Information needs, psychological distress, and coping during the diagnostic phase of prostate cancer

A mixed methods study

by

Maja Elisabeth Juul Søndergaard

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University of Stavanger
NO-4036 Stavanger
NORWAY
www.uis.no

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Summary

Background: Prostate cancer (PCa) is the second most common cancer in men worldwide, accounting for about 15% of all cancers among men. In Norway, patients are referred to specialist healthcare services for diagnostic evaluation in cases of an elevated prostate-specific antigen (PSA) level and/or a suspicious digital rectal examination finding. According to national guidelines, the PSA test should be conducted only after thorough consideration of the potential harms and benefits. In 2017, general practitioners in the relevant region of Norway were instructed to use the Stockholm3 test instead of the PSA test as the standard procedure for diagnosing PCa. To reduce unnecessary non-medical delay in the diagnostic process and initiation of treatment, patients are referred to a standardised PCa care pathway.

Previous research has indicated that men may experience frustrations and uncertainty when confronted with an elevated PSA level and further diagnostic evaluations. The PSA test and subsequent prostate biopsy are suggested to be associated with hidden psychological costs, even in patients who are not eventually diagnosed with PCa. In cases of a potential cancer diagnosis, a cognitive appraisal process is initiated in response to an unknown future. Appraisal and applied coping strategies may influence the quality of life of men with PCa and are of importance for emotional adjustment. However, knowledge about patients' perception of information, psychological distress, and coping during the diagnostic phase of PCa is limited.

Objectives: The overall aim of this thesis was to develop knowledge concerning patients' perceptions of information, psychological distress, and coping during the diagnostic phase of PCa.

The objectives were as follows:

1. To explore men`s perception of information and their possible emotional strain in the diagnostic phase of prostate cancer (study I)
2. To explore and compare men’s perception of information and possible experience of distress between a PSA group and a Stockholm3 group during the diagnostic phase of prostate cancer (study II).
3. To investigate the associations between patient characteristics, psychological distress, and coping in the diagnostic phase of prostate cancer. (study III).

Methods: This thesis utilised a convergent mixed methods design. 1) A qualitative explorative interview study was conducted among patients evaluated for PCa (n = 10). 2) A comparative convergent mixed methods study was performed to compare the perceptions of information and psychological distress between a PSA group (quantitative analysis: n = 130, qualitative analysis: n = 10) and a Stockholm3 group (quantitative analysis: n = 120, qualitative analysis: n = 10) during the diagnostic phase of PCa. 3). A cross-sectional multicentre study was conducted to investigate the associations between patient characteristics, psychological distress, and coping during the diagnostic phase of PCa (n = 250).

Results: The patients had different information and support needs. Although they did not report severe symptoms of psychological distress, their emotions seemed to fluctuate. The period leading up to a possible PCa diagnosis could be perceived as emotionally demanding (study I). The patients in the Stockholm3 group received more satisfactory information from their general practitioner than did those in the PSA group. A subgroup of patients experienced symptoms of anxiety and depression (studies II and III). However, the qualitative analysis revealed that the patients might not have defined their emotions as anxiety or worry but still experienced psychological distress that affected their well-being (study II). A negative correlation was found between ageing and symptoms of anxiety. Poorer self-reported health was associated with more symptoms of both anxiety and depression, expanded use of social support, and wishful thinking. Increased symptoms of anxiety and depression were associated with increased use of all five measured coping strategies. Most patients appraised their situation as a challenge. The patients who appraised their situation as a threat experienced more symptoms of anxiety and depression and utilised more emotion-focused coping than did the patients who appraised their situation as a challenge or benign (study III).

Conclusions: This thesis demonstrated that a significant proportion of patients had unmet information needs during the diagnostic phase of PCa. The thesis was conducted in the context of the implementation of the Stockholm3 test, contributing new knowledge. The mandatory questions related to the Stockholm3 test may have facilitated communication about the test and the challenges of diagnosing PCa. The patients displayed a wide range of emotions towards the suspicion of PCa, including psychological distress. Threat appraisal was related to increased symptoms of anxiety and depression and the use of emotion-focused coping. These findings reveal focal points for healthcare providers to address when identifying patients in need of additional support and information.

Abbreviations

DRE	Digital rectal examination
GP	General practitioner
GPs	General practitioners
HADS	Hospital Anxiety and Depression Scale
ISUP	International Society of Urological Pathology
MAX-PC	Memorial Anxiety Scale for Prostate Cancer
PCa	Prostate cancer
PSA	Prostate-specific antigen
REK	Regional Committee for Medicine and Health Research Ethics in Norway
RWCCL	Revised Ways of Coping Checklist
STC	Systematic text condensation
TMSC	Transactional model of stress and coping
VAS	Visual analogue scale

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1 Introduction

In an article by the Danish Cancer Society the expression “wounded lions” was used to describe men attending a patient support group for men affected by prostate cancer (PCa) (Wohlebe, 2022). This expression illustrates how PCa may affect the self-perception of affected men. The psychosocial- and emotional impacts of PCa have been identified as focal points that affect the well-being of men during the trajectory of the disease. Prostate cancer and the late effects after treatment can significantly influence men’s quality of life (Mottet et al., 2023). Patients may experience increased symptoms of anxiety if they receive insufficient information before prostate biopsy (Wade et al., 2015). Some patients also require additional and personalised information beyond the scope of the standardised PCa care pathway (Aunan et al., 2021; Schildmeijer et al., 2019). Research has indicated that some men experience symptoms of psychological distress for up to years after diagnosis and treatment (De Sousa et al., 2012; Occhipinti et al., 2019). Psychological distress related to a potential cancer diagnosis has not been adequately explored and it is estimated that a considerable number of patients experiencing psychological distress remain unidentified (Brocken et al., 2012).

There is a knowledge gap concerning psychological distress during the diagnostic phase of PCa, and previous data appear ambiguous (Dillard et al., 2017). Previous research has highlighted the importance of assessing coping strategies because of their influence on the quality of life of men with PCa (Ahmad et al., 2005; Guan et al., 2020). Rand et al. (2012) found that a more positive cognitive illness appraisal predicted less psychological distress in men with advanced PCa. They suggested that patients’ well-being may be enhanced by supporting them in modifying their cognitive appraisal and applied coping strategies. However, knowledge about appraisal and applied coping strategies during the diagnostic phase of PCa is limited (Groarke et al., 2018).

This thesis addresses the knowledge gap regarding patients' perception of information, psychological distress, and coping during the diagnostic phase of PCa. The project is a substudy of the "From PSA to Stockholm3" project, which aims to analyse the effectiveness of the Stockholm3 test in regular clinical practice, including both primary care and specialised healthcare (Clinical trials, 2023). In the main project, all general practitioners (GPs) in the relevant region of Norway are recommended to use the Stockholm3 test in place of the prostate-specific antigen (PSA) test as a new tool for early detection of PCa (Viste et al., 2020). As a substudy, this thesis was conducted during the transition period from the PSA test to the Stockholm3 test, contributing knowledge from patients' perspectives in a new context.

2 Background

This chapter presents central concepts and previous research, which constitute the background and rationale for the studies conducted in this thesis. The aim and specific objectives of the thesis are then presented at the end.

2.1 Prostate cancer

Prostate cancer is a major health concern in men. With an estimated number of diagnosis of 1.4 million worldwide in 2020, PCa is the second most common cancer among men (Ferlay et al., 2021). After Australia/New Zealand and Northern America, Western and Northern Europe have the highest incidence of PCa partly due to the widespread use of PSA test and the ageing population (European Association of Urology, 2023). In Norway, PCa is the most frequently diagnosed cancer among men, with approximately 5000 new cases per year (Cancer Registry of Norway, 2022). Family history and ethnic background are related to an increased incidence of PCa, and several genetic factors, such as the *BRCA2* gene, are associated with aggressive PCa (European Association of Urology, 2023).

Although the expected 5-year relative survival rate for men diagnosed with high-risk locally advanced PCa in Norway is 96.2% (The Norwegian Directory of Health, 2023b), men are still faced with a potentially fatal cancer and the prospect of late effects after treatment. Altered masculinity and sexuality, urinary incontinence, and bowel changes have been identified as some of the late effects that men may be confronted with after treatment (Hoyt et al., 2013; Schildmeijer et al., 2019; Spendelow et al., 2018). European guidelines for PCa emphasise that PCa care should not only focus on an organ in isolation because the side effects or late adverse effects of treatment may have a major influence on patients' quality of life (Mottet et al., 2023).

2.1.1 Prostate-specific antigen test

Prostate-specific antigen is a protein produced by both normal and malignant cells of the prostate gland. The PSA level is measured in the blood and is often elevated in men with PCa (David & Leslie, 2022). However, an elevated level can also be caused by an infection or a benign enlargement of the prostate gland (European Association of Urology, 2023). The PSA test was introduced in 1987; thereafter, an enormous increase in the reported incidence of PCa has been reported. The widespread use of the PSA test has led to a shift towards early detection and better short-term outcomes. However, the long-term benefits remain unclear (Barry, 2001). Norwegian national guidelines for the diagnosis, treatment, and monitoring of PCa emphasise that systematic screening of the PSA level and early diagnosis of PCa can reduce prostate-specific mortality. However, the lack of evidence on improved overall survival compared with the adverse effects of overdiagnosis and overtreatment implies that there is reluctance to recommend population-based PSA screening (The Norwegian Directory of Health, 2023a). Prostate-specific antigen test is recommended for men with a genetic predisposition or a suspicious digital rectal examination (DRE) finding. In the absence of suspicious symptoms, the PSA test should be conducted only after thorough consideration of the potential harms and benefits (The Norwegian Directory of Health, 2023a).

2.1.2 Stockholm3 test

The Stockholm3 test was developed at the Karolinska Institute in Stockholm, Sweden, aiming to increase the specificity of a combined PCa test compared with the PSA test alone without reducing the sensitivity for high-risk PCa (Grönberg et al., 2015). The Stockholm3 test is a blood-based test involving a combination of plasma protein biomarkers including the PSA level, genetic polymorphisms, and clinical variables. With this test, PCa mortality can be reduced while also reducing overdiagnosis (Grönberg et al., 2015). In addition, findings show that the Stockholm3 test can not only reduce the number of biopsies and the detection rate of low-grade PCa but also maintain the detection rate of International Society of Urological Pathology (ISUP) grade group 2 or higher (Möller et al., 2019). The ISUP grade group system is the most commonly used system for grading PCa; it grades PCa from 1 (least aggressive) to 5 (most aggressive) (Epstein et al., 2016).

The Stockholm3 test contains mandatory initial questions that GPs need to discuss with patients prior to the test. The answers to these questions are a part of the algorithm that determines the risk score and pertain to family history of PCa, use of medication related to the prostate, and any previous prostate biopsies. The main differences between the PSA test and the Stockholm3 test are the initial questions, risk score, and recommendation from the laboratory analysing the test findings. A risk score of ≥11% indicates an increased risk of PCa. In contrast, the PSA level is interpreted by a GP (Viste et al., 2020).

In 2017, GPs in the relevant region of Norway were instructed to use the Stockholm3 test instead of the PSA test as the standard procedure for diagnosing PCa (Viste et al., 2020). The same recommendations for considering information about the potential benefits and harms first apply to the Stockholm3 test. The Stockholm3 test is a novel test, and more knowledge about the long-term effects is needed.

2.2 The prostate cancer care pathway

In 2015, a PCa care pathway was introduced in Norway to reduce unnecessary non-medical delay in the diagnostic process and initiation of treatment (The Norwegian Directory of Health, 2022). Figure 1 presents a section of the flowchart of the PCa care pathway for the diagnostic phase of PCa.

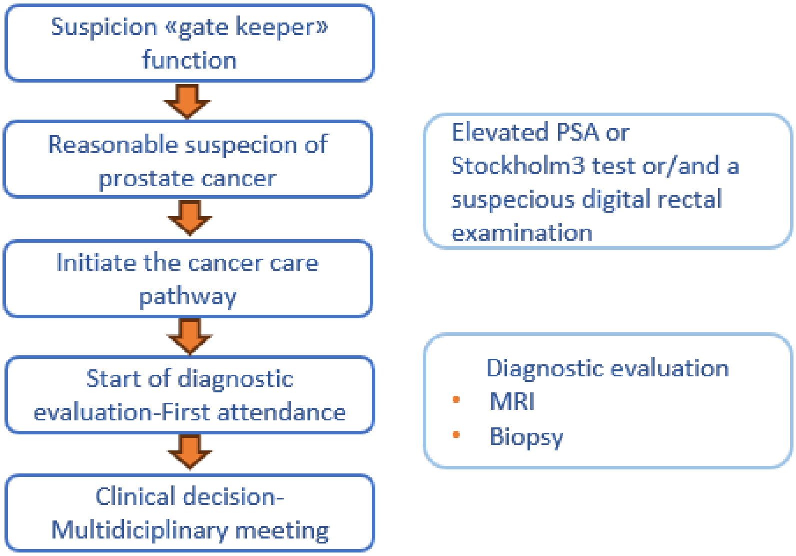

Figure 1 Flowchart of the diagnostic evaluation of prostate cancer based on the national cancer care pathway for prostate cancer in Norway (The Norwegian Directory of Health, 2022)

In the PCa care pathway, patients are referred to specialist healthcare services for further diagnostic evaluation when an elevated PSA level/Stockholm3 test score and/or a suspicious DRE finding is detected. Contrary to other cancer care pathways, the PCa care pathway requires urologists to determine whether there is reasonable suspicion of PCa in patients. The decision is based on elevated PSA levels, suspicious palpation findings, and the possibility of metastases. In cases of reasonable suspicion of PCa, patients are entitled to receive information about the potential PCa and what the pathway entails (The Norwegian Directory of Health, 2022). The national standardised PCa care pathway is based on national Norwegian guidelines, which are derived and adapted from European guidelines (Mottet et al., 2021). The national guidelines have established GPs' role as an independent position with a responsibility as a gate keeper. This role includes a balancing act between avoiding overdiagnosis and referring patients who meet the criteria for further diagnostic evaluation at a urological outpatient clinic. The guidelines further emphasise that unnecessary anxiety should be avoided in relation to the diagnostic evaluation of PCa (The Norwegian Directory of Health, 2023a).

According to the Essential Requirements for Quality Cancer Care, diagnostic evaluation should be organised as an interdisciplinary collaboration (Brausi et al., 2020). A PCa diagnosis is confirmed at a multidisciplinary meeting after prostate biopsy. The multidisciplinary meeting involves a urologist, an oncologist, a pathologist, a radiologist, and, sometimes, a nurse coordinator. Patients are informed of the diagnosis by the urologist, and the recommendation from the multidisciplinary meeting is presented. The final decision of treatment should be based on sufficient information and a joint decision between the urologist and patients (The Norwegian Directory of Health, 2022).

The PCa care pathway intends to provide patients and their next of kin with predictability and security. Information should be tailored to meet individual needs, preferences, and values. Patients are assigned a coordinator, most often a nurse, who will supervise the diagnostic phase and ensure that scans, appointments, and potential treatments are scheduled. In addition, the coordinator maintains contact with patients and next of kin (The Norwegian Directory of Health, 2022). Nurses are a part of the interdisciplinary team caring for patients and have versatile and pivotal functions throughout the cancer care pathway, including providing information, care, and support to patients and their next of kin (Brausi et al., 2020).

2.3 Patient information during the trajectory of prostate cancer

Information regarding test accuracy, benefit–harm balance, and awareness of subsequent procedures/consequences has been identified as important before the PSA test is conducted (Kuss et al., 2021). According to both national and international guidelines, providing adequate information on the potential risks and benefits is strongly recommended before patients undergo the PSA test, and the decision should be shared between physicians and patients (Mottet et al., 2023; The Norwegian Directory of Health, 2023a). However, research has indicated that many patients receive insufficient information about the PSA test as well as PCa and its treatment options (Bhuyan et al., 2017; Kannan et al., 2019). In addition, patients with PCa commonly request more timely and accurate information. Providing information on treatment and its side effects simultaneously with the diagnosis is considered too late (King et al., 2015; Nanton et al., 2009). A large-scale American study found that only 9.2% of patients received information about all the following established domains: expert opinions about the PSA test, accuracy of the PSA test, side effects of PCa treatment, and treatment needs of patients with PCa (Bhuyan et al., 2017). A Norwegian national survey revealed that information from GPs regarding diagnostic evaluation of cancer and potential treatments had a great potential for improvement. Less than 50% of patients evaluated for cancer within the last 12 months responded that they had received satisfactory information from their GP (Iversen & Bjertnæs, 2020).

Previous research has indicated that access to information throughout the PCa care pathway is central for patients to manage uncertainty. In addition, information is identified as an important factor in patients' evaluation of care. Unclear or insufficient information from specialist care services is associated with increased anxiety or psychological distress (Appleton et al., 2019). Even though patients generally perceive healthcare providers to be pleasant and professional, a lack of information is found to be a common experience during the trajectory of PCa. Diagnostics and treatment are also perceived as long and complex (Schildmeijer et al., 2019).

2.4 Psychological distress related to prostate cancer

Previous research regarding patients during the diagnostic phase of PCa has shown mixed findings in relation to psychological distress. Some studies have found that the incidence of clinically significant anxiety in men with an elevated PSA level is low and that only a small group of men evaluated for PCa has significant psychological distress (Awsare et al., 2008; Wade et al., 2013). In contrast, a review revealed that 30–40% of men with suspected PCa reported that anxiety affected their day-to-day life (De Sousa et al., 2012). In another study, psychological distress was noted in 49% of men after undergoing prostate biopsy (Sharp et al., 2018). Wade et al. (2013) reported low levels of anxiety across different time points of the diagnostic phase of PCa, whereas Dillard et al. (2017) found that anxiety increased as men came closer to receiving the findings of their prostate biopsy. Another study found increased levels of anxiety before biopsy, which then disappeared after the biopsy and increased again after a confirmed diagnosis (Sefik et al., 2020).

A recent study including men diagnosed with localised PCa found that patients experienced a phase of elevated anxiety immediately after diagnosis; however, the anxiety levels were mostly within a subclinical range (Otto et al., 2022). Psychological distress has been found to be associated with a set of beliefs and personal variables in patients newly diagnosed with PCa. Several factors such as aggressive disease, younger age, poorer decision-making ability and self-efficacy, and greater masculine identity threats have been noted to be related to increased psychological distress (Orom et al., 2015). However, previous research has shown inconsistent findings regarding the correlation between age and anxiety at different stages of the PCa trajectory. A few studies have found nonsignificant associations between higher age and lower level of anxiety (Johanes et al., 2013; Sánchez et al., 2020). In contrast, Esser et al. (2020) found that increased symptoms of both anxiety and depression were associated with younger age.

A qualitative study suggested that patients diagnosed with PCa may experience elevated stress levels and symptoms of anxiety and depression as early as when their GP informs them about the possibility of PCa (Sharpley et al., 2018). Other studies indicated that some patients experienced symptoms of distress up until years after diagnosis and treatment (De Sousa et al., 2012; Occhipinti et al., 2019). Another study identified elevated psychological distress in patients before prostate biopsy and a significantly higher risk for psychological distress at 6 months following PCa diagnosis. The findings emphasise the need for further research regarding distress before prostate biopsy (Oba et al., 2017). Sharp et al. (2018) argued that there is a hidden psychological cost associated with the PSA test and biopsy, even in patients who are not eventually diagnosed with PCa.

2.5 Appraisal and applied coping strategies in patients affected by prostate cancer

Previous research has highlighted the importance of assessing appraisals and coping strategies because of their influence on the quality of life of men with PCa (Ahmad et al., 2005; Guan et al., 2020). Appraisal is an evaluation process that depends on personal significance and options for coping. Stressful events tend to generate a complex array of emotions that indicate the importance to individuals (Folkman, 2020).

According to Kessler (2020) cognitive appraisals constitute a target point for interventions to support and improve the quality of life of patients diagnosed with cancer. Similarly, perceived stress based upon appraisal has been found to be the strongest predictor of adjustment in men both pre- diagnosis and across the further trajectory of PCa (Groarke et al., 2020; Groarke et al., 2018). Groarke et al. (2020) further assessed perceived cancer-related masculine identity threat in association with psychological distress and found that a higher perceived masculine identity threat predicted a higher level of psychological distress, which was mediated by personal resources. Screening for high levels of stress was suggested to provide timely psychological interventions and reduce the negative impact on the quality of life and emotional adjustment up to 5 years after the diagnosis of PCa.

Challenge appraisal has been associated with a higher predicted quality of life and threat appraisal with a lower predicted quality of life. More positive cognitive illness appraisal has been found to predict less psychological distress in patients with advanced PCa, and modifying cognitive appraisal and applied coping strategies has been suggested to enhance patients' well-being (Rand et al., 2012). In the study by Ahmad et al. (2005), threat appraisal was less frequently used than other types of appraisal. The thoughts of living with PCa were possibly perceived as less threatening because of the high survival rate of PCa. Threat appraisal was used the most right after a cancer diagnosis, likely because of uncertainty about the future, treatment, and changes in daily life. Patients with an elevated PSA level may experience uncertainty due to a lack of understanding about their future health and their risk for PCa. To manage this uncertainty and possible related anxiety, they engage in different coping strategies, such as information seeking, healthcare seeking, and defensive cognitive strategies (Biddle et al., 2017).

A qualitative review identified numerous coping strategies applied by patients with PCa (Spendelow et al., 2018). Many of these strategies involved attempts to positively reframe how symptoms and side effects were perceived. For example, one strategy involved characterising PCa symptoms and side effects as normal consequences of growing old, rather than being a single part of an underlying cancer. The findings of this review suggest that sex socialisation and masculinities may contribute to the selection and use of coping strategies. Flexibility in the perception of masculinity and coping strategies seemed to be adaptive. Patients applying more emotion-focused coping have been found to have higher levels of anxiety than patients applying a more balanced use of both emotion- and problem-focused coping (Otto et al., 2022). Certain emotion-focused coping strategies such as avoidance have been associated with poorer adjustment and mental well-being (Guan et al., 2020; Matheson et al., 2020).

2.6 Summary

This chapter highlighted previous research results, showing ambiguous findings regarding psychological distress during the diagnostic phase of PCa (Dillard et al., 2017). The quality of information seems to be of importance in relation to appraisal and psychological distress in patients with PCa both pre- and post-diagnosis (Appleton et al., 2019). In addition, psychological distress has been associated with personal characteristics, appraisal, and coping strategies (Rand et al., 2012). Symptoms of psychological distress may be present in patients with PCa until years after diagnosis and treatment (De Sousa et al., 2012; Occhipinti et al., 2019). However, psychological distress and applied coping strategies during the diagnostic phase of PCa are not well understood. Further studies are needed to explore these factors to establish more knowledge about the information and support needs of affected patients.

2.7 Aims

The overall aim of this thesis was to develop knowledge concerning patients' perceptions of information, psychological distress, and coping during the diagnostic phase of PCa.

Three studies with different objectives were conducted to address the overall aim. These objectives were as follows:

1. To explore men`s perception of information and their possible emotional strain in the diagnostic phase of prostate cancer (study I/paper I).
2. To explore and compare men's perception of information and possible experience of distress between a PSA group and

a Stockholm3 group during the diagnostic phase of prostate cancer (study II/paper II).

3. To investigate the associations between patient characteristics, psychological distress, and coping in the diagnostic phase of prostate cancer. (study III/paper III).

3 Theory

This section provides an introduction to the transactional model of stress and coping (TMSC) by Lazarus and Folkman (1984), which encompasses essential concepts in this thesis, including psychological distress, information needs, and coping. Coping is informed by cognitive appraisal and the emotional response to stress. In the context of the diagnostic phase of PCa, the TMSC provides insights into the relationship between the stressors, appraisal process, and psychological and social resources among patients.

3.1 Coping

In this thesis, coping is defined as ‘constantly changing cognitive and behavioural efforts to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of the person’(Lazarus & Folkman, 1984, p. 141). The rationale for studying coping is the presumption that certain ways of coping are more and less effective in promoting the emotional well-being of individuals in a given culture and/or situation. Further, the idea that it is possible to address issues that cause distress and affect the way people cope is an important motivation for exploring and developing the concept of coping (Folkman & Moskowitz, 2004). Based on the theoretical assumptions presented in this thesis, healthcare providers may constitute an important resource in supporting a favourable composition between coping strategies when patients are confronted with the uncertainty of the diagnostic phase of PCa.

3.1.1 The transactional model of stress and coping

The TMSC is an appraisal-based model that forms the foundation of the cognitive theory of stress applied in this thesis. The term ‘transaction’ implies that a new relational meaning emerges from the abstraction between individuals and environments. Coping presumes the existence of stress, and stress occurs when people are confronted with a situation that taxes or exceeds their ability to manage it (Lazarus & Folkman, 1984). Stress as a construct has been frequently used in psychological, psychosomatic, and nursing research and relates to emotional and physical discomfort (Lyon, 2012). It can be described as a psychological or behavioural response to an undesirable situation, which constitutes a real or interpreted threat (Fink, 2016). Stress is typically associated with different negative outcomes, such as depression, anxiety, and physical symptoms (Folkman & Moskowitz, 2004). Uncertainty in relation to illness has been identified as a significant stressor that can cause psychological distress, which largely applies to situations such as unknown illness or diagnostic evaluation of an illness such as cancer (Mishel, 1988). This further emphasises the utility of the TMSC to inform the interplay between patients' appraisal, coping strategies, and experiences of psychological distress during the diagnostic phase of PCa. Figure 2 illustrates the TMSC within the context of the diagnostic phase of PCa.

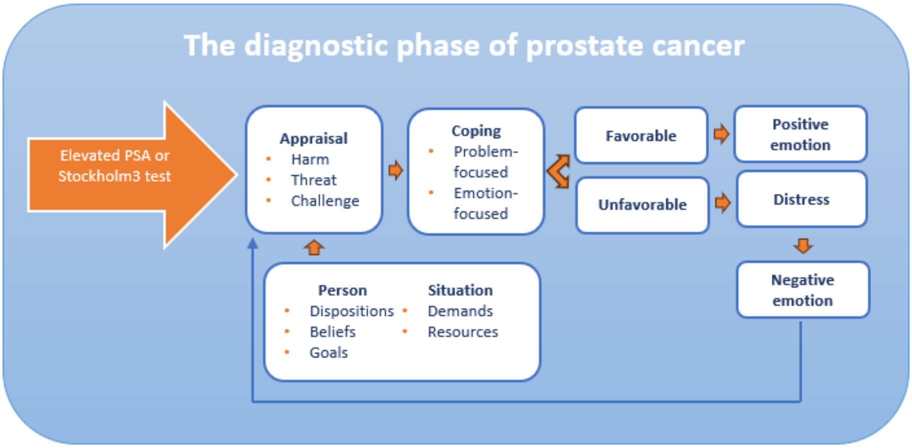

Figure 2 Illustration of the transactional model of stress and coping within the context of the diagnostic phase of prostate cancer (Folkman & Moskowitz, 2000; Lazarus & Folkman, 1984).

Appraisal is defined as a process that determines to what extent one or several transactions between individuals and environments are stressful (Lazarus & Folkman, 1984). This process involves an evaluation of certain stimuli within environments and a subsequent assessment of available resources. Appraisal is categorised as primary and secondary. A primary appraisal determined as a harm, threat, or challenge results in coping strategies being initiated to manage emotions or attempts to address the stressor. The coping process produces an outcome, which is then reappraised. Reappraisal includes a reassessment of the stressful situation based on further information from the environment and outcome of the coping process. This may result in a change to the initial appraisal (Biggs et al., 2017).

Lazarus and Folkman (1984) suggested two overall coping strategies: emotion- and problem-focused coping. Emotion-focused coping often occurs in situations where individuals appraise that nothing can be done to alter harmful, threatening, or challenging environmental conditions. This type of coping extends over a broad range of cognitive processes directed at minimising emotional distress. It includes strategies such as avoidance/distancing and positive comparison. A few emotion-focused coping strategies, such as blamed-self, may even enhance acute distress. Individuals may subsequently experience an improvement, reflecting a principle akin to feeling worse before feeling better. Emotion-focused coping may change the meaning of a stressful transaction but not objectively (Lazarus & Folkman, 1984). Traditionally, this type of coping has been associated with higher levels of psychological distress. However, this understanding has later been proposed as insufficient due to deficient measurements and analysis methods. Emotion-focused coping may prove to be beneficial in the short term but may transform into rumination in the long term, resulting in increased symptoms of anxiety and depression. It includes maintaining hope and optimism but also involves denying both facts and implications, leading to self-deception or reality distortion (Folkman & Moskowitz, 2000).

Avoidance, denial, and wishful thinking are disengagement coping efforts directed at escaping psychological distress. They may offer temporary relief but are generally ineffective over an extended period (Carver, 2019).

Problem-focused coping is more likely to occur when a situation is appraised as amenable to alteration and is often directed at defining problems and generating alternative solutions. This type of coping shares many similarities with problem-solving strategies. However, problem-solving strategies are primarily aimed at the environment, while problem-focused coping includes strategies that are directed inward. Problem-focused coping may involve information seeking and information evaluation. Emotion- and problem-focused coping can both facilitate and impede each other during the coping process (Lazarus & Folkman, 1984). Both of these strategies are used in stressful situations and are not separated. The composition between thoughts, wants, emotions, actions, and environments must be well balanced to determine whether coping efforts are successful (Lazarus, 2012).

Since the introduction of the TMSC, the model has evolved, and new perspectives have been added. Lazarus (2006a) elaborated on the definition of the coping process as applied in this thesis and argued that the TMSC should include personal meaning. Personal meaning is important because it incorporates personal goals, beliefs, and situational intentions. The TMSC is structured around transactions between environmental variables such as demands and resources and personal variables such as motives and beliefs about oneself, mediating processes and outcomes (Devonport, 2011). Unsuccessful coping and related psychological distress may trigger meaning-focused coping, which is often applied when stressors are uncontrollable (Biggs et al., 2017). Lazarus (2006b) argued that psychological stress appears in different subdivisions and is interdependent on different emotions. Certain emotions such as anger, jealousy, fright, shame, and anxiety are referred to as stress emotions because they are often associated with harmful, threatening, or challenging conditions. In addition, emotions that are more positively toned (e.g. relief and hope) can also be closely related to a harm or threat. Stress, emotion, and coping exist in a conceptual unit. Positive emotions appear to be of significant importance during the stress process and may facilitate adaptive coping and adjustment. Positive emotions appear to be of importance during stress and may facilitate adaptive coping and adjustment. These emotions have three main adaptive functions during stress: sustaining coping efforts, providing a pause, and restoring resources (Folkman & Moskowitz, 2000).

3.1.2 Psychological distress in relation to coping

In this thesis, psychological distress is used to explore the psychological impact of the diagnostic evaluation of PCa as well as its association with coping. According to the TMSC, psychological distress occurs when initiated coping strategies fail to manage a situation, thereby reducing emotional well-being (Lazarus & Folkman, 1984).

The National Comprehensive Cancer Network defines psychological distress in relation to cancer as '*a multifactorial, unpleasant experience of a psychologic (ie, cognitive, behavioural, emotional), social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment'* (Riba et al., 2019, p. 1230).

Psychological distress extends from common feelings of fear, sadness, and vulnerability to more disabling symptoms such as anxiety, depression, or existential crisis (Riba et al., 2019). It is a discomforting emotional state in response to a specific stressor or demand that results in harm to individuals (Ridner, 2004). According to Lazarus and Folkman (1984), psychological distress arises from negative individual and/or environmental transactions.

Miovic and Block (2007) suggested that psychological distress in an oncological setting can be perceived as an adjustment disorder, which is most frequently characterised by symptoms of anxiety or depression. Unresolved situations may trigger emotions such as anxiety. Anxiety often emerges when life is characterised by uncertainty and existential threats, and regulation of this emotion is vital in coping (Lazarus, 2006a). Anxiety is described as an emotion characterised by tension and worry. It may be accompanied by physical changes, such as increased blood pressure. Anxiety does not always originate from an identifiable source, and the cause may seem diffuse. It is often oriented towards the future as opposed to fear, which is directed towards the present (Kazdin, 2000). Anxiety and depression are closely related and frequently co-occur during stressful life events (Hammen, 2016). Depression is characterised by extreme sadness or despair that lasts more than days. It may affect the ability to concentrate and increase feelings of worthlessness and guilt. Physical symptoms such as pain, altered sleeping patterns, and weight loss are also common in patients experiencing depression (Kazdin, 2000).

Recent work emphasises that the relationship between anxiety, depression, and coping is multidirectional and changes over time. Individual differences in vulnerability factors, such as personality and childhood experiences, also affect this relationship. Quantitative measurements alone have been criticised for being too simple and one-sided in exploring such relationship. Interviews have been suggested as a way to illuminate aspects of acute stress within the broader context of life experiences with stress (Hammen, 2016). Lazarus (2006a) also addressed this issue, emphasising that his and Folkman's early work developing the Ways of Coping Questionnaire neglected important factors such as personal history, beliefs about oneself and the world, and emotional traits; this limited the understanding of coping and related emotions. Based on this presumption, this thesis also obtained qualitative data to grasp a deeper understanding of coping and psychological distress related to the diagnostic evaluation of PCa.

3.1.3 Perception of information needs

Information needs are defined as a recognition that personal knowledge is inadequate to satisfy a personal goal within a specific context/situation at a specific period (Ormandy, 2011). These needs are influenced by cognitive, physiological, and psychological factors such as existing knowledge, prejudices, emotions, and preferences. A lack of information on a potential illness may threaten the achievement of individual central life goals, thereby generating more stress and consequently influencing the ability to cope. In response to a potential cancer diagnosis, information needs and preferences inevitably change (Ormandy, 2011). Information needs are unique and subjective and may be expressed spontaneously in an event of a life change (Timmins, 2006).

The need for information exists primarily to assist coping with a certain stressor, and meeting such need reduces stress and aids coping. However, individual needs should not be based on normative presumptions for healthcare providers to support coping. Otherwise, information may be perceived as a burden or information overload, resulting in reduced coping (Timmins, 2006). Information seeking is motivated by multiple and individual factors, which also include the perception of the knowledge gap. The final goal of information seeking is to satisfy information needs. Information seeking in relation to a potential health threat is often characterised as a problem-focused coping strategy, with gaining information about the threat as a focal point to reducing stress (Lalazaryan & Zare-Farashbandi, 2014). In the context of the diagnostic phase of PCa, patients' perception of their information needs constitutes an important factor for their well-being, and the information provided by healthcare providers may support patients in adapting to their situation (Timmins, 2006). Therefore, the use of the concept of information needs in this thesis is based on the presumption that extended knowledge of patients' current information needs and information sources can assist in presenting information in a way that suites patients' actual information needs (Clarke et al., 2016).

4 Methodology

This chapter presents the methodology including the philosophical underpinnings and the research design of the three studies. The chapter also describes methodological reflections, research ethics, and trustworthiness.

4.1 Philosophical underpinnings of mixed methods research

This thesis is philosophically grounded in pragmatism, which provides a worldview of beliefs and assumptions about the knowledge that informs this thesis (Creswell & Clark, 2018). Pragmatism implies an intersubjective approach that enables a connection between subjective and objective approaches, capturing both individual interpretations of the world and a single real world (Morgan, 2007). It emphasises creating knowledge through actions by extracting knowledge from a certain context using a specific method and then applying this knowledge under other appropriate circumstances. This process is referred to as transferability and implies a recognition of the existing knowledge as a foundation for new knowledge (Morgan, 2007). Human actions cannot be separated from past experiences and beliefs emerging from these experiences (Kaushik & Walsh, 2019). Thus, pragmatism is concerned with purposeful human activity, and inquiry begins with a practical problem using a 'whatever works' strategy. The truth lies in the knowledge that serves personal purpose (Allmark & Machaczek, 2018).

Pragmatism has been applied by a large number of researchers as suitable for underpinning mixed methods research. This principle enables combining deductive and inductive thinking as both quantitative and qualitative methods are mixed (Creswell & Clark, 2018). Morgan (2007) described this use of deduction and induction as an abductive reasoning, moving back and forth between the two approaches. Thereby, the process evaluates prior inductions by their ability to predict the workability for future inquiries.

Although Creswell and Clark (2018) embraced the use of more than one worldview in different phases of a mixed methods study, this thesis uses the pragmatic approach as an all-encompassing worldview given the nature of a convergent mixed methods design. A mixed methods approach was assumed to be the best strategy to understand how patients perceive information and psychological distress during the diagnostic phase of PCa and their use of appraisal and coping strategies, ultimately achieving the overall aim of the thesis.

4.2 Study design

This thesis adopted a convergent mixed methods design, with an equal emphasis on qualitative and quantitative strands (Creswell & Clark, 2018). Methodological eclecticism in mixed methods research enables researchers to select and creatively integrate different techniques from a broad range of quantitative and qualitative methods (Teddlie & Tashakkori, 2012). In this thesis, the convergent mixed methods design was chosen based on the assumption that data from a single method are insufficient in achieving the overall aim of the thesis. Mixed methods research combines elements of qualitative and quantitative approaches for comparing or combining findings to obtain different but complementary data (Creswell & Clark, 2018). This type of research has gradually become more common in healthcare services owing to its potential to address health science topics and generate a richer and deeper understanding of complex issues. It seeks to combine the strengths of quantitative and qualitative methods (Zhang & Creswell, 2013).

In this thesis, two parallel strands of quantitative and qualitative data were collected and separately analysed using different analysis procedures. Study I involved qualitative data; study II, both qualitative and quantitative data; and study III, only quantitative data. The analysed data from the three studies constituted the strands of quantitative and qualitative data. Finally, the findings were merged: The quantitative and qualitative results were organised side-by-side in a section of text for comparison. Presenting the findings side-by-side allowed a direct comparison of the quantitative and qualitative results to determine to what extent they cohered. The interpretation included searching for confirmation, disconfirmation, and expanded understanding of the overall aim of this thesis (Creswell & Clark, 2018). Figure 3 illustrates the mixed methods design of this thesis.

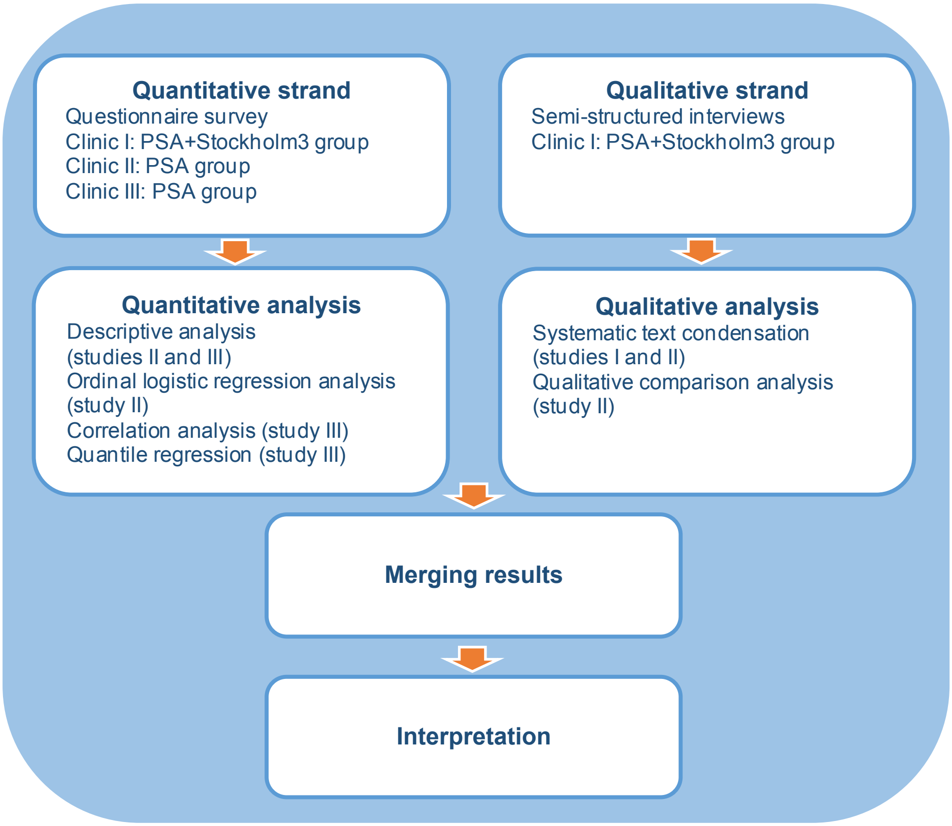

Figure 3 Overview of the thesis's convergent mixed methods design based on a figure by Creswell and Clark (2018, p. 70).

An interview guide was developed based on questions as suggested by Fetters et al. (2013) and used in studies I and II to facilitate merging of the quantitative and qualitative results.

4.2.1 Design of the three studies

Table 1 presents an overview of the three studies. This section provides a description of the study design applied in each study.

Table 1 Overview of studies I, II and III

Study	Participants (n)*	Design	Data collection	Analysis
I	10 patients from clinic I who underwent the PSA test	Qualitative explorative design	Semi-structured interview	Systematic text condensation
II	130 patients who underwent the PSA test from clinics I, II, and III 120 patients who underwent the Stockholm3 test from clinic I	Convergent mixed methods design	Questionnaire survey	Descriptive statistics Ordinal logistic regression Binary logistic regression
	10 patients who underwent the PSA test and 10 patients who underwent the Stockholm3 test from clinic I		Semi-structured interview	Systematic text condensation Qualitative comparison
III	250 patients from clinics I, II, and III	Cross-sectional design	Questionnaire Survey	Descriptive statistics Correlation analysis Quantile regression analysis

* All with an elevated test finding and/or a suspicious palpation finding.

Study I

A qualitative, explorative descriptive design was adopted in study I because of its usefulness in uncovering little-understood phenomena (Polit & Beck, 2021). Explorative research possesses the ability to develop descriptions and understandings of an area of social or psychological life (Hunter et al., 2019). This design is suitable when researchers seek to understand who is involved, what is involved and where events take place in relation to the phenomena of interest (Caelli et al., 2003). In study I, the focus was to explore patients' perception of information and possible emotional strain during the diagnostic phase of PCa. Through interviews, patients' experience was elucidated, with special attention to the received information and the psychological impact during the diagnostic phase of PCa.

Study II

A convergent mixed methods design was adopted in study II because of the need for a more complete understanding of the research problem and the limited time for data collection (Creswell & Clark, 2018). The PSA test was replaced with the Stockholm3 test at clinic I before data collection was completed, without the research team being able to influence this aspect. A component of a trailing research approach was added to the design to accommodate this challenge. The objective was to obtain insights into the change initiated by the implementation of the Stockholm3 test by following the process in real time, without the research team influencing such change (Stensaker, 2013). A trailing research approach is distinct from an action research approach in that research teams avoid being involved in the implementation of an intervention. In the trailing research approach, knowledge generated through both dialogue and methods of measurement is acknowledged for exploring and evaluating a phenomenon (Olsen & Lindøe, 2004). Therefore, a component of the trailing research approach was considered to cohere well with the convergent mixed methods design in this study.

Study III

A cross-sectional design was found to be appropriate for study III to investigate the associations between patient characteristics, psychological distress, and coping during the diagnostic phase of PCa. In this study, participants were selected according to the inclusion and exclusion criteria and variables; patient characteristics, symptoms of anxiety and depression, primary appraisal, and coping strategies were measured at a single period (Setia, 2016).

4.3 Study settings and sample

Data were collected within a single phase, and data from all three studies with different objectives were obtained. Data were collected from three urological outpatient clinics at three hospitals organised under the same health trust in Norway. The hospitals differed in size and organisation. Clinics I and II were located at university hospitals with a catchment area of approximately 350,000 and 450,000 inhabitants, respectively, while clinic III was located at a local hospital with a catchment area of approximately 150,000 inhabitants (Norwegian Statistics, 2023). All three clinics adhered to the national cancer care pathway for PCa and were obliged to follow the same regional and national policies, which made them comparable. The data collection was initiated at clinic I, collecting questionnaire data from the PSA group. Simultaneously, patients from the PSA group were recruited for semi-structured interviews, which were all completed at clinic I (study I). Given that this thesis is a substudy to the “From PSA to Stockholm3” project, data were collected during the transition from the PSA test to the Stockholm3 test among GPs. The PSA test was replaced with the Stockholm3 test before the PSA data collection was completed. Therefore, two more urological outpatient clinics (clinics II and III) had to be included to complete the data collection for the PSA group (studies II and III). Both the questionnaire survey and semi-structured interviews for the Stockholm3 group were conducted at clinic I, which was the only clinic where the

Stockholm3 test was implemented. Questionnaire data for the PSA group at clinics II and III were collected simultaneously with the Stockholm3 data at clinic I. At the time of data collection, all three clinics performed transrectal ultrasound-guided prostate biopsies, which implied approximately 1-hour waiting time between antibiotic treatment and the procedure.

Settings and sample for study I

The semi-structured interviews were conducted at clinic I before the PSA test was replaced with the Stockholm3 test. The interviews took place in suitable private rooms at the outpatient clinic, at an affiliated satellite clinic, or in a conference room at the hospital.

Purposive sampling was used to ensure a variation in age and PSA level at the time of referral (Polit & Beck, 2021). The selected patients were invited to participate in an interview immediately after they had agreed to participate in the questionnaire survey used in study II and III. Patients were considered eligible if they did not have a previous PCa diagnosis, could read, understand, and speak Norwegian and did not have cognitive impairment. Patients who participated in the semi-structured interviews were recruited by the author of this thesis after they had received oral information and antibiotics from a nurse. Patients who considered participating received further information about the interview in a consultation room. After patients were informed about their biopsy findings, they were re-contacted via phone, and an interview was scheduled. The interviews took place within the same day patients received their test findings and up to approximately 2 weeks later. The time and place of the interviews were scheduled in accordance with patients' wishes.

Settings and sample for study II

For study II, quantitative data were collected at clinic I (PSA level and Stockholm3 score), clinic II (PSA level), and clinic III (PSA level). Participants were provided with a click board and a pen. Some participants completed the questionnaire in the waiting zone at the clinic, while others chose a private room at the clinic or the cafeteria at the hospital. About 6% received a stamped envelope and completed the questionnaire at home. The semi-structured interviews with the PSA group were conducted at clinic I only to facilitate comparison between the two groups and owing to the geographical proximity of the research team. The individual semi-structured interviews with the Stockholm3 group were conducted at clinic I. The settings for the semi-structured interviews were identical with those described in study I. Patients referred for diagnostic evaluation of PCa were recruited via consecutive sampling, which intended to include all available and eligible patients (Thewes et al., 2018). Patients were approached at the clinics after they had received antibiotics and oral information about the biopsy from a nurse. Selected nurses at the three urological outpatient clinics recruited patients after they had received a brief introduction and training from the research team. The author of this thesis assisted in the recruitment and data collection at clinic I. The criteria for participation in study II were similar to those in study I, and participants for the Stockholm3 group were recruited as described for the PSA group in study I.

Settings and sample for study III

Study III was conducted at clinic I (PSA level and Stockholm3 score), clinic II (PSA level), and clinic III (PSA level). In study III, the PSA group and the Stockholm3 group from study II were combined into a single group to perform a secondary data analysis. Therefore, the settings and sample for study III were identical with those for study II relative to the quantitative data.

4.4 Data collection

4.4.1 Qualitative data collection

Data were collected from September 2017 to February 2019. Ten patients from the PSA group and 10 patients from the Stockholm3 group participated in semi-structured interviews. An interview guide was used to direct the conversations according to the objectives of studies I and II (Appendix 1). The interview guide used in studies I and II was designed to elaborate on the questions in the questionnaire (Appendix 2), with three topics as the focal point (Creswell & Clark, 2018). These topics were consultations with GPs, consultations and communication with healthcare providers at the urological outpatient clinic, and possible psychological distress. At the beginning of each interview, participants were invited to speak freely about their experience during the diagnostic evaluation, starting with the reason why they contacted their GP. The interviews lasted 25–52 minutes and were audiotaped and subsequently transcribed verbatim. The characteristics of patients who participated in the interviews (studies I and II) were collected via the questionnaire survey (Appendix 2), which they had to complete before their biopsy. Participants disclosed their biopsy findings during the interviews.

For the interviews, a continuous visual analogue scale (VAS) was developed as described by Glegg (2019) (Figure 4). The continuous VAS was used as a visual tool for participants to elaborate on, but which was not included as data. Visual tools or rating scales have been used in qualitative research to enable discussions of feelings and facilitate in-depth descriptions (Glegg, 2019). Among the 10 participants from the PSA group and the Stockholm3 group, a pre-filled coherent curve was employed in relation to worries (Y axis) during the diagnostic phase of PCa from when the PSA test/Stockholm3 test was conducted to when the biopsy findings were received (X axis). The united VAS diagram for the 10 participants in the PSA group illustrated how patients perceived the emotional impact of the diagnostic phase at different time points and facilitated conversations about emotions. In addition, the continuous VAS diagram was linked to questions included in the interview guide directed at the specific time points.

The qualitative data from the 10 participants in the PSA group were included in studies I and II, while those from the 10 participants in the Stockholm3 group were included in study II.

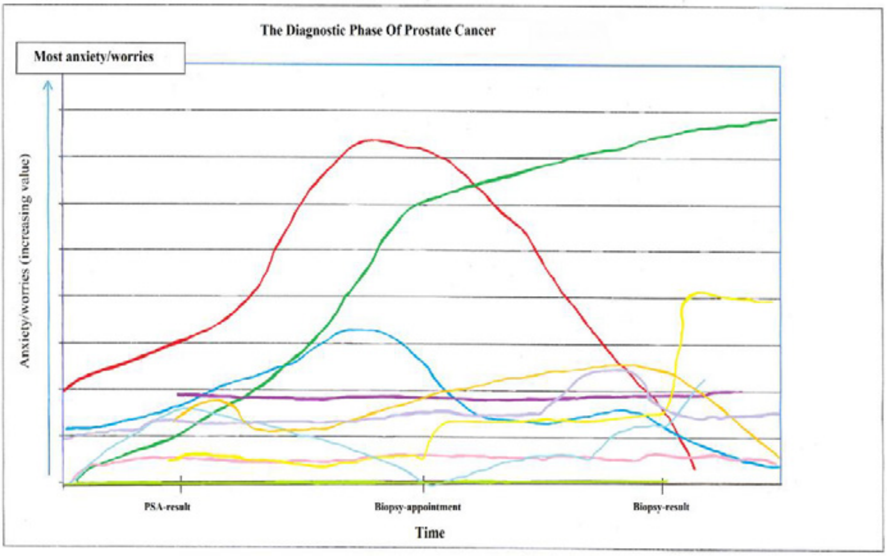

Figure 4 Completed VAS curve used as a visual tool for 10 participants in the PSA group to elaborate on during semi-structured interviews.

4.4.2 Quantitative data collection

For studies II and III, data were collected via the questionnaire survey (Appendix 2) from September 2017 to November 2019.

Patient characteristics

The patient characteristics collected in studies I, II, and III at the beginning of the questionnaire survey included age, self-reported health, civil status, educational level, and occupation (Appendix 2). Self-reported health reflects an overall subjective assessment of individuals' general health. It is typically measured as a single item. In this thesis, patients rated their current status on a 5-point scale ranging from excellent to poor (Organisation for Economic Co-operation and Development, 2019).

4.4.3 Measurements

Items from a survey conducted on the general population and patients with cancer in Norway

Four items from a national survey previously conducted on the general population and patients with cancer in Norway were selected (Iversen & Bjertnæs, 2016) (Appendix 2). These items addressed patient experiences with the diagnostic evaluation of cancer and aimed to explore different conditions and challenges in healthcare services for patients with cancer. The four items were as follows: 1) "Did you find that your GP gave you satisfactory information about what was going to happen related to the diagnostic evaluation of possible prostate cancer?", 2) "Did you find the waiting time from hospital referral to the first attendance acceptable?", 3) "Did you find that the referring doctor/GP and the hospital worked well together?", and 4) "Were you told what you thought was necessary regarding how examinations would be conducted?". The items were scored on a Likert scale ranging from 1 (not at all) to 5 (to a very large extent), with an additional option of "not relevant". A higher score indicated a more satisfactory experience for each variable (Iversen & Bjertnæs, 2016). The four items were used in study II.

Hospital Anxiety and Depression Scale (HADS)

The HADS is a self-assessment scale developed by Snaith and Zigmond (1986) (Appendix 2). It evaluated the likelihood of anxiety disorders and depression among patients in non-psychiatric hospital clinics. Symptoms of anxiety and depression are frequently used to assess psychological distress in oncological settings (Miovic & Block, 2007). The HADS consists of two subscales, with a score ranging from 0 to 21: one assessing symptoms of anxiety (HADS-A) and another assessing symptoms of depression (HADS-D). Together, the two subscales constitute the HADS-T, with a score ranging from 0 to 42 (Snaith & Zigmond, 1986). According to the literature, the HADS can identify possible psychological distress. However, the most optimal cut-off score for a case of possible anxiety or depression remains unclear. A previous review found that the most optimal balance between sensitivity and specificity as screening parameters for the two subscales was achieved at a cut-off score of ≥8 (Bjelland et al., 2002). Data from the HADS were included in studies II and III, and a cut-off score of ≥8 was applied. The Norwegian Knowledge Centre for Health Services conducted a psychometric assessment of the Norwegian version of the HADS in 2016 and concluded that the HADS is a relatively well-validated Norwegian screening tool for psychological distress. Cronbach's alpha values of ≤0.70 were reported for both HADS-A and HADS-D (Leiknes et al., 2016). In the current dataset, the Cronbach's alpha value reflecting internal consistency was 0.88 and 0.82 for the HADS-A and HADS-D, respectively.

<u>Revised Ways of Coping Checklist (RWCCL)</u>

Coping styles were assessed using Vitaliano and colleagues (1985) RWCCL (Appendix 2) in study III. Participants were initially asked how they perceived their situation with respect to the diagnostic evaluation of PCa to assess their primary appraisal. The response options were benign, challenge, or threat/loss/harm. The original Ways of Coping Checklist was derived from Lazarus and Folkman's TMSC. The checklist measures behavioural and cognitive modes and strategies that can be used within the context of a stressful situation (Lazarus & Folkman, 1984). The scale consists of 42 items with five sub-scales measuring problem-focused coping, social support, wishful thinking, blamed-self and avoidance. Problem-focused coping and social support are both characterised as problem-focused coping strategies, while wishful thinking, blamed-self and avoidance are characterised as emotion-focused coping strategies. Participants respond to these coping items on a 4-point Likert response scale (0 = does not apply /not used, 1 = used somewhat, 2 = used quite a bit, and 3 = used a great deal), with respect to the diagnostic evaluation of PCa as the potential stressor. Higher scores indicate that the related coping strategy is used more frequently. The RWCCL showed Cronbach's alpha values ranging from 0.73 to 0.88 (Vitaliano et al., 1985). The Norwegian version of the RWCCL was translated into Norwegian and back translated to minimise distortions of item contents (Falkum et al., 1997). The RWCCL has previously been used to study coping strategies in patients affected by cancer (Chen et al., 2022; Elani & Allison, 2011). In the current dataset, the Cronbach's alpha values were 0.87 for problem-focused coping, 0.80 for social support, 0.59 for blamed-self, 0.85 for wishful thinking, and 0.67 for avoidance. The Cronbach's alpha values for blamed-self and avoidance were both below 0.7.

4.5 Data analysis

4.5.1 Study I

Data were analysed thematically using systematic text condensation (STC) (Malterud, 2017). Systematic text condensation was developed by Malterud (2012) to offer novice researchers a process that makes analysis visible and transparent. It is a descriptive approach, which implies analytic reduction with specified shifts between decontextualisation and recontextualisation, and includes four steps of analysis: 1) collection of the total impression, from chaos to themes; 2) identification and sorting of meaning units, from themes to codes; 3) condensation, from codes to meaning; and 4) synthesis, from condensation to descriptions and concepts (Malterud, 2012; Malterud, 2017).

The 10 interviews were transcribed by the author of this thesis. The full transcripts were distributed within the research team for reading to obtain an overall impression of the data. Preliminary analysis, consisting of the first two steps of STC, was then performed. Six preliminary themes were identified. In the second step, meaning units were sorted and classified into code groups related to the preliminary themes. The preliminary data were entered into a matrix for comprehensibility and then presented at an analysis seminar within the research team. The identified preliminary themes, code labels, and codes were discussed and adjusted to ensure that they reflected the narratives. According to Malterud (2012), analysis benefits from being conducted by more than one researcher to create a wider analytic space. The third step was performed by the author of this thesis and involved abstraction of meaning. The content of each theme was reduced into a condensate reflecting the meaning of the text. The research team then reduced and renamed the preliminary themes into three final themes. The fourth step was initially performed by the author and required the condensates to be synthesised into generalised descriptions. The descriptions were then evaluated by the research team, ensuring that they reflected the original context.

4.5.2 Study II

Study II applied a convergent mixed methods design (Creswell & Clark, 2018). All quantitative data were analysed using IBM SPSS version 26 and Stata version 16.1, while all qualitative data were analysed using STC and qualitative comparison analysis. The quantitative data from the PSA group and the Stockholm3 group were statistically compared. The qualitative results for each group were subsequently compared before the results from both quantitative and qualitative analyses were merged.

Quantitative analysis

Initially, power calculation was performed using an independent samples t-test, and the required sample size was estimated to be 100 participants in each group to reach a power of 80% and detect a standardised difference of 0.4 at a two-sided significance level of 5%. The target sample size was increased to 120 participants in each group to accommodate the ordinal nature of the outcomes and non-parametric testing (Neuhäuser, 2011).

Descriptive statistics, including frequencies and percentages, were used to present the data. Pearson's chi-squared test was used to assess any significant difference in the categorical variables between the PSA group and the Stockholm3 group (McHugh, 2013). Ordinal logistic regression was employed to compare the PSA group and the Stockholm3 group for each of the four dependent variables concerning patient experience, while adjusting for age, living alone (yes/no), and educational level. In ordinal logistic regression, outcome variables are typically ranked and have more than two levels (Liu, 2009). The resulting odds ratios represent the relative odds of answering in a higher rather than a lower category on the scales – the Stockholm3 group versus the PSA group in this thesis. The 95% confidence interval was presented for each odds ratio to reflect the uncertainty in the estimate (Szumilas, 2010). Test of effects was performed using Wald tests, and p-values of ≤0.05 were considered statistically significant. The proportional odds assumption was checked for all ordinal regression analyses using likelihood ratio tests, and all p-values were >0.05 (Liu, 2009). Binary logistic regression was conducted to compare the proportions of potential anxiety and/or depression between the two groups. P-values of ≤0.05 were considered statistically significant.

Qualitative analysis

Similar to study I, STC was used to analyse the 10 interviews with the PSA group and 10 interviews with the Stockholm3 group in study II. A secondary analysis of the interviews from study I was conducted based on the objective of study II. The interview data from the two groups were analysed separately. The entire research team participated in the analysis in the same manner as described in study I.

Comparison

The final step of the qualitative analysis entailed that the STC analysis data of the two groups were combined for comparison. The qualitative analysis involved comparing themes and identifying key similarities and differences between the two groups. The findings were based on relevance, prevalence, and perceived importance with respect to the study objective (Rawlings et al., 2018). The themes and descriptions from both groups were compared systematically and balanced against the objective and context. Matrices were used to organise the descriptions of the themes to establish an overview and identify similarities and differences (Lindsay, 2019). After the themes were compared, the similarities and differences were discussed. The descriptions were adjusted according to the objective of the study until consensus was reached within the research team.

Side-by-side mixed methods analysis

The final step of the mixed methods analysis in study II was to merge the strands from the quantitative and qualitative analyses. This was achieved via a side-by side comparison, which represented the integration of the convergent design. This step included identifying common concepts across the findings to determine whether the findings from the two sets of analyses confirmed, disconfirmed, or expanded on each other (Creswell & Clark, 2018). The author of this thesis conducted the preliminary merging of the findings by making a direct comparison, placing the quantitative and qualitative results within a section of the text. After several rounds of analysis, an editing agreement was reached within the research team.

4.5.3 Study III

In study III, the data were analysed using IBM SPSS version 26, except for the partial Spearman's rank correlation coefficients, which were estimated using R version 4.2.3 with the PResiduals package. The patient characteristics were analysed and presented as frequencies and percentages. Because of the skewness of the data, the clinical outcomes were presented as medians and interquartile ranges, with the ranges defined by the first and third quartiles of the observed data (Mishra et al., 2019). The non-parametric Mann–Whitney U test and Kruskal–Wallis test were used to examine differences in the HADS and RWCCL scores between the groups according to the patient characteristics. In particular, the Mann–Whitney U test was applied to examine differences between two independent groups and the Kruskal–Wallis test between more than two independent groups of ranked data (Polit & Beck, 2021). Spearman's rank correlation coefficients (rho: ρ) were used to assess the strength and direction of the relationship between the HADS and RWCCL scores and age and self-reported health (Schober et al., 2018). Unadjusted associations between the HADS and RWCCL scores were assessed using Spearman's correlation coefficients and adjusted associations using partial Spearman's correlation coefficients. Differences in the HADS and RWCCL subscores according to the primary appraisals with respect to the diagnostic evaluation of PCa were evaluated using the Kruskal–Wallis test, Mann–Whitney U test, and quantile (median) regression with adjustment for patient characteristics (for adjusted comparisons). Two-sided tests were applied, and p-values of <0.05 were considered statistically significant for all analyses.

4.6 Research ethics

The project was approved by the Regional Committee for Medicine and Health Research Ethics in Norway (REK) under reference number 2017/71 (Appendix 3). The Stockholm3 test was implemented before the data collection for studies II and III in the PSA group was completed, resulting in the need to add two more clinics. Consequently, two additional approval applications to the REK were submitted with two change notifications.

01.12.17: Approval for adding clinic II [Appendix 3]

11.06.19: Approval for adding clinic III [Appendix 3].

The leaders at all three clinics were contacted, and an information meeting was scheduled. After a positive response to the request was received, approval was sought from the hospital administrations at the hospitals, and a signed agreement was obtained.

The thesis was conducted in accordance with the Declaration of Helsinki (World Medical Association, 2013). Potential participants received both oral and written information about the study and were guaranteed confidentiality (Appendices 4 and 5). Participation was voluntary, and participants were informed that they had the right to withdraw from the project at any time. All participants signed an informed consent form before the questionnaire survey and individual interviews.

Researchers' role

When conducting qualitative research, researchers are an integral part of the process and the findings. Transparency and reflexivity are essential for ensuring reliability and validity (Galdas, 2017). According to Polit and Beck (2021), establishing confidence in qualitative data relies on the qualifications, experiences, and reflexivity of researchers. In this thesis, strategies to promote reflexivity were applied to uncover the researchers' effect on the data collection, analysis, and interpretation. Recognising the relationship between the researchers and any interpretations was highly prioritised, with special emphasis on the close relation of the author of this thesis to the research field. The research team consisted of a medical doctor, two researchers in nursing science, and one specialist nurse (author of this thesis), all of whom had previous experience in managing patients affected by cancer and conducting qualitative and quantitative research. The author of this thesis is a former cancer coordinator at the urological department at clinic I. Thereby, the author could be described as an embedded researcher because of the employment within the organisation while maintaining an affiliation with an academic institution (Cecilia et al., 2017). As a cancer coordinator for bladder and kidney cancer, the author had no direct contact to patients with suspected PCa. However, some knowledge and experience related to the diagnostic phase of PCa at clinic I emerged during the study period. After the data collection and analysis, the author has been employed at clinic I in a position that was not related to patients attending the prostate centre at the clinic. Nevertheless, knowledge about the context and procedures was obtained, which was relevant for conducting this thesis and understanding the standpoint from which interpretations were made (Creswell & Miller, 2000).

The multidisciplinary composition of the research team strengthened the process of reflexivity during the analysis. Different professional perspectives and experiences with the affected patient group helped visualise and reveal personal prejudices and perspectives. Despite efforts to reduce researcher bias and assumptions by performing reflexive auditing in the research team, preconceptions may have affected the inquiry (Stahl & King, 2020). In addition, the author of this thesis may have affected the participants during the interviews, thereby influencing the data.

4.7 Methodological considerations

This section includes considerations about the quality of this thesis relative to its mixed methods design. Validation inspects the quality and interpretation of data. It addresses potential threats to achieving correct interferences and assessments from merged data in mixed methods research. There is an ongoing discussion about strategies for evaluating the validity and quality of mixed methods research, which extends from detailed quality criteria for both qualitative and quantitative methods to more passive approaches (Creswell & Clark, 2018). According to Creswell and Clark (2018), the validity of specific quantitative and qualitative methods used as well as applied mixed methods must be evaluated. McCrudden and Marchand (2020) argued that each strand must maintain high standards of rigour, which implies that the quantitative strand reports sufficient validity and reliability, while the qualitative strand reports sufficient trustworthiness, but with clear expectations related to the mixing of the two. Hirose and Creswell (2023) reported six core quality criteria essential to evaluate mixed methods research. These criteria were applied in this thesis after a review of the quality of the quantitative and qualitative strands.

4.7.1 Reliability and validity of the measures

The scales used for measuring the data were chosen because of their applicability to assess the constructs of focus in this thesis. Good reliability and validity have been reported for both the HADS (Leiknes et al., 2016) and RWCCL (Vitaliano et al., 1985). Reliability and validity refer to the accuracy and ability of tools to measure what they intend to measure, respectively (Tang et al., 2014).

Reliability is concerned with instruments' stability and ability to produce scores that are stable over time (Bannigan & Watson, 2009). Strong reliability of instruments improves statistical power by providing more precise measurements of constructs (Mellinger & Hanson, 2017). *Internal consistency* assesses whether items designed to measure the same general construct yield similar scores. The most frequently used measure of internal consistency is the Cronbach's alpha value (α), which estimates the mean of the correlations between items (Tang et al., 2014). In general, Cronbach's alpha values of ≥0.7 are considered acceptable (Nunnally & Bernstein, 1994). The internal consistency in study III was acceptable for both the HADS and RWCCL, with Cronbach's alpha values above 0.7 except for the blamed-self and avoidance subscales.

Validity refers to how trustful instruments are in measuring what they intend to measure (Sürücü & Maslakci, 2020). *Internal validity* is defined as the degree to which observed data represent the truth in the chosen population (Patino & Ferreira, 2018). A duplicated study under similar conditions is expected to observe similar effects. Potential confounding variables were controlled to minimise the risk of alternative effects to strengthen the internal validity in studies II and III (Slack & Draugalis, 2001).

Given that the current thesis is a substudy to the “From PSA to Stockholm3” project, the data collection was conducted during the transition to the implementation of the Stockholm3 test. The rapid introduction of the Stockholm3 test implied that the data collection for the PSA group could not be completed at clinic I. Therefore, one more clinic was added, but the data collection did not progress as planned due to local challenges, such as busyness and staff shortages. A third clinic was then added to complete the data collection for the PSA group. Differences in the patient characteristics between the three clinics were tested using Pearson’s chi-squared test, and no significant differences were found. Although the three clinics had similar procedures according to the standardised cancer care pathway and adhered to the same health trust, local differences were expected. This may represent a threat to the internal validity of studies II and III due to inequality with respect to the non-measured variables between the groups (Slack & Draugalis, 2001). Consecutive sampling was used for studies II and III, which may have enhanced the risk of selection bias/threat since the sample was not randomly selected.

The sample size was calculated before data collection was initiated for an independent samples t-test to establish the minimum number of participants required to reach a power of 80% and detect a standardised difference of 0.4 at a two-sided significance level of 5%. Subsequent discussions with the statistician indicated that a new sample size needed to be calculated since the assumption of normality was not satisfied and to accommodate the ordinal nature of the outcomes. Increasing the number of participants to a minimum of 120 in each group ensured that the criteria were met (Neuhäuser, 2011). Power is the ability to correctly reject a null hypothesis that is false (type II error).

External validity refers to the extent to which the findings of a study can be generalised into other situations or settings (Patino & Ferreira, 2018). The use of a non-probability sampling method may have reduced the generalisability of the findings of studies II and III. Thus, the inclusion and exclusion criteria were discussed within the research team and set to reflect the population for which the study was intended to enhance external validity (Patino & Ferreira, 2018).

4.7.2 Trustworthiness of the qualitative data

This section describes the strategies used to enhance the trustworthiness of the qualitative strand. Lincoln and Guba (1985) first introduced trustworthiness in their framework for evaluating qualitative research, which concerns the research process being reported as accurate as possible. Evaluating trustworthiness has since been discussed and further developed by several researchers. Trustworthiness involves establishing credibility, transferability, dependability, and confirmability in a qualitative study.

Credibility concerns the extent to which findings and conclusions can be trusted and to what extent they reflect the reality of the phenomenon explored. To promote credibility of the qualitative analysis, the research team participated in several analysis sessions, where the different steps of the analysis were discussed until consensus was reached. In a retro perspective, the study would have benefitted from involving participants in verifying the findings, which would have enhanced the credibility. Prolonged engagement is another way of enhancing credibility; for example, researchers may engage in a research cycle following the sites and participants closely to collect richer descriptions (Stahl & King, 2020). Owing to personal situations that the diagnostic evaluation of PCa entailed, this approach was omitted to preserve the integrity of the participants in this thesis. With previous experience as a coordinator and as a nurse in the clinical field both before and after data collection, the author of this thesis has gained knowledge of the context and culture in the urological department. During this experience, a certain prolonged engagement has been created. Qualitative inquiry attempts to expand understanding by transferring findings to other contexts or groups.

Transferability depends on thick descriptions of the context, ensuring that the factors that might influence the findings are uncovered. This includes sufficient descriptions of methods and data collection (Stahl & King, 2020). Transferability requires descriptions of participant characteristics and context to enable considerations about how it may influence and shape the findings (Stenfors et al., 2020). An interview guide was used to ensure a systematic data collection in studies I and II. Patients who participated in the interviews had completed the questionnaire survey at clinic I before their biopsy. The patient characteristics were obtained from the completed questionnaire survey, except for the biopsy findings, which were disclosed during the interviews.

Dependability refers to the reliability of data over time and to what extent findings can be repeated if a study is performed again under similar conditions (Polit & Beck, 2021). The author of this thesis was present throughout the research process to ensure consistency. Providing detailed and accurate descriptions of the research process and analysis was prioritised (Malterud, 2012). However, some information may have been lost during multiple steps of the analysis. According to Malterud (2012), standardised text condensation incorporates reflections regarding how the process affects the findings and conclusions as well as feasibility, while maintaining a responsible level of methodological rigour. Conducting analysis within the research team also served as peer scrutiny to illuminate embedded interpretations by the author of this thesis (Stahl & King, 2020). In addition, the analyses and findings were presented in research seminars at the hospital and at the university to enhance dependability. The sample size was determined in accordance with the guidelines by Malterud et al. (2016): It was estimated based on the concept of information power, which implies considerations of aim, specificity, theory, dialogue, and analysis. There is a dynamic interaction between these items, which makes it possible to adjust the balance between different items. For example, the objective of study I was relatively broad; therefore, a denser specificity and strong dialogue were prioritised. The greater the information power a sample holds, the smaller sample is needed (Malterud et al., 2016). Purposive sampling was used in study I and the qualitative strand in study II. The sample varied in age and PSA level or Stockholm3 score at the time of referral. The balance between maintaining dense specificity and exhibiting variation in the patient experiences was discussed continuously during data collection and analysis. Study I was not guided by a specific theory, which reduced the information power; nevertheless, in conjunction with the other items, the information power was considered sufficient.

The final aspect related to trustworthiness is *confirmability*, which is demonstrated when findings arise directly from participants and when efforts are made to keep interpretations as neutral as possible (Polit & Beck, 2021). Reflexivity is important to strengthen confirmability. This aspect is described above (c.f. 4.6) and was incorporated into the STC analysis. The research team prioritised uncovering preconceptions.

4.7.3 Mixed methods

In this thesis, six core quality criteria essential for evaluating mixed methods research were applied to explain the rationale behind selecting the design (Hirose & Creswell, 2023). This evaluation was published after the three studies were conducted. The criteria were developed by Hirose and Creswell (2023) based on the perspectives of international researchers, best practice guidelines from the National Institute of Health and Office of Behavioural and Social Science in the US, and standards developed by the APA and the Communications Task Force Report on Journal Article Reporting Standards for Qualitative Research. The six criteria are described below.

1. Advance a rationale for the use and appropriateness of mixed methods methodology

The use of mixed methods in this thesis was based on the literature presented in the introduction and background, which revealed a knowledge gap in the present topic. The aim was developed by the research team, which possessed both quantitative and qualitative research experience. It was assumed that a single method would be inadequate for investigating the overall aim and objectives of the thesis. Accordingly, a mixed methods approach was chosen to achieve a deeper and more comprehensive understanding of the topic (Creswell & Clark, 2018). As an advantage, this design enabled the exploration of the similarities and discrepancies between the quantitative and qualitative findings (Harrison et al., 2020). From the qualitative data, important themes were identified, which illuminated patients' perception of information and ambiguous and fluctuating feelings towards psychological distress. The qualitative and quantitative data complemented each other, resulting in a deeper and more comprehensive understanding of the topic under investigation.

2. Write quantitative, qualitative, and mixed methods questions or aims

The objective of the qualitative method in study I focused on understanding the details of central phenomenon in this thesis. The objective of the mixed methods in study II generated results based on the integration of the quantitative and qualitative data, while that in study III addressed the relationship among the variables (Hirose & Creswell, 2023). The constructs of the overall aim and the specific objectives were guided by Creswell and Clark (2018) to ensure that the overall aim of this thesis was built upon the objectives of the quantitative, qualitative, and mixed methods. This approach enhanced the transparency of the research process.

3. Report quantitative and qualitative data separately

The quantitative and qualitative data collection and analysis were specified (Hirose & Creswell, 2023). In all three papers, both data collection and analysis were thoroughly described. Separate tables with numbers were presented the quantitative results. Examples of the analysis method for STC were presented in tables with sections of texts, and the findings were presented as texts and direct citations. Each analysis was identified as either quantitative or qualitative analysis in the headings and was presented in separate sections. In study II, the findings were combined after the separate analysis.

4. Name and identify the type of mixed methods design and present a diagram of it

The convergent mixed methods design applied is illustrated in Figure 3. Parts of the research involved a direct comparison of the PSA group and the Stockholm3 group. In study II, the convergent design was also applied and presented in a figure.

5. State the use of integration in a joint display

In Paper II (study II), the quantitative and qualitative results were presented in a side-by-side discussion as recommended by Creswell and Clark (2018). The results from studies I, II, and III are jointly displayed in Table 2.

6. Discuss how meta-inferences and value resulted from the integration analysis.

Meta-inferences were drawn from the integration of the quantitative and qualitative findings in the joint display. Table 2 presents the data for each key topic from top to bottom for the quantitative findings, followed by the qualitative findings and the mixed methods synthesis (Hirose & Creswell, 2023). After the quantitative and qualitative findings were integrated, new insights were gained beyond what was found by using a single method. For example, the meta-inferences contributed deeper insights into patients' perception of the provided information regarding the PSA test. The meta-inferences also revealed complex contexts and relationships, which may provide a basis for further research.

5 Results

This chapter presents an overview of the findings of each study in this thesis. It concludes with a synthesis presenting the meta-inferences drawn from the findings of the three studies relative to the overall aim and specific objectives of this thesis.

5.1 Paper I

Men's perception of information and descriptions of emotional strain in the diagnostic phase of prostate cancer—a qualitative individual interview study

Paper I, reports findings from a qualitative individual interview study (Study I), including 10 semi-structured interviews about patient experiences during the diagnostic phase of PCa. The ten participants were aged 50–80 years. Six of them were diagnosed with PCa, while the remaining four had benign biopsy findings. The results revealed three themes with related subthemes.

The first theme addressed the participants' perception of the information that they received from healthcare providers from when their PSA level was assessed to when they received their biopsy finding. The findings indicated that the participants had insufficient knowledge and information about the PSA test, prostate biopsy, and PCa, generating uncertainty and reducing predictability. Consequently, the participants' will and opportunity to be involved in making decisions about their own health seemed to be affected. Some patients preferred short and precise information and trusted that healthcare providers possessed the necessary competence to take care of them. The second theme highlighted how relationships could constitute an important source of support and information. Even though some participants were reluctant to disclose their current situation, others valued conversations with men with similar experiences. The commonality of PCa created a sense of affinity with other men affected by PCa. The third theme referred to the participants' emotional strain related to the suspicion of PCa. Prostate cancer was considered a less aggressive cancer; nevertheless, thoughts about the disease could still cause concerns and ambiguous feelings. The information the participants' received about PCa seemed to affect their emotions towards PCa.

5.2 Paper II

Men's perception of information and psychological distress in the diagnostic phase of prostate cancer: a comparative mixed methods study

The study presented in paper II adopted a multicentre comparative mixed methods design. The study aimed to explore and compare men's perception of information and possible experience of distress between a PSA group and a Stockholm3 group during the diagnostic phase of PCa. The data were collected from both the PSA group and the Stockholm3 group and from both the questionnaire survey and semi-structured interviews. The patient characteristics; four items addressing patient experiences with information, collaboration, and waiting time during the diagnostic evaluation of PCa; and HADS scores were obtained from the questionnaire survey.

The results demonstrated that the Stockholm3 group reported more sufficient information received from GPs than did the PSA group. Similarly, the Stockholm3 group was more likely to indicate that they had received sufficient information regarding how examinations would be conducted than the PSA group. No differences were found between the groups regarding waiting time and psychological distress. Three main themes emerged from the qualitative data of the two groups.

The first theme was 'information affects the experience of comprehension', which illustrated how the quality and amount of initial information affected how well the patients felt prepared for further diagnostic evaluation. In general, the Stockholm3 group seemed to have received more information than did the PSA group. However, the information received about the further process, PCa, and benefits and harms varied between the groups.

The second theme was ‘stepping into the world of the healthcare system’, which described how the patients in both groups were generally satisfied with the healthcare system. However, episodes with confusing or mixed-up information were reported. In addition, both groups described similar experiences regarding information from the urological outpatient clinic, but whose quality differed.

The third theme was ‘periodical feelings of distress’, which concerned the patients’ emotions during the diagnostic phase. Both groups reported corresponding findings and described fluctuating emotions with periods of worry. There was a common perception that the diagnostic phase of PCa was not associated with anxiety but with some underlying emotions that could not be entirely ignored.

5.3 Paper III

Associations between patient characteristics, symptoms of psychological distress and coping in the diagnostic phase of prostate cancer: A cross-sectional multicentre study

Paper III presents the results of study III, which utilised a multicentre cross-sectional design. It investigated the associations between the patient characteristics, psychological distress, and coping during the diagnostic phase of PCa. The patient characteristics and HADS and RWCCL scores were obtained from the questionnaire survey. The participants constituted a single group, independent of which initial diagnostic test was conducted.

The results showed that almost 15% and 5% of the patients experienced symptoms of anxiety and depression, respectively. A negative correlation was detected between age and higher scores for anxiety symptoms. Higher age was also related to less application of wishful thinking. Poorer self-reported health was associated with increased use of social support and wishful thinking. Symptoms of anxiety and depression were associated with increased use of all five coping strategies. The patients who appraised their situation as a threat experienced more symptoms of anxiety and depression and applied more emotion-focused coping than did the patients who appraised their situation as a challenge or benign.

5.4 Synthesis

This section presents a joint display of the integration of the quantitative and qualitative data from studies I, II, and III with the intent to match the findings by comparing them. Table 2 presents the joint display, which is organised by key topics with related summaries of the quantitative and qualitative findings. The summaries of the qualitative findings from studies I and II contained illustrative quotations (Creswell & Clark, 2018). As suggested by Creswell and Clark (2018), the combined findings organised by key topics were interpreted with respect to the overall mixed methods aim used in this thesis. After the findings of the three studies were read thoroughly, common concepts across the quantitative and qualitative analyses were identified. The joint display was then developed to make comparison more attainable, and expansions, confirmations, and discordances were identified by the author of this thesis. The joint display was then reviewed by the research team and commented on by each member. Subsequently, the joint display was revised and finally reviewed at a supervision meeting.

Table 2 Joint display of the integration of the quantitative and qualitative findings from studies I, II and III.

Key topics	**Perceptions of information provided by GPs GPs**
Quantitative	**Study II** Did you find that your GP gave you satisfactory information about what was going to happen related to the diagnostic evaluation of possible PCa? (item 1): Approximately 53.2% of the patients in the PSA group and 28.3% of the patients in the Stockholm3 group responded either “not at all”, “to a small extent”, or “to some extent”. The Stockholm3 group found the information provided by their GPs more satisfactory than did the PSA group (OR = 2.61; 95% CI = 1.59 to 4.28; p < 0.001) (item 1).
Qualitative	**Study I** **Theme 1: Different needs and perceptions of information** *He [the GP] was saying that there [at the hospital] they go in and examine the prostate, but he did not say anything more specific as far as I can recall, so after this first consultation or couple of consultations, I had no clear idea of what follows* (PSA, ID5). *He [my GP] said it indicates that it may be cancer that was what he said, so I ... but he also said it can be an indication that you have an infection. I didn't know that PSA was to indicate prostate cancer, I had no idea. (PSA, ID30).* **Study II** **Theme 1: Information affects the experience of comprehension** Initial introduction: *He [the GP] took a blood sample, uh I had no idea of what he was going to do with it”* (PSA, ID30). Perception of the diagnostic test: *I guess I received information that they would do, well, a Stockholm test instead of the PSA because the Stockholm test seemed to be more accurate. So, if there was something there, they could catch it, and if there was nothing, then you avoided going through the whole process of setting off a huge mechanism [further diagnostic evaluation] and all that stuff. So, that’s what I got from my GP* (Stockholm3, ST207). Receiving the test result: *No, nothing else except that he would refer me to this place [the hospital] so they could take a biopsy, quite simply* (Stockholm3, ST267). *Yes, it might be that you, I would almost say, would be sexually incapacitated and you could get [urine] leakage and some such unpleasantness that they did not want you to get, so he [the GP] explained that* (PSA, ID40).
Mixed methods	**Expