] Ihlebaek C, Eriksen HR, Ursin H. Prevalence of subjective health complaints (SHC) in Norway. Scand J Public Health 2002;30:20–9.
[39] Nault T, Gupta P, Ehlert M, Dove-Medows E, Seltzer M, Carrico DJ, Gilleran J, Bartley J, Peters KM, Sirls L. Does a history of bullying and abuse predict lower urinary tract symptoms, chronic pain, and sexual dysfunction? Int Urol Nephrol 2016;48:1783–8.
[40] As-Sanie S, Clevenger LA, Geissner ME, Williams DA, Roth RS. History of abuse and its relationship to pain experiences and depression in women with chronic pelvic pain. Am J Obstet Gynecol 2014;210:317.e317–8.
[41] Paras ML, Murad MH, Chen LP, Goranson EN, Sattler AL, Colbenson KM, Elamin MB, Seime RJ, Prokop LJ, Zirakzadeh A. Sexual abuse and lifetime diagnosis of somatic disorders. JAMA 2009;302:550–61.
[42] Hilden M, Schei B, Swahnberg K, Halmesmäki E, Langhoff-Roos J, Offerdal K, Pikarinen U, Sidenius K, Steingrimsdottir T, Stoum-Hinsverk H, Wijma B. A history of sexual abuse and health: a Nordic multicentre study. BJOG 2004;111:1121–7.
[43] Miller-Matero LR, Saulino C, Clark S, Bugenski M, Eshelman A, Eisenstein D. When treating the pain is not enough: a multidisciplinary approach for chronic pelvic pain. Arch Womens Ment Health 2016;19:349–54.
[44] Bryant C, Cockburn R, Plante AF, Chia A. The psychological profile of women presenting to a multidisciplinary clinic for CPP: high levels of psychological dysfunction. J Pain Res 2016;16:1049–56.

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ORIGINAL RESEARCH ARTICLE

Group-based multimodal physical therapy in women with chronic pelvic pain: A randomized controlled trial

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Abstract

Introduction: Chronic pelvic pain in women is a complex condition, and physical therapy is recommended as part of a broader treatment approach. The objective of this study was to compare structured group-based multimodal physical therapy in a hospital setting (intervention group) with primary-care physical therapy (comparator group) for women with chronic pelvic pain.

Material and methods: Women aged 20-65 years with pelvic pain ≥6 months and referred for physical therapy were eligible. The primary outcome measure was change in the mean pelvic pain intensity from baseline to 12 months, measured using the numeric rating scale (0-10). Secondary outcomes were changes in scores of "worst" and "least" pain intensity, health-related quality of life, movement patterns, pain-related fear of movements, anxiety and depression, subjective health complaints, sexual function, incontinence, and obstructed defecation. The differences between the groups regarding change in scores were analyzed using the independent t test and Mann-Whitney U test. Sensitivity analysis of the primary outcome was performed with a linear regression model adjusted for the baseline value. A *P* value <.05 was considered statistically significant.

Results: Of the 62 women included, 26 in the intervention group and 25 in the comparator group were available after 12 months for data collection and analysis. The difference between the groups for change in the mean pain intensity score was −1.2 (95% CI −2.3 to −0.2; *P* = .027), favoring the intervention group. The intervention group showed greater improvements in respiratory patterns (mean difference 0.9; 95% CI 0.2-1.6; *P* = .015) and pain-related fear of movements (mean difference 2.9; 95% CI −5.5 to −0.3; *P* = .032), and no significant differences were observed between the groups for the other secondary outcomes.

Conclusions: Although the reduction in the mean pelvic pain intensity with group-based multimodal physical therapy was significantly more than with primary-care

Abbreviations: CPP, chronic pelvic pain; NRS, numeric rating scale; RCT, randomized controlled trial.

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physical therapy, the difference in the change between the groups was less than expected and the clinical relevance is uncertain.

KEYWORDS
body awareness, chronic pelvic pain, group-based, patient education, physical therapy, randomized trial, women

1 | INTRODUCTION

Chronic pelvic pain (CPP) in women is a complex condition, with a suggested worldwide prevalence of 6%-27%.[1] CPP is defined as "chronic or persistent pain for at least 6 months, perceived in structures related to the pelvis, and often associated with negative cognitive, behavioral, sexual and emotional consequences and symptoms of lower urinary tract, sexual, bowel, pelvic floor or gynecological dysfunction."[2] CPP is further subdivided into pain syndromes according to the location of the pain; however, in this study, we did not differentiate between these syndromes.[2]

Compared with the general female population, women with CPP report poorer total health, higher number of surgeries in the pelvic area, and more incidences of physical, sexual, and psychological abuse.[1-3] Altered movement and respiratory patterns are observed,[4] and pain-related fear of movements are reportedly present.[5] Long symptom duration and extensive investigations and treatments in different specialties are reported, often without satisfactory results.[1]

Clinical guidelines recommend a biopsychosocial approach including physical therapy, pain education, and active patient participation.[2] A systematic review of physical therapy treatment for CPP summarized that positive results can be achieved with single modalities such as manual techniques and exercises, but the evidence is limited.[6] Physical therapy focusing on body awareness and cognitive techniques has been highlighted as a promising therapy, and a future avenue for research in CPP.[6]

Group-based physical therapy is considered time saving and cost efficient; it can be as effective in reducing pain as individual treatment and can provide social affinity for the participants.[7] Despite this, no randomized controlled trials (RCTs) on group-based physical therapy for CPP have been identified.

A group-based multimodal physical therapy program that combines body awareness therapy and patient education has been developed at the Pelvic Floor Center at the University Hospital of North Norway.[8-10] Traditionally, women with CPP are referred for primary-care physical therapy after assessment by specialist doctors at hospitals.

The objective of this RCT was to compare group-based multimodal physical therapy (intervention group) with primary-care physical therapy (comparator group) in women with CPP. The primary hypothesis was that the intervention group will show greater reduction in the mean pain intensity than the comparator group after 12 months.

Key Message

The reduction in the mean pain intensity with group-based multimodal physical therapy in a hospital setting was significantly more than that with primary-care physical therapy, but the difference in the change between the groups was less than expected and the clinical relevance is unclear.

2 | MATERIAL AND METHODS

This was a parallel group RCT with an allocation ratio of 1:1. Participants were recruited from the outpatient clinic at the Pelvic Floor Center at the University Hospital of North Norway, after assessment by medical specialists. Eligibility and exclusion criteria are listed in Table 1.

The study intervention was based on the biopsychosocial model,[11] combined body awareness therapy,[8,12] patient education,[9,13] and cognitive approach of "acceptance and commitment therapy"[10] in a group setting. There was a pre-planned schedule, with an initial 10-day session followed by 2-day sessions after 3, 6, and 12 months. The aim was to reduce pain and improve daily function by challenging avoidance habits and providing new positive body experiences.[8,12] Detailed information about the intervention is shown in Supporting material, Table S1 (schedule) and Table S2 (TidiER checklist).

Women in the comparator group were referred to a physical therapist in primary health care with competence in women's health. The therapists received an information letter (Supporting material, Appendix S1), and they were asked to provide treatment according to their academic competence and in consultation with the woman. The deductibles of the physical therapy treatment were refunded.

The randomization database was administered by the Clinical Research Department at the hospital, and was available only for the primary researcher and the project leader. Randomization with alternating block sizes of four and six was applied. A nurse at the Pelvic Floor Center provided the referrals to the treatment groups.

Baseline data were collected at the outpatient clinic at the time of inclusion before randomization, and all outcomes were collected again after 12 months. Information about pain intensities was also collected by mail at 3 and 6 months. Women who did not manage to travel to the hospital for the post-test for practical reasons were contacted by phone and mail. Two physical therapists (ASN and MFE) performed the baseline and follow-up tests.

TABLE 1 Eligibility criteria

Inclusion criteria	Exclusion criteria
Norwegian-speaking women	Malignancy and conditions requiring special medical attention
Age 20-65 years	Pregnancy at the time of inclusion or childbirth during the previous 12 months
Chronic pelvic pain diagnosis[a]	Drug addiction
Motivated to participate in a group intervention	Serious psychiatric diagnosis
	Previous treatment by the physical therapists involved in the intervention
	Intra-abdominal or pelvic surgery within the last 6 months
	Botulinum toxin injections in the pelvic area in the last 4 months

[a]Engeler et al, European Association of Urology Guidelines on Chronic Pelvic Pain 2017. https://uroweb.org/guideline/chronic-pelvic-pain/.

A semi-structured interview was used to collect demographic information (age, body mass index, smoking, children, civil status, education, and work status) and medical history (pain duration, previous surgeries, other diagnosis, and abuse exposure). At 12 months, the number of consultations and type of treatment were also registered. Supporting material, Appendices S2 and S3 show the interview guides.

The primary outcome measure was change in mean pain intensity from baseline to 12 months of follow up. The mean pelvic pain intensity during the previous 7 days was recorded on the validated 11-point numeric rating scale (NRS, 0 = no pain, 10 = worst pain imaginable).[14]

The "worst" and "least" pain intensities during the last 7 days were registered as secondary outcome measures using the NRS.[14]

Movement patterns were assessed using the Standardized Mensendieck test, which evaluates performance of standing and sitting posture, active movements, gait, and respiration patterns according to criteria based on functional anatomy.[15] The test was video recorded before a blinded physical therapist scored the five domains on a scale of zero to seven (0 = least optimal, 7 = optimal) (Supporting material, Appendix S4). The Standardized Mensendieck test was validated in a sample of Norwegian women with CPP.[15]

Pain-related fear of physical movement and activity was registered with the validated Tampa scale for Kinesiophobia.[16] The women reported to what extent they agreed with the 13 different statements regarding associations between movement and possible injury or pain on a four-point Likert scale (1 = strongly disagree, 4 = strongly agree), and the total was calculated in the score range of 13-52.

Health-related quality of life was measured using the EQ5D-5L questionnaire. An EQ5D-index and an EQ visual analogue scale (VAS) score were reported.[17] The EQ5D-index ranges from −0.624 to 1.000, with higher scores indicating better health, whereas the EQ VAS records total health on a VAS (0-100), where 100 is the best health you can imagine.[17]

Symptoms of anxiety and depression were recorded using the Hopkins Symptom checklist-25 (0-4, higher scores indicating more severe symptoms).[18] Common somatic and psychological health complaints during the last 30 days were recorded using the Subjective Health Complaints questionnaire (0-87, higher scores indicating more complaints).[19] The presence and extent of urinary incontinence (yes/no, scores 0-21),[20] anal incontinence (yes/no, scores 0-24),[21] and obstructed defecation (yes/no, scores 0-25)[22] were recorded using validated questionnaires. Sexual function was mapped with questions regarding whether the women were sexually active (yes/no), had reduced/lack of sexual desire (yes/no), and/or had presence of pain during intercourse (yes/no). Pain intensity during intercourse was registered using an NRS (score 0-10).[23,24]

2.1 | Statistical analyses

The sample size was calculated based on the results from an RCT conducted on women with CPP that applied an intervention similar to the one in this study, though it was individually delivered. The aforementioned study showed a change of 2.2 on the NRS for mean pain intensity between the groups after 3 months,[25] which indicated a difference of one standard deviation in the change. Based on these assumptions, the effect size was estimated as "1". With a significance level of 0.05, a power of 90%, and an estimated dropout rate of 30%, 33 women should be included in each group.

Descriptive statistics were presented as mean and standard deviation or median and interquartile range for the continuous variables, and frequencies and percentages for the categorical variables. In case of missing data on sub-items of the secondary outcome measures, averages of the available responses were used.[26]

Statistical analyses followed the intention-to-treat approach. For continuous data, independent samples *t* test or Mann-Whitney *U* test was used for primary analyses of group differences in the change in the groups from baseline to 12 months. The assumptions for parametric tests of normal distribution of residuals and equality of variances were checked before analyzing the data. For the categorical variables, changes in the number of women reporting problems were described. Sensitivity analysis of the primary outcome was performed with a linear regression model adjusted for the baseline value. The significance level was set at $P = .05$. Statistical analyses were conducted using the Statistical Package for the Social Sciences, version 25 for Macintosh (IBM SPSS Statistics).[27]

2.2 | Ethical approval

This study was conducted in accordance with the principles of the Declaration of Helsinki. Written and oral study information was provided to the participants, and the informed consent forms were signed. The study was approved by the Regional Committee for

Medical and Health Research Ethics North (18.09.2014 2014/1398) and by the Institutional Review Board at the University Hospital of North Norway (0444/24.02.2015). The trial was registered at clinicaltrials.gov (NCT02356796, 5 February 2015) and reported in accordance with the CONSORT statement (Supporting material, Table S3).[28]

2.3 | Deviations from registered trial protocol

Regrettably, the registration of the primary outcome at clinicaltrials.gov was misleading, including mean, least, and worst recorded pain intensities at three different time-points. Some secondary outcomes were also registered as measured at different time-points. However, the objective of the trial was to analyze changes from baseline to 12 months. Additionally, the sample size calculation was 46 and not 50, as registered at clinicaltrials.gov.

3 | RESULTS

Sixty-two women were randomly assigned to the intervention group (n = 30) and the comparator group (n = 32) between March 2015 and November 2016. Data collection was completed in January 2017, with the data of 26 and 25 women available for the 12-month analyses from the intervention and comparator groups, respectively. Participant selection flow, including reasons for dropout, is shown in Figure 1. Table 2 provides the baseline characteristics of the participants in both groups. A detailed description of the sample was provided in a previously published paper.[24]

The majority of women in the intervention group attended all the sessions. One woman attended only for the first 10-day session, and seven attended 12-14 days of the total 16 treatment days (median 16, interquartile range 2). In the comparator group the median number of physical therapy consultations was 14 (interquartile range 29). One-third of the comparator group women reported that they had received pelvic floor muscle training combined with general exercises and/or relaxation exercises, 50% had received soft-tissue treatment alone or in combination with exercises, and 50% reported that dialogue with the therapist was a part of the treatment.

For the primary outcome the group-difference in change was −1.2 (95% CI −2.3 to −0.2, P = .027) (Table 3). In the intervention group, 19 women reported improvement, whereas four women reported no change and three reported worsening in mean pain intensity as compared with the 17, 3, and 5 women, respectively, in the comparator group. Except for a lack of reduction in pain, no adverse effects were registered.

Regarding the secondary outcomes, statistically significant differences were detected only in the respiratory patterns and pain-related fear of movements (Tables 4 and 5). Sixteen women (62% and 64% in the intervention and comparator groups, respectively) from both groups reported being sexually active both at baseline and 12 months. Among those, 12 (86%, two missing) in the intervention group and 12 (75%) in the comparator group reported reduced sexual desire at baseline. After 12 months, eight

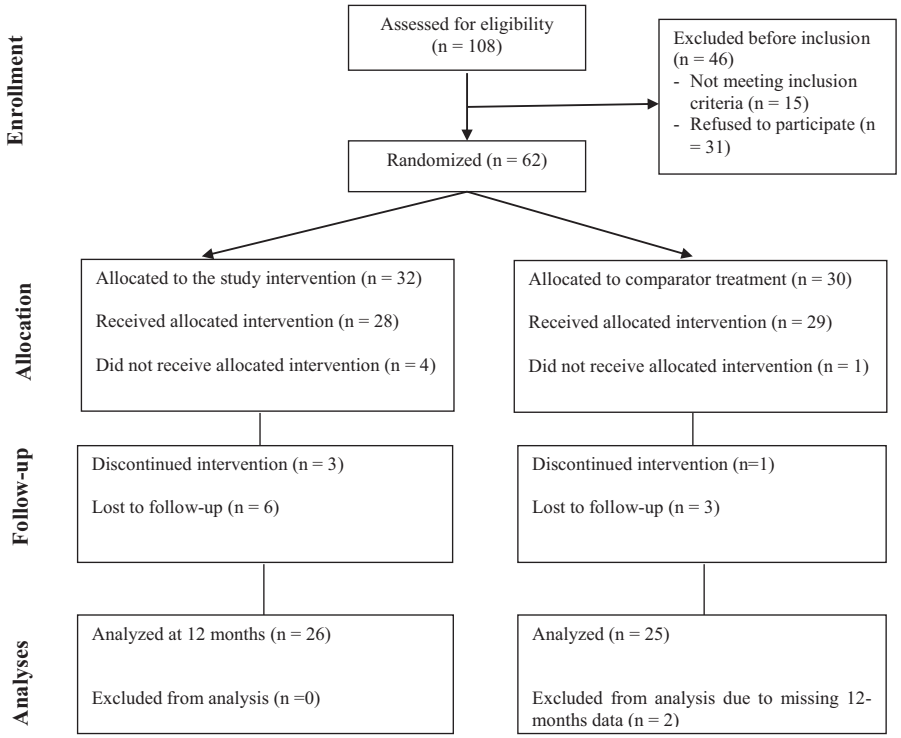

FIGURE 1 Participant flow including reasons for dropout

TABLE 2 Baseline characteristics of the participants in the intervention group and comparator group

	Intervention group (n = 32)		Comparator group (n = 30)	
	Mean, n or median	SD, % or IQR	Mean, n or median	SD, % or IQR
Age, years	39.7	10.9	36.2	13.8
BMI, kg/m^2	26.7	5.8	26.9	5.6
Smoking, yes	8	25	6	20
Premenopausal, yes	23	77	22	76
Children, number	2.0	1.5	1.3	1.2
Married or cohabiting, yes	27	84	21	70
Education, higher[a], yes	13	41	15	50
Working or student, yes	16	50	18	60
Currently on sick leave, yes	5	16	7	23
Sick leave >12 weeks last year, yes	11	34	7	23
Receiving social benefits, yes	12	38	11	37
Previous surgery (lower abdomen or pelvis), yes	22	71	20	67
Previous surgeries, number	1.5	0-3	1.0	0-2
Previous diagnosis in the pelvic area, yes				
Ovarian cysts	13	41	9	30
Urinary tract infections, repeated	9	28	7	23
OASIS	4	13	4	13
Endometriosis	3	9	6	20
Exposed to abuse (physical, psychological or sexual), yes	13	41	18	60
Duration of pelvic pain, years				
1-2	4	12.5	4	13.3
2-4	7	21.9	4	13.3
4-6	8	25	4	13.3
6-10	1	3.1	4	13.3
>10	12	37.5	14	46.7
Mean pelvic pain intensity, NRS	4.4	2.0	4.5	2.8

Abbreviations: BMI, body mass index; IQR, interquartile range; NRS, numeric rating scale; OASIS, obstetric anal sphincter injuries; SD, standard deviation.

[a]Completed ≥1 year at the University College or University.

TABLE 3 Differences between the intervention and comparator groups regarding the changes in the primary outcome from baseline to 12 months

Mean pain, NRS 0-10	Baseline		12 months		Change baseline to 12 months		Difference in change between the groups					
							Primary analysis			Sensitivity analysis[a]		
	Mean	SD	Mean	SD	Mean	95% CI	Mean	95% CI	*P*	Mean	95% CI	*P*
Intervention group (n = 26)	4.7	2.0	3.0	2.4	−1.8	−2.6 to −1.0	−1.2	−2.3 to −0.2	.027	−1.2	−2.3 to −0.1	.030
Comparator group (n = 25)	4.5	2.8	4.0	2.9	−0.5	−1.3 to 0.3						

Abbreviations: NRS, numeric rating scale; SD, standard deviation.

[a]Adjusted for baseline values of mean pain intensity.

TABLE 4 Descriptive statistics of mean, "worst" and "least" pain intensities at different time-points

	Intervention group (n = 26)								Comparator group (n = 25)							
	Baseline		3 months		6 months		12 months		Baseline		3 months		6 months		12 months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Mean pain (NRS 0-10)	4.7	2.0	3.7	2.0	4.3	2.1	3.0	2.4	4.5	2.8	3.7	2.4	4.2	2.9	4.0	2.9
Worst pain (NRS 0-10)	6.5	2.5	6.0	2.5	5.9	2.7	4.0	3.3	6.3	2.6	5.5	2.8	5.9	2.7	5.0	3.1
Least pain (NRS 0-10)	2.2	2.0	1.9	2.9	1.8	1.8	1.7	2.0	2.2	2.5	1.5	2.0	1.5	2.0	1.5	1.6

Abbreviations: NRS, numeric rating scale; SD, standard deviation.

(50%) in the intervention group and 10 (63%) in the comparator reported reduced sexual desire. At baseline, nine (75%, four missing) in the intervention group and 11 (73%, one missing) in the comparator group reported painful intercourse. After 12 months, six (38%) women in the intervention group and 10 (63%) in the comparator group reported painful intercourse. Pain intensity during intercourse was reduced by 3.0 on the NRS from baseline to 12 months in the intervention group compared with a reduction of 1.1 reduction in the comparator group (difference in groups −1.9; 95% CI −5.6 to 2.0; P = .326). There were no differences in the total scores for incontinence or obstructed defecation between the groups (Table 5).

4 | DISCUSSION

To our knowledge, this is the first RCT comparing a group-based treatment consisting of body awareness therapy, patient education, and cognitive techniques with primary-care physical therapy for women with CPP. We found a smaller than expected difference between the groups with respect to reduction in mean pelvic pain intensity after 12 months, but the difference was statistically significant. The intervention group showed additional improvements in the respiratory patterns and in pain-related fear of movements. However, changes in "worst" and "least" pain intensities, health-related quality of life, other movement patterns, symptoms of anxiety and depression, subjective health complaints, sexual function, incontinence, and obstructed defecation were not statistically different between the groups.

The strengths of this study are the RCT design, validated outcome measures, and the use of a definition and intervention in accordance with the clinical guidelines.[2] The primary outcome measure was defined as change in pain intensity, which reflects just one aspect of CPP,[1] and other end points might be better suited to this type of intervention. Comparing the study intervention with non-standardized physical therapy can be considered a limitation because of the heterogeneous treatment. However, there is no consensus on a standardized physical therapy approach in CPP,[6] and comparing the intervention with the "usual treatment" offered to these women provides real-world clinical data. Furthermore, the lack of blinding of the data collectors and patients is a limitation, and there might be a selection bias because one-third of the eligible women declined to participate. Reasons for not attending were economic concerns, and practical or emotional challenges of staying away from home. The dropout rate was 18%, which influences the generalizability of our findings. These results apply only to women with characteristics similar to the 51 participants included in the 12-month analyses of this study. The limited number of participants and the low power of the study mean that the results of all the secondary outcomes should be interpreted with caution.

The difference between the groups regarding the change in mean pain intensity was small compared with the results of a

TABLE 5 Differences between the intervention (n = 26) and comparator (n = 25) groups regarding the changes in the secondary outcomes from baseline to 12 months

	Baseline		12 months		Change from baseline to 12 months		Difference in change between the groups		
	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean	95% CI	*P*
Worst pain, NRS 0-10									
Intervention group n = 24	6.8	2.4	4.0	3.3	−2.7	3.5	−1.4	−0.4 to 3.1	.117
Comparator group, n = 25	6.3	2.6	5.0	3.1	−1.3	2.5			
Least pain, NRS 0-10									
Intervention group n = 21	2.2	2.0	1.7	2.0	−1.7	2.1	0.3	−0.9 to 1.4	.651
Comparator group n = 22	2.2	2.5	1.5	1.6	0.5	1.4			
Movement patterns, SMT 0-7									
Posture									
Intervention group n = 24	4.8	0.7	5.0	0.5	0.2	0.7	0.3	−0.1 to 0.7	.104
Comparator group, n = 22	4.8	0.6	4.8	0.7	−0.1	0.7			
Active movements									
Intervention group n = 24	4.2	1.2	5.0	0.7	0.7	1.1	0.1	−0.5 to 0.8	0.637
Comparator group, n = 22	4.0	1.1	4.7	1.0	0.6	0.9			
Sitting posture									
Intervention group n = 23	5.1	1.3	5.5	1.1	0.4	1.0	0.1	−0.7 to 0.6	.838
Comparator group, n = 22	4.9	1.2	5.2	1.0	0.3	1.2			
Gait									
Intervention group n = 22	4.5	1.2	5.1	1.0	0.5	0.8	0.0	−0.6 to 0.6	.881
Comparator group, n = 22	4.2	1.3	4.7	1.4	0.5	1.1			
Respiration									
Intervention group n = 23	4.1	1.3	5.0	1.2	0.8	1.4	0.9	0.2-1.6	**.015**
Comparator group, n = 21	3.9	1.2	4.1	1.0	−0.1	0.9			
Pain-related fear of movements, TSK 13-52									
Intervention group, n = 24	24.4	4.8	19.4	4.3	−5.0	3.7	−2.9	−5.5 to −0.3	**.032**
Comparator group, n = 25	23.0	6.3	20.8	5.9	−2.1	5.3			
Health-related quality of life, EQ5D-5L									
EQ5D index value, −0.624 to 1.000									
Intervention group, n = 26	0.67	0.14	0.72	0.19	0.05	0.16	−0.01	−0.09 to 0.07	.814
Comparator group, n = 25	0.64	0.19	0.70	0.21	0.06	0.13			
EQ-VAS, 0-100									
Intervention group, n = 24	58.0	19.1	62.1	20.3	4.1	22.4	−2.0	−14.9 to 10.9	.757
Comparator group, n = 25	58.2	22.5	64.2	18.1	6.1	22.5			
Symptoms of anxiety and depression, HSCL-25 0-4									
Intervention group, n = 21	1.83	0.45	1.52	0.38	−0.30	0.46	−0.15	−0.41 to 0.11	.241
Comparator group, n = 22	1.78	0.51	1.64	0.54	−0.15	0.39			
Subjective Health Complaints, SHC 0-87									
Intervention group, n = 22	20.9	11.6	22.4	12.2	1.5	16.8	7.2	−2.6 to 17.1	.146
Comparator group, n = 25	20.3	11.6	14.6	11.2	−5.7	16.7			
Urinary incontinence, ICIQ-UI, 0-21 (median, IQR)									
Intervention group, n = 23	4.0	8.0	3.0	6.0	0.0	3.0			.370[a]
Comparator group, n = 25	3.0	4.5	3.0	6.5	0.4	1.5			

(Continues)

TABLE 5 (Continued)

	Baseline		12 months		Change from baseline to 12 months		Difference in change between the groups		
	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean or median	SD or IQR	Mean	95% CI	*P*
Anal incontinence, St. Marks 0-24 (median, IQR)									
Intervention group, n = 24	0.0	2.0	0.0	2.0	0.0	0.0			.120[a]
Comparator group, n = 25	0.0	7.5	0.0	4.0	0.0	2.0			
Obstructed defecation, ODS 0-25 (median, IQR)									
Intervention group, n = 25	5.0	8.0	6.0	7.0	−2.0	4.0			.337[a]
Comparator group, n = 25	7.0	8.0	6.0	7.0	0.0	3.5			

Note: Bold values are statistically significant ($P < .05$).

Abbreviations: HSCL-25, Hopkins Symptom Check List; ICIQ-UI; ICIQ -Urinary Incontinence Short Form; IQR, interquartile range; NRS, numeric rating scale; ODS, obstructed defecation score; SD, standard deviation; SHC, Subjective Health Complaints questionnaire; SMT, Standardized Mensendieck Test; TSK-13, Tampa Scale of Kinesiophobia.

[a]Mann-Whitney *U* test.

previous RCT by Haugstad et al[25] The clinical relevance of a difference of only 1.2 must be questioned, despite its statistical significance. Approximately one quarter of the women in the intervention group reported unchanged or worse mean pain intensity scores, which contrasts with results by Haugstad et al, where only one of the 19 women in the group receiving physical therapy combined with cognitive techniques reported unchanged pain intensity.[25] This possibly reflects the differences between the study samples, but it could also indicate a need for refining both the study intervention and selection criteria. Some women with CPP may respond better to individual treatment. Group-based treatment as well as treatments aiming to change personal habits can be challenging for some patients.[7] Future studies should investigate predictors for different treatment approaches.[29]

A recently published RCT on 49 women with CPP by Ariza-Mateos et al compared a combination of manual physical therapy, exercises, and pain education with manual physical therapy alone.[30] The primary outcome was fear-avoidance behavior, which showed significantly more improvement in the combined treatment group. The difference between the groups regarding pain reduction was 1.1, which was similar to our result. The larger difference between the groups in the study by Haugstad et al could be because the combined physical therapy treatment was compared with standard gynecological care only, and the participants had higher baseline pain scores.[25]

The greatest reduction in mean pain intensity in the intervention group was observed between 6 and 12 months. This suggests that the long duration of the treatment is important, which is in accordance with theories of behavioral change that emphasize that it takes time to integrate new experiences and obtain lasting changes.[31] A subject for future studies would be to perform another follow up 12 months after the end of treatment.

Reduced pain intensity reflects only one aspect of positive changes for women with the complex condition of CPP, and selection of appropriate end points is challenging.[1,2] The greater improvements in respiratory patterns and pain-related fear of movement in the intervention group corroborate with the previous results presented by Haugstad et al[25] and Ariza-Mateos et al.[30] Improved respiratory patterns, in terms of increased deep respiration with abdominal expansion, may be related to the relaxation techniques and body awareness therapy applied in the study intervention, so may be related to pain reduction. Pain-related fear of movements is emphasized as a key mechanism for the development and maintenance of chronic pain, and hence it is a relevant outcome to include.[32]

For health-related quality of life, we observed that the baseline scores for EQ5D-5L were low compared with the population scores.[33] No significant differences in change were found for either the EQ5D-index or EQ-VAS scores. In future studies, a symptom-specific measure of health-related quality of life might add more information, because EQ5D-5L may not be sufficiently responsive to detect changes.[34] Differences between the groups for symptoms of anxiety and depression were not observed. The outcome measures for sexual, urological, and bowel functions were included according to the CPP definition,[2] and no group differences were detected.

Studying complex interventions for a complex condition such as CPP has several challenges. The optimal treatment is still uncertain, and more research is needed to refine the multimodal intervention, probably by tailoring the treatment for different subgroups of women with CPP.

5 | CONCLUSION

The reduction in the mean pelvic pain with group-based multimodal physical therapy was significantly more than that of primary-care physical therapy after 12 months. However, the expected difference

was not found, and we cannot conclude that a group-based intervention including body awareness therapy, patient education, and cognitive techniques is clinically better than primary-care physical therapy for women with CPP.

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CONFLICTS OF INTEREST

The authors report no conflicts of interest in connection with this paper.

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REFERENCES

1. Ayorinde AA, Macfarlane GJ, Saraswat L, Bhattacharya S. Chronic pelvic pain in women: an epidemiological perspective. *Womens Health (Lond)*. 2015;11:851-864.
2. Engeler DS, Baranowski AP, Borovicka J, et al. European Association of Urology Guidelines on Chronic Pelvic Pain 2017. https://uroweb.org/guideline/chronic-pelvic-pain/. Accessed December 1, 2019.
3. Sewell M, Churilov L, Mooney S, Ma T, Maher P, Grover SR. Chronic pelvic pain – pain catastrophizing, pelvic pain and quality of life. *Scand J Pain*. 2018;18:441-448.
4. Haugstad GK, Haugstad TS, Kirste UM, et al. Posture, movement patterns, and body awareness in women with chronic pelvic pain. *J Psychosom Res*. 2006;61:637-644.
5. Alappattu MJ, Bishop MD. Psychological factors in chronic pelvic pain in women: relevance and application of the fear-avoidance model of pain. *Phys Ther*. 2011;91(10):1542-1550.
6. Klotz SGR, Schön M, Ketels G, Löwe B, Brünahl CA. Physiotherapy management of patients with chronic pelvic pain (CPP): a systematic review. *Physiother Theory Pract*. 2018;28:1-17.
7. O'Keeffe M, Hayes A, McCreesh K, Purtill H, O'Sullivan K. Are group-based and individual physiotherapy exercise programmes equally effective for musculoskeletal conditions? A systematic review and meta-analysis. *Br J Sports Med*. 2017;51:126-132.
8. Mehling WE, Gopisetty V, Daubenmier J, Price CJ, Hecht FM, Stewart A. Body awareness: construct and self-report measures. *PLoS ONE*. 2009;4:e5614.
9. Louw A, Zimney K, Puentedura EJ, Diener I. The efficacy of pain neuroscience education on musculoskeletal pain: a systematic review of the literature. *Physiother Theor Pract*. 2016;32:332-355.
10. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: model, processes and outcomes. *Behav Res Ther*. 2006;44:1-25.
11. Borrell-Carrió F, Suchman AL, Epstein RM. The biopsychosocial model 25 years later: principles, practice, and scientific inquiry. *Ann Fam Med*. 2004;2:576-582.
12. Bergland A, Olsen CF, Ekerholt K. The effect of psychomotor physical therapy on health-related quality of life, pain, coping, self-esteem, and social support. *Physiother Res Int*. 2018;23:e1723.
13. Butler D, Moseley L. *Explain pain*, 2nd edn. Adelaide, Australia: Noigroup Publications; 2013.
14. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs*. 2003;14:798-804.
15. Haugstad GK, Haugstad T, Kirste U, et al. Reliability and validity of a standardized Mensendieck physiotherapy test. *Physiother Theory Pract*. 2006;22:189-205.
16. Haugen AJ, Grøvle L, Keller A, Grotle M. Cross-cultural adaptation and validation of the Norwegian version of the Tampa Scale for Kinesiophobia. *Spine*. 2008;33:E595-E601.
17. EurQol. EQ-5D-5LUser Guide Basic information on how to use the EQ-5D-5L instrument: EuroQol Research Foundation; 2019. https://euroqol.org/publications/user-guides Accessed January 10, 2020.
18. Nettelbladt P, Hansson L, Stefansson CG, Borgquist L, Nordström G. Test characteristics of the Hopkins Symptom Check List-25 (HSCL-25) in Sweden, using the Present State Examination (PSE-9) as a caseness criterion. *Soc Psychiatry Psychiatr Epidemiol*. 1993;28:130-133.
19. Eriksen HR, Ihlebæk C, Ursin H. A scoring system for subjective health complaints (SHC). *Scand J Public Health*. 1999;27:63-72.
20. Abrams P, Avery K, Gardener N, Donovan J. The International Consultation on Incontinence Modular Questionnaire: www.iciq.net. *J Urol*. 2006;175(3):1063-1066.
21. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut*. 1999;44:77-80.
22. Renzi A, Brillantino A, Di Sarno G, d'Aniello F. Five-item score for obstructed defecation syndrome: study of validation. *Surg Innov*. 2012;20:119-125.
23. Træen B, Stigum H. Sexual problems in 18–67-year-old Norwegians. *Scand J Public Health*. 2010;38:445-456.
24. Nygaard AS, Stedenfeldt M, Øian P, Haugstad GK. Characteristics of women with chronic pelvic pain referred to physiotherapy treatment after multidisciplinary assessment: a cross-sectional study. *Scand J Pain*. 2019;19:355-364.
25. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. *Am J Obstet Gynecol*. 2006;194:1303-1310.
26. Parent M. Handling item-level missing data: simpler is just as good. *Couns Psychol*. 2016;41:568-600.
27. IBM. *IBM SPSS Statistics for Macintosh, Version 25.0*. Armonk, NY: IBM Corp.; 2017.
28. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2012;10:28-55.
29. Allaire C, Williams C, Bodmer-Roy S, et al. Chronic pelvic pain in an interdisciplinary setting: 1-year prospective cohort. *Am J Obstet Gynecol*. 2018;218:e1-e12.
30. Ariza-Mateos MJ, Cabrera-Martos I, Ortiz-Rubio A, Torres-Sanchez I, Rodriguez-Torres J, Valenza MC. Effects of a patient-centered graded exposure intervention added to manual therapy for women with chronic pelvic pain: a randomized controlled trial. *Arch Phys Med Rehabil*. 2019;100:9-16.
31. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot*. 1997;12:38-48.
32. Vlaeyen JWS, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain*. 2000;85:317-332.
33. Janssen B, Szende A. Population norms for the EQ-5D. In: Szende A, Janssen B, Cabases J, eds. *Self-Reported Population Health: An*

International Perspective based on EQ-5D. Dordrecht: Springer, Netherlands; 2014:19-30.
34. Payakachat N, Ali MM, Tilford JM. Can the EQ-5D detect meaningful change? A systematic review. *Pharmacoeconomics*. 2015;33(11):1137-1154.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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Appendices

Appendix 1 Schedule for the first 10 days of the group-based multimodal physical therapy intervention

Week 1	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
08.30	Individual assessments, including the SMT-test	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)
09.00					
10.00	Information and presentation	Patient education and workbook: To live with chronic pain Reflection about own pain situation	Patient education: Pelvic anatomy, physiology and functions	Patient education: Coping strategies	Patient education: Physical activity and pain
11.30		Movement break	Movement break	Movement break	Movement break
11.45					
12.30	Movement and body awareness therapy: Intro	Patient education: Pain neurobiology	Patient education: and workbook: Introduction to ACT Change of focus	Movement and body awareness therapy	Patient education and workbook: ACT To set goals
14.00	Individual assessments, including the SMT-test	Movements and relaxation	Movement and body awareness therapy	Movements and relaxation	Movements and relaxation

Week 2	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**
08.30	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)	Movement and body awareness therapy (pool)
09.00					
10.00	Patient education: Relaxation and breathing in relation to pain	Patient education: Muscle function	Workbook: Reflection about own future	Patient education and workbook: ACT To set goals	Patient education and workbook: Making long-term goals
11.30	Movement break	Movement break	Movement break	Movement break	Movement break
11.45					
12.30	Patient education: The autonomous nervous system	Patient education: Pelvic pain (gynecologist)	Patient education: Nutrition (nutritionist)	Movement and body awareness therapy	Evaluation
14.00	Movement and body awareness therapy	Movements and relaxation	Movement and body awareness therapy		

ACT, acceptance and commitment therapy

TIDieR Template for Intervention Description and Replication

Appendix 2: The TIDieR (Template for Intervention Description and Replication) Checklist

Item number	Group-based Multimodal Physical Therapy for women with Chronic Pelvic Pain Description of the intervention	Where located Page number in Paper II or appendix number in thesis
	BRIEF NAME	
1.	Group-based multimodal physical therapy	
	WHY	
2.	The primary aim of the intervention is to challenge habits of avoidance, give new positive bodily experiences and to facilitate change in terms of reduced pain and improved daily function.[1-3] The theoretical basis is that the body is seen as a functional and interacting entity with indivisible body and mind, and that physical and psychological strains over time may influence the whole body.[4 5] The treatment program is in accordance with the latest clinical guidelines for CPP, which recommend a holistic approach enhancing both physical, psychological, social and sexual factors, active patient involvement and provision of information that is responsive to the patient's problems.[6]	Page 7
	HOW	
3.	The treatment program consists of a total of 16 days organized as one 10-days session followed by two-day sessions after 3, 6 and 12-months. A one-day program starts at 8.30 and lasts until 15.00, with a combination of movement classes, lectures and discussions every day. There is a pre-planned schedule for all the 16 days. The intervention is a combination of movement therapy[2, 5] patient education[1, 7] and Acceptance and Commitment Therapy (ACT).[8] A more detailed description is given under "Procedures". The study intervention is run by physical therapists with competence in psychosomatic physical therapy and chronic pain management. A gynecologist and a nutritionist contribute on one lecture each. The treatment program starts and ends with an individual physical therapy assessment, and the rest of the program is given in a group setting with 5-10 women in each group. The whole program is run in Tromsø.	Page 7. Appendix 1.

4. WHAT PROCEDURES:

Referral and inclusion: The participants are recruited from the multidisciplinary Pelvic Floor Center at the University Hospital of North Norway (UNN), after assessment by a medical specialist. Written and oral study information is given, and consent forms signed in accordance with the principles of the Declaration of Helsinki. Page 7.

First assessment: An individual physical therapy assessment is performed on day one or two. The anamnesis covers predetermined questions about patients´ perception of cause of CPP, challenges in the daily life, thoughts about need for more medical examinations, previous assessments and treatment, childhood, expectations to the program, hobbies, interests and social life. A physiotherapeutic assessment is performed, including an introduction to body awareness exercises. The first assessment has a time limit of 60 minutes.

Daily program: Every day of the program has the same basic structure; hydrotherapy in a heated pool (32°C) (60 minutes), two sessions of lectures (90 minutes each), short "movement break" (15 minutes), body awareness therapy in the gym (60 minutes). The detailed description of the intervention components are: Appendix 1.

1. Body awareness therapy*:*
Explorative exercises aiming to increase the awareness of own respiration- and movement patterns, of posture and of the difference between muscle tension and relaxation were applied.[5] Reflections about how these functions are influenced by each other and by physical, emotional or social strain were integrated in the movement classes.[2, 5] The participants are challenged to gradually re-introduce movements or functions that have been restricted or avoided. Page 7.

The body awareness therapy is performed with different types of exercises, both in the gym and as hydrotherapy.

Exercises in the gym include:

- Awareness exercises focusing on own respiration, movement patterns, posture and the difference between muscle tension and relaxation.[5]
- Pelvic floor muscle exercises, especially focusing on recognition of tension versus relaxation.
- Establishing solid postural stability, i.e. to be able to stand firmly on one's legs or to be properly "grounded"[9]
- Exploration and re-introduction of functional movements that has been avoided or restricted.
- Reflections about how the different functions can be related and/or influenced by each other, such as muscle tension linked to respiration, posture is linked to respiration and muscle tension etc.
- Progressive relaxation, one session every day.

Hydrotherapy involves gentle movements of the whole body, aiming to allow for larger range of movements, increased

stability and strength. The reduced weight bearing, the warm water and the compressive effects of hydrostatic pressure are considered to have favorable effects for adults with musculoskeletal pain.[10]

2. Patient education:
Patient education with lectures about topics related to living with CPP, both focusing on the biological and psychosocial factors connected to pain. Special attention is given to the role of the autonomic nervous system in pain, and why pain can persist despite lack of objective findings and after the expected time for tissue healing.[1, 7]

The following topics are addressed in the lectures:

- Pain neurobiology
- "The body": pelvic anatomy, urinary and bowel functions, sexual function, diaphragm-model (respiration) and the autonomous nervous system.
- Nutrition (by a nutritionist)
- Pelvic pain (by a gynecologist)
- Living with chronic pain
- Muscle function
- Change of focus
- To set goals (three sessions)
- The associations between unrestricted respiration, ability to rest and sense of security.
- Coping strategies
- Acceptance and Commitment Therapy (ACT)
- The relation between movements/ physical activity and pain

Group discussions and individual tasks related to the topics are a part of the educational sessions.

3. Acceptance and Commitment Therapy (ACT):
ACT focuses on behaviour change rather than symptom reduction, and the aim is to help the women to accept that the pain is present, set goals and commit to use available resources despite the pain.[3, 11, 12] ACT includes mindfulness (learning to see your thoughts in a new way, not let the pain define you), acceptance (accepting that the pain is present, but not letting it define your life), commitment and values based living (do things you want, try to get in touch with your desired life).[3] ACT is incorporated both in the education and movement therapy.

5. MATERIALS:

Equipment: For exercises in the gym soft therapy mats, exercise balls (size 60-75 cm) and wooden rollers are used. Pillows and blankets are available in the gym/therapy room. For the hydrotherapy flotation devices ("pool noodles") are used.

A compact digital camera and a tripod are used to record participants performing SMT-test before and after treatment.

Furniture needed is a big table and chairs to seat all participants and physical therapists.

Workbook: The participants receive a workbook with short texts covering the topics presented in the lectures. The workbook also contains individual tasks for the women to work with between the sessions (a copy in Norwegian can be obtained by contacting the first author, ASN).

Manual for the Standardized Mensendieck Test: The Standardized Mensendieck Test is video taped both at the start and at the end of the treatment period, and is used as an educational tool to illustrate to participants the changes they achieve during the treatment period. The test is a physiotherapeutic test developed to assess movement quality in women with CPP. Posture, movement, gait, sitting posture and respiration are evaluated.[13] A copy in Norwegian can be obtained by contacting the first author, ASN.

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Website developed by the Norwegian National Advisory Unit on Incontinence and Pelvic Floor Health with information in Norwegian language about chronic pelvic pain and with sound files with instructions for pelvic floor muscles exercises, progressive relaxation, and mindfulness and for relaxation before going to bed (to promote sleep). The website is public.

Website: http://nkib.helsekompetanse.no/tilstander/langvarige-underlivssmerter/behandling

Books: The participants are given information about relevant books, such as "Explain pain"[7] by Butler and Moseley.

WHO PROVIDED

6. The study intervention is run by three physical therapists with competence in psychosomatic physical therapy and chronic pain management. A gynecologist and a nutritionist contribute on one lecture each.

WHERE

7. The location for the treatment program is outside the hospital. A combined gym and a teaching room, a heated pool (32**°C)** and a therapy room used for the individual talks and the assessment are the premises used, in addition to a restroom. The gym was comfortably heated and the level of light could be adjusted during the different movement tasks. The participants themselves book accommodation, and payment is largely refunded from the Norwegian Health Authorities (Pasientreiser/HELFO).

WHEN and HOW MUCH

8. The first session lasts for 10 coherent days, and then there are two-day sessions after three, six and 12 months. After each session the participants go back to their homes and to their normal daily life.

TAILORING

9. The program is designed for the group setting, and the participants are encouraged to participate in the entire program. Still, some participants express strong wishes about not participating in e.g. pool exercises, and then receive alternative exercises.

MODIFICATIONS

10.‡ A total of six treatment groups were run before a sufficient number of participants for the trial had completed. No specific modifications were done, but variations will always be present between different groups although the basic program is the same.

HOW WELL

11. The physical therapists have a pre-planned schedule with descriptions of topics for theoretical lectures, and an "exercise bank" for the practical lessons.

The participants' adherence to the intervention was recorded at 12 months by registration of number of days attended..

12.‡ Of the 32 women starting the treatment program in our study, 26 completed.

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1. Louw A, Zimney K, Puentedura EJ, Diener I. The efficacy of pain neuroscience education on musculoskeletal pain: A systematic review of the literature. Physiotherapy theory and practice. 2016;32(5):332-355.
2. Mehling WE, Gopisetty V, Daubenmier J, Price CJ, Hecht FM, Stewart A. Body Awareness: Construct and Self-Report Measures. PLoS ONE. 2009;4(5):e5614.
3. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and commitment therapy: model, processes and outcomes. Behav Res Ther. 2006;44(1):1-25.
4. Bunkan BH, Thornquist E. Psychomotor therapy: an approach to the evaluation and treatment of psychosomatic disorders. London: Churchill Livingstone; 1990.
5. Bergland A, Fromholt Olsen C, Ekerholt K. The effect of psychomotor physical therapy on health-related quality of life, pain, coping, self-esteem, and social support. Physiother Res Int. 2018;23(4).
6. Engeler DS, Baranowski AP, Borovicka J, et al. EAU Guidelines on Chronic Pelvic Pain. 2017.
7. Butler D, Moseley L. Explain pain. 2. ed. Adelaide, Australia: Noigroup Publications; 2013.
8. Hayes SC, Smith S. Get out of your mind and into your life. Oakland, Canada: New Harbinger Publications, Inc.; 2005.
9. Thornquist E, Bunkan BH. What Is Psychomotor Physiotherapy? Oslo: Norwegian University Press; 1991.
10. Barker AL, Talevski J, Morello RT, Brand CA, Rahmann AE, Urquhart DM. Effectiveness of Aquatic Exercise for Musculoskeletal Conditions: A Meta-Analysis. Arch Phys Med Rehabil. 2014;95(9):1776-1786.
11. Hann KEJ, McCracken LM. A systematic review of randomized controlled trials of acceptance and commitment therapy for adults with chronic pain: outcome domains, design quality, and efficacy. J Context Behav Sci. 2014;3:217–227.
12. Veehof MM. Acceptance- and mindfulness-based interventions for the treatment of chronic pain: a meta-analytic review. Cogn Behav Ther. 2016;45(1):5-31.
13. Haugstad GK, Haugstad T, Kirste U, et al. Reliability and validity of a standardized Mensendieck physiotherapy test. Physiother Theory Pract. 2006;22(4):189-205.

Appendix 3

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
UNIVERSITETSSYKEHUSET NORD-NORGE

Til fysioterapeut som får henvist pasient:

Informasjon om forskningsprosjekt på kroniske bekkensmerter

Ved UNN Tromsø pågår nå et forskningsprosjekt på kroniske bekkensmerter hos kvinner. Prosjektet innebærer at en del kvinner henvises for oppfølging hos fysioterapeut nær pasientens hjemsted, slik vanlig praksis for behandling av denne pasientgruppen er. Denne informasjonen sendes til fysioterapeuter som får henvist pasienter som deltar i prosjektet.

Hensikten med prosjektet er å sammenligne effekten av en gruppebasert behandling i regi av UNN Tromsø, med det å få oppfølging hos fysioterapeut lokalt. Det gjennomføres en randomisert kontrollert studie, hvor deltakerne trekkes til å motta ett av de to behandlingsalternativene.

Deltakerne i prosjektet er kvinner med langvarige smerter i bekken eller underliv. De er utredet hos gynekolog, gastrokirurg eller urolog, og malignitet eller andre tilstander som krever medisinsk eller kirurgisk behandling skal være avkreftet før inklusjon i prosjektet. Deltakerne følges opp i ett år, med registrering av opplysninger om smerte, livskvalitet og andre helseplager. Dersom de ønsker vil deltakerne etter studieperioden få tilbud om deltakelse i gruppebehandlingen i Tromsø.

Vi er klar over at det er variasjon i innhold og organisering av fysioterapibehandling hos ulike terapeuter i primær- og spesialisthelsetjenesten, og behandlingsopplegg for den enkelte avgjøres av fysioterapeut i samråd med pasient. Vi ønsker at du skal behandle denne pasienten slik som du ville gjort uavhengig av at hun deltar i et forskningsprosjekt.

Vi er takknemlige for om ventetiden før oppstart av behandling blir så kort som mulig. Dersom pasienten ønsker å bytte til annen behandler underveis i perioden er dette i orden, men vi er da takknemlige for om henvisning sendes med videre eller at det bes om ny henvisning. Deltakere i prosjektet får refundert utgifter (egenandel) ved behandling hos fysioterapeuter med refusjonsrett. De må derfor ta vare på kvitteringer. Eget refusjonsskjema sendes til pasient.

Ved spørsmål er du velkommen til å ta kontakt med oss.

Vennlig hilsen

Ane Sigrid Henriksen
Fysioterapeut MSc/ PhD-stipendiat, Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom.

Kontakt:
Torunn Pedersen**,** prosjektkoordinator
Tlf.: 77627267 (ti, to fre oddetallsuker). Torunn.K.pedersen@unn.no

Appendix 4

Conservative treatment of chronic pelvic pain
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-mail: ane.sigrid.henriksen@unn.no
Phone: +47 92 2* ** **

Background information at inclusion

Date: ☐☐.☐☐.☐☐☐☐

Participant number: ☐☐

Participant initials: ☐☐☐☐

Inclusion criteria:

Female 20-65 years: ☐ Yes ☐ No

Pelvic / abdominal pain> 6 months: ☐ Yes ☐ No

Motivated to participate in group-based treatment in Tromsø: ☐ Yes ☐ No

Exclusion criteria:

Previous treatment by physical therapist at KIB: ☐ Yes ☐ No

Pregnancy and childbirth last 12 months: ☐ Yes ☐ No

Not Norwegian speaking: ☐ Yes ☐ No

Drug addiction, or use of larger doses of analgesics: ☐ Yes ☐ No

Severe psychiatry, or not consent competence: ☐ Yes ☐ No

Detected malignant disease of the pelvis or other medical treatment requiring pathology of the pelvis (including initiation of systemic hormone therapy): ☐ Yes ☐ No

Pain only during menstruation that is not associated with negative consequences of cognitive, behavioral, sexual or emotional nature: ☐ Yes ☐ No

Major intra-abdominal, vaginal or rectal surgery during the last 6 months: ☐ Yes ☐ No

If yes: *May be included later if possible to achieve 6 months after surgery first.*

Surgical intervention date: ☐☐.☐☐.☐☐☐☐

Can be included from date: ☐☐.☐☐.☐☐☐☐

Botox injection during the last 4 months: ☐ Yes ☐ No

If yes: *Can be included later if possible to achieve 4 months without Botox first.*

Last injection date: ☐☐.☐☐.☐☐☐☐

Can be included from date: ☐☐.☐☐.☐☐☐☐

Conservative treatment of chronic pelvic pain
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-mail: ane.sigrid.henriksen@unn.no
Phone: +47 92 2* ** **

Background information at inclusion

Demographic variables:

Participant number: ☐☐

Age (year): ☐☐ Year of birth: ☐☐☐☐

Height (cm): ☐☐☐ Weight (kg): ☐☐☐,☐ BMI: ☐☐,☐

Do you smoke: ☐ Yes ☐ No

Civil status: ☐ Married/cohabiting ☐ Live alone/ single

Highest completed education: ☐ Primary school
(Tickt only one box)
☐ Vocational higher education, vocational school
☐ Upper secondary school
☐ College or university, less than 4 years
☐ College or university, 4 years or more

Working conditions / what is your main activity: ☐ Occupational full-time ☐ Insured
(Tick one ore more boxes)
☐ Occupational part-tim ☐ Unemployed
☐ Homemaker ☐ Student / military service
☐ Pensioners ☐ Sick leave
If yes, enter percentage: ☐☐☐

Have you been on sick leave due to the pelvic pain during the last 3 years? ☐ Yes ☐ No

If yes: - total weeks last 3 years: ☐☐☐ - total number of weeks last year: ☐☐

Children (number): ☐☐ Number of pregnancies: ☐☐

Number of abortions: Spontaneous: ☐☐ Number of weeks: ☐☐☐☐☐☐☐☐☐☐

Provoked: ☐☐ Number of weeks: ☐☐☐☐☐☐☐☐☐☐

Extra-uterine pregnancy: ☐ Yes ☐ No If yes, number: ☐☐

Surgical intervention: ☐ Yes ☐ No

Specify: ☐☐☐☐☐☐☐☐☐☐

Past Births, (number): ☐☐

Vaginal delivery (number): ☐☐ Spontaneous (number): ☐☐ Operational (vacuum / forceps): ☐☐

Caesarean section (number): ☐☐ Episiotomy (number): ☐☐

Year of childbirths: 1. ☐☐☐☐ 2. ☐☐☐☐ 3. ☐☐☐☐ 4. ☐☐☐☐

5. ☐☐☐☐ 6. ☐☐☐☐ 7. ☐☐☐☐ 8. ☐☐☐☐

9. ☐☐☐☐ 10. ☐☐☐☐

Treatment and pain related variables:

Participant number: ☐☐

What is your main bother: ☐ Pain in the pelvic area ☐ General pain in the body

When started the pain condition in abdomen / pelvis:
☐ 6 months ago
☐ 7 - 12 months ago
☐ 1 - 2 years ago
☐ 2 - 4 years ago
☐ 4 - 6 years ago
☐ 6 - 10 years ago
☐ More than 10 years ago

How long has the pain in the abdomen / pelvis been at the same level as now?

☐ 0 - 3 months ☐ 4 - 6 months ☐ 7 - 12 months ☐ 1 - 5 years ☐ 6 years or more

Background / cause of the pain:

Can you describe the type of pain:

Localization:

How often pain:

Triggering factors / when does the pain occur:

Do you consider yourself to be sufficiently assessed/examined? ☐ Yes ☐ No

Special investigations you think should have been done? Specify:

Previous surgery in the abdomen or pelvis: ☐ Yes ☐ No

If yes: how long since the last: ☐☐☐ Total number of surgeries: ☐☐

Type inngrep: (Sett evt. flere kryss)

☐ Anorectal Specify:

☐ Urinary or gynecological Specify:

☐ Intraabdominal surgery Specify:

☐ Other Describe:

Participant number: ☐☐

Previous diseases related to the pelvis/abdomen: (Tick several boxes if necessary)

☐ Obstetric injury Type: ☐

If sphincter damage, degree: ☐

☐ Fistula

☐ Inflammation

☐ Adhesions

☐ Neurological disease / injury

☐ Repeated UTI during the last 1-2 years

☐ Endometriosis

☐ Ovarian cysts (right / left). Treated?

☐ Other If other, specify: ☐

Systemic disease: ☐ Yes ☐ No

If yes, specify: ☐

Neurological disease, injury or surgery: (If necessary, add several crosses)

☐ Back injury (incl. Prolapse) ☐ MS ☐ Cerebral insult ☐ Other

If other, specify: ☐

Previous treatment of pelvic / abdominal pain (other than surgery, eg radiation, physiotherapy, etc.):

☐ Yes ☐ No If yes, specify: ☐

Do you use medication in relation to pelvic pain: ☐ Yes ☐ No

If yes, specify the type and frequency of use for the last 4 weeks:

A: Less often than every week
B: Every week, but not daily
C: Daily
D: Not used

Painkillers, over the counter:	☐ A	☐ B	☐ C	☐ D
Painkillers on prescription:	☐ A	☐ B	☐ C	☐ D
Sleeping aids:	☐ A	☐ B	☐ C	☐ D
Beroligende medicines:	☐ A	☐ B	☐ C	☐ D
Anti-depressants:	☐ A	☐ B	☐ C	☐ D
Hormonal meds:	☐ A	☐ B	☐ C	☐ D
Other: ☐	☐ A	☐ B	☐ C	☐ D

How much do you usually take daily? (Number of tabl, suppositories)

☐

Participant number: ☐☐

Menstruation

Pre- or postmenopausal: ☐ Premenopausal

☐ Postmenopausal Date of last menstrual period: ☐☐.☐☐.☐☐

Any menopause disorders: ☐ Yes ☐ No

If premenopausal: ☐ Regular Interval and duration (eg 30/5): ☐☐/☐

(Sett kun ett kryss)

☐ Not regularly Interval and duration: ☐☐/☐

☐ Amenorrhea If so, date of last menstrual period: ☐☐.☐☐.☐☐

☐ Absence of menstruation due to hormone spiral or similar

If pre-, you have dysmenorrhea / much pain associated with menstruation: ☐ Yes ☐ No

Do you have any complaints other than those associated with the pelvic area:

Have you been exposed to incidents that you experienced as abuse, of a physical, mental or sexual nature:

☐ Yes ☐ No

If yes: (Put only one cross) ☐ Got help ☐ Have not received help

Approximate time (child / adult):

Any other information:

Are there anything else than what we have talked about until now you put in context with your pelvic complaints, el. other things you want to add:

Conservative treatment of chronic pelvic pain
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-mail: ane.sigrid.henriksen@unn.no
Phone.: +47 92 2* ** **

Treatment related activity during the study

Registration at 12 months

Participant number: ☐☐

Date: ☐☐.☐☐.☐☐☐☐ Participant initials: ☐☐☐☐

Which treatment group was you randomized to:

☐ Usual physical therapy ☐ Group based multimodal PT

During what period of time did you receive the treatment?

Approximate number of consultations (number of days): ☐☐

What kind of treatment did you receive:

☐ Active exercises, pelvic floor

☐ Active exercises, general

☐ Soft tissue treatment (triggerpoints, massagje, strethching, needling)

☐ Conversations

☐ Relaxation exercises

☐ Other

Other information you want to add regarding the treatment you received?

Did you seek other treatment due to your abdominal/pelvic pain during the study?

☐ Yes ☐ No

If yes, where? Approximate number of consultations:

☐ General practitioner ☐☐

☐ Physical therapist ☐☐

☐ Specialist health care ☐☐

☐ Other ☐☐

Other illnesses/ijuries during the study period?

☐ Yes ☐ No If yes, specify:

Any treatment?

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E-mail: ane.sigrid.henriksen@unn.no
Phone.: +47 92 2* ** **

VI BRYR OSS - SAMMEN TAR VI ANSVAR
UNN

Treatment related activity during the study

Use of medication

Participant number: ☐☐

Do you use medication in relation to pelvic pain: ☐ Yes ☐ No

If yes, specify the type and frequency of use for the last 4 weeks:

A. Less often than every week.
B: Every week, but not daily
C: Daily.
D· Not used

Painkillers, over the counter·	☐ A	☐ B	☐ C	☐ D
Painkillers on prescription	☐ A	☐ B	☐ C	☐ D
Sleeping aids:	☐ A	☐ B	☐ C	☐ D
Sedative/ calming medicines:	☐ A	☐ B	☐ C	☐ D
Anti-depressants:	☐ A	☐ B	☐ C	☐ D
Hormonal meds:	☐ A	☐ B	☐ C	☐ D
Other: ☐	☐ A	☐ B	☐ C	☐ D

How much do you usually take daily? (Number of tabl, suppositories)

Have you used other medications during the study period than today? If yes, specify type, dosage and treatment duration.

Demographic variables

Weight (kg)· ☐☐☐,☐

Civil status: ☐ Married/cohabiting ☐ Live alone/ single

Do you smoke· ☐ Yes ☐ No

Highest completed education: *(Tickt only one box)*

- ☐ Primary school
- ☐ Vocational higher education, vocational school
- ☐ Upper secondary school
- ☐ College or university, less than 4 years
- ☐ College or university, 4 years or more

Conservative treatment of chronic pelvic pain
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-mail: ane.sigrid.henriksen@unn.no
Phone.: +47 92 2* ** **

Treatment related activity during the study

Participant number: ☐☐

Working conditions / what is your main activity: *(Tick one ore more boxes)*

☐ Occupational full-time ☐ Insured
☐ Occupational part-time ☐ Unemployed
☐ Homemaker ☐ Student / military service
☐ Pensioners ☐ Sick leave
If yes, enter percentage: ☐☐☐

Number of pregnancies: ☐☐

Number of abortions. Spontaneous. ☐☐ Number of weeks: ☐☐
Provoked: ☐☐ Number of weeks. ☐☐

Extra-uterine pregnancy: ☐ Yes ☐ No If yes, number: ☐☐ Surgical intervention: ☐ Yes ☐ No
Specify: ☐☐☐☐☐☐☐☐☐☐

Previous childbirths, (number) ☐☐

Vaginal delivery (number): ☐☐ Spontaneous (number): ☐☐ Operational (vacuum / forceps): ☐☐

Caesarean section (number): ☐☐

Year of childbirths: 1. ☐☐☐☐ 2. ☐☐☐☐ 3. ☐☐☐☐ 4. ☐☐☐☐
5. ☐☐☐☐ 6. ☐☐☐☐ 7 ☐☐☐☐ 8. ☐☐☐☐
9. ☐☐☐☐ 10. ☐☐☐☐

Treatment and pain related variables:

What is your main bother: ☐ Pain in the pelvic area ☐ General pain in the body

When started the pain condition in abdomen/pelvis.
☐ 6 months ago ☐ 4 - 6 years ago
☐ 7 - 12 months ago ☐ 6 - 10 years ago
☐ 1 - 2 years ago ☐ More than 10 years ago
☐ 2 - 4 years ago

How long has the pain in the abdomen / pelvis been at the same level as now?
☐ 0 3 months ☐ 4 6 months ☐ 7 - 12 months ☐ 1 5 år ☐ 6 years or more

Background / cause of the pain

Conservative treatment of chronic pelvic pain
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-mail: ane.sigrid.henriksen@unn.no
Phone.: +47 92 2* ** **

VI BRYR OSS - SAMMEN TAR VI ANSVAR
UNN

Treatment related activity during the study

Participant number: ☐☐

Can you describe the type of pain:

Localization

How often pain:

Triggering factors / when does the pain occur:

Do you consider yourself to be sufficiently assessed/examined? ☐ Yes ☐ No

Previous surgery/ies in the pelvic or abdominal area? ☐ Yes ☐ No

If yes, how long ago (months): ☐☐ Total number: ☐☐

Menstruation

Pre- or postmenopausal: ☐ Premenopausal

☐ Postmenopausal Date of last menstrual period:

Any menopause disorders. ☐ Yes ☐ No

If premenopausal: ☐ Regular Interval and duration (eg 30/5):

(Put only one cross)

☐ Not regularly Interval and duration:

☐ Amenorrhea If so, date of last menstrual period: ☐☐.☐☐.☐☐

☐ Absence of menstruation due to hormone spiral or similar

If pre-, you have dysmenorrhea / much pain associated with menstruation: ☐ Yes ☐ No

Have you been exposed to incidents that you experienced as abuse, of a physical, mental or sexual nature:

☐ Yes ☐ No

If yes: (Put only one cross) ☐ Got help ☐ Have not received help

Approximate time (child / adult):

Are there anything else than what we have talked about until now you put in context with your pelvic complaints, el. other things you want to add:

Konservativ behandling av kroniske bekkensmerter
Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
E-post: ane.sigrid.henriksen@unn.no
Tlf.: +47 92 25 85 82

Seksualfunksjon

Baseline ☐ 12 mnd ☐

Deltakernr: ☐☐

Initialer: ☐☐☐☐

Dato: ☐☐.☐☐.☐☐☐☐

Spørsmål om mulige problemer knyttet til seksualitet og til samleie

Er du seksualt aktiv?:

☐ Ja ☐ Nei

Hvis nei, angi grunn:

Har noen av alternativene som er nevnt nedenfor forekommet i ditt seksualliv i løpet av de siste 12 mnd?

Sett et kryss pr linje:

Manglende/liten seksuell lyst:

☐ Hele tiden ☐ Nesten hele tiden ☐ Ganske ofte ☐ Ganske sjelden ☐ Aldri

Smerte (i underlivet) ved samleie:

☐ Hele tiden ☐ Nesten hele tiden ☐ Ganske ofte ☐ Ganske sjelden ☐ Aldri

Hvis smerter ved samleie, angi grad av smerte på skalaen under. Verdi ”0” indikerer ”ingen smerter” mens verdi 10 indikerer ” verst tenkelige smerte”.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

ingen smerter — *verst tenkelige smerte*

Annet (spesifiser):

Appendix 7

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord	Veronica Sørensen	77620758	17.11.2014	2014/1398/REK nord
			Deres dato:	Deres referanse:
			09.11.2014	

Vår referanse må oppgis ved alle henvendelser

Pål Øian
Kvinneklinikken Postboks 24

2014/1398 Kroniske bekkensmerter hos kvinner - konservativ tverrfaglig behandling i gruppe sammenlignet med standard behandling.

Forskningsansvarlig institusjon: Institutt for Klinisk Medisin (IKM)
Prosjektleder: Pål Øian

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet på fullmakt av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord).

Prosjektleders prosjektomtale
Kroniske bekkensmerter (KBS) er en tilstand som medfører store plager. Det finnes begrenset kunnskap om årsak og behandling av KBS. Nyere retningslinjer anbefaler helhetlig og tverrfaglig tilnærming, og det etterspørres studier på dette. Ved UNN er det startet et tverrfaglig gruppetilbud for kvinner med KBS. Formålet med dette prosjektet er å undersøke effekt av gruppetilbudet sammenlignet med effekt av standard individuell behandling. Resultatene vil gi økt kunnskap om pasientgruppen og om effekt av behandlingstilnærmingene, som igjen kan bidra til forbedret behandlingstilbud. Pasienter med KBS som skal behandles konservativt kan delta i studien, og de trekkes tilfeldig til å motta ett av behandlingstilbudene. Behandlingen går over ett år. Opplysninger om smerte, livskvalitet og andre helseplager samles inn med spørreskjema, og fysioterapeutisk undersøkelse gir opplysninger om bevegelseskvalitet og respirasjon. Målinger gjøres ved start, og etter 6 og 12 måneder. Mer info i protokoll.

Vurdering
Vi viser til skjema for tilbakemelding av 09.11.14.
Rek anser at tilbakemeldingen er i tråd med der merknader komiteen gav i sitt utsettelsesvedtak av 29.9.14

Etter fullmakt er det fatte slikt:

Vedtak
Med hjemmel i helseforskningsloven §§ 2,9 og 10, samt forskningsetikkloven § 4 godkjennes prosjektet.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK nord på eget skjema senest 01.09.2018, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK nord dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

Besøksadresse:
MH-bygget UiT Norges arktiske universitet 9037 Tromsø

Telefon: 77646140
E-post: rek-nord@asp.uit.no
Web: http://helseforskning.etikkom.no/

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Veronica Sørensen
rådgiver

Kopi til: Eyvind.j.paulssen@uit.no

Appendix 8

Forespørsel om deltakelse i forskningsprosjektet

"Konservativ behandling av kroniske bekkensmerter"

Bakgrunn og hensikt
Kroniske smerter i bekken/underliv medfører store plager og redusert livskvalitet for mange kvinner. Slike smerter kan ha sammensatte årsaker og man har dessverre begrenset kunnskap om hva som er den beste behandlingen.

Dette er en forespørsel til deg om å delta i et forskningsprosjekt for å undersøke effekt av to ulike behandlingsalternativer. Ved Universitetssykehuset Nord-Norge (UNN) i Tromsø er det startet et gruppebasert behandlingstilbud til kvinner med kroniske bekkensmerter. Vi er usikre på effekten av gruppetilbudet sammenlignet med det som er vanlig behandlingstilbud på landsbasis, nemlig individuell oppfølging hos fysioterapeut med egnet kompetanse nærme pasientens hjemsted. I dette forskningsprosjektet ønsker vi å undersøke effekten av disse to behandlingstilbudene nærmere.

Hva innebærer studien?
Hvis du takker ja til deltakelse vil du innkalles til fysioterapeut ved UNN. Det registreres informasjon om deg og dine plager, og det gjennomføres en fysioterapitest. Etter testen trekkes du tilfeldig til et av behandlingsalternativene. Vi følger deg opp i ett år for å vurdere effekt av behandlingstilbudet du får.

Mulige fordeler og ulemper
Dersom du deltar vil du være med å tilføre fagfeltet ny viktig kunnskap, og du vil få mulighet til å gi tilbakemelding om hvordan du opplever det tilbudet du har fått. Deltakelse i studien innebærer at du i tillegg til behandlingen du får skal møte fysioterapeut ved UNN to ganger i løpet av et år. Dette kan for noen oppleves som en ulempe pga tidsbruk, mens andre kan oppleve at dette er en fordel fordi man får flere samtaler med fysioterapeut. Studien varer i ett år etter oppstart av behandling, og det er av stor betydning for resultatene at du deltar helt til testing etter et år er gjennomført.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn, fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du en samtykkeerklæring før inklusjon i studien. Dersom du har spørsmål kan du kontakte:

UNN HF, Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom: Torunn Pedersen, prosjektkoordinator. Tlf.: 77627267 (ti, to, fre i oddetallsuker). E-post: torunn.k.pedersen@unn.no.

Prosjektgruppen består av:

Ane Sigrid Henriksen Fysioterapeut MSc/Stipendiat Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom, UNN HF, Tromsø ane.sigrid.henriksen@unn.no	**Pål Øian** Professor/Overlege Kvinneklinikken, UNN HF, Tromsø pal.oian@unn.no	**Mona Stedenfeldt** Fysioterapeut PhD/ Faglig rådgiver, Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom, UNN HF, Tromsø, mona.stedenfeldt@stolav.no	**Gro Killi Haugstad** Fysioterapeut PhD/ Førsteamanuensis Fysioterapiutdanningen, Høgskolen i Oslo og Akershus grokilli.haugstad@hioa.no

Ytterligere informasjon om studien finnes i kapittel A.
Ytterligere informasjon om personvern og forsikring finnes i kapittel B.
Samtykkeerklæring følger etter kapittel B.

Kapittel A- utdypende forklaring av hva studien innebærer

Bakgrunn for studien
Kroniske bekkensmerter er et sammensatt og belastende helseproblem for de som rammes, og det er et stort behov for mer kunnskap om hvordan man skal behandle slike plager. Vi ønsker å se nærmere på to behandlingstilbud som gis i dag, for å kunne gi et best mulig tilbud til kvinner med slike smerter. Studien inngår i doktorgradsprosjektet " Konservativ behandling av kroniske bekkensmerter" som gjøres av fysioterapeut Ane Sigrid Henriksen i samarbeid med Nasjonal Kompetansetjeneste for inkontinens og bekkenbunnsykdom ved UNN.

Undersøkelser ved inklusjon i studien
Dersom du samtykker i deltakelse i studien vil du bli innkalt til et møte med fysioterapeut ved UNN. Gjennom en samtale registreres relevant informasjon om dine plager (varighet, tidligere behandling etc). Deretter gjennomføres en fysioterapitest med fokus på daglige bevegelsesoppgaver. Under denne testen skal du ha på deg klær som gjør det lett å observere hvordan du beveger deg (f.eks shorts og singlet). Testen videofilmes for at forsker senere skal kunne sammenligne filmen med en som tas etter endt behandling. I løpet av møtet med fysioterapeut fyller du ut spørreskjemaer som går på smerte, livskvalitet, funksjon i daglige aktiviteter og generelle helseplager. Totalt vil dette møtet ta ca 1,5 time.

Tilfeldig trekking av behandlingsalternativ
En datamaskin avgjør ved "randomisering" (loddtrekning) hvilken behandling du skal få. Du får informasjon om hvilken behandling du er trukket til over telefon og per post.

Gruppebehandling i Tromsø eller individuell fysioterapi nær ditt hjemsted
Den gruppebaserte behandlingen består av 4 samlinger i Tromsø fordelt over 12 måneder, hvorav den første samlingen er på to uker og de påfølgende på to dager. Dersom du blir trukket til å få oppfølging lokalt får du henvisning til fysioterapeut med egnet kompetanse så nærme ditt bosted som mulig. Du vil da få tilbud om å delta i gruppebehandlingen etter et år, dersom du ønsker dette.

Oppfølging underveis i studien
Ved deltakelse vil du få tilsendt fire spørreskjemaer i posten etter 3 og 6 måneder. Du blir også ringt opp med påminnelse om å returnere skjemaene. Etter 12 måneder blir du igjen innkalt til en time hos fysioterapeut på UNN. De samme registreringene som ved første møte gjennomføres.

Kriterier for deltakelse
For å vite at det er effekten av fysioterapibehandlingen vi måler ønsker vi at du ikke skal motta annen inngripende behandling i bekken/underliv mens du deltar i prosjektet. Dette kan f.eks være kirurgi, injeksjoner, blæreinstillasjoner, eller oppstart av ny hormonbehandling. Dette er årsaken til at vi før inklusjon ber om at du er utredet hos lege og derfra henvist til konservativ oppfølging.

Dersom annen behandling blir nødvendig i løpet av studieperioden skal du selvfølgelig ha det, men vi ønsker å få vite dette. Smertestillende medisiner og annen behandling som ikke er inngripende (som TENS, fysioterapi, osteopati, øvelser etc) er tillatt. Du er velkommen til å ta kontakt med oss dersom du har spørsmål i forhold til dette i løpet av månedene studien pågår.

Testing ved avbrutt behandling
Vi håper du vil benytte deg av behandlingstilbudet du blir trukket til, at du vil returnere spørreskjema etter 3 og 6 måneder og møter opp til testing etter 12 måneder. Dette er av stor betydning for å oppnå best mulig kvalitet på resultatene av studien. Vi vil også spørre deg om å fylle ut spørreskjema og møte til 12-måneders testing om du ikke har kunnet følge opp behandlingen du ble trukket til.

Frivillig deltakelse
Dersom du velger å ikke delta i studien vil du få det tilbudet for konservativ oppfølging som gis ved UNN i dag. Dette er henvisning til oppfølging lokalt, individuell fysioterapi ved UNN eller gruppebehandling. Ventetid må da påregnes.

Kapittel B - Personvern, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er bakgrunnsinformasjon om dine plager, opplysningene du gir på spørreskjemaene og video av fysioterapiundersøkelsen. Alle data blir anonymisert, og merket med dine initialer og et deltakernummer. Det er kun prosjektkoordinator og fysioterapeuten som gjennomfører testing ved oppstart og avslutning av prosjektet som har adgang til navnelisten og som kan finne tilbake til deg.

Videofilmen vil ikke vises til andre enn fysioterapeutene involvert i forskningsprosjektet, samt at du selv kan få se den om du ønsker.

Fysioterapeut Ane Sigrid vil ha tilgang til din pasientjournal, men har kun tillatelse til å bruke den for å innhente opplysninger som er nødvendige i forhold til studien og vil da informere deg om at dette blir gjort. Informasjonen som er lagret og bildene som er tatt skal slettes 3 år etter at datainnsamlingen avsluttes. Universitetssykehuset Nord-Norge ved administrerende direktør er databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi
Omkostninger ved reise og opphold dekkes etter gjeldende regler fra Pasientreiser. Dette vil si at du som ved ordinær behandling, reise- eller opphold i forbindelse med behandling vil betale en egenandel. Du må sørge for å ta vare på kvitteringer på reiseutgifter slik at du får dekket det du har rett på.

Egenandel ved oppfølging hos fysioterapeut med refusjonsrett (opp til egenandelstaket på 2670 kr per kalenderår) vil ved deltakelse dekkes av prosjektet. Det er viktig at du tar vare på kvitteringer slik at du får refundert disse utgiftene. Vi gjør oppmerksom på at dette kun gjelder for behandlere med refusjonsrett, og at vi ikke refunderer utgifter ved behandling hos fysioterapeut uten slik avtale med kommunen.

Studien er finansiert gjennom forskningsmidler fra Fysiofondet og Helse Nord.

Forsikring
Pasientskadeloven gjelder ved deltakelse i studien på samme måte som ved vanlig oppfølging i spesialisthelsetjenesten.

Informasjon om utfallet av studien
Når resultatene fra studien publiseres vil de være tilgjengelige for deg. Det er planlagt publisering både i vitenskapelige tidsskrifter, og på nettsider og tidsskrifter for brukerorganisasjoner.

Nasjonal kompetansetjeneste for inkontinens og bekkenbunnsykdom
UNIVERSITETSSYKEHUSET NORD-NORGE

UNIVERSITETSSYKEHUSET NORD-NORGE
DAVVI-NORGGA UNIVERSITEHTABUOHCCEVIESSU

Samtykke til deltakelse i studien

"Kroniske bekkensmerter hos kvinner"

Jeg har lest informasjonen og samtykker i å delta i studien

(Prosjektdeltaker, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Tester/fysioterapeut, dato)

(BEHOLDES AV DELTAKER)

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(Tester/fysioterapeut, dato)

(RETURNERES TIL PROSJEKTLEDER VED SAMTYKKE TIL DELTAKELSE)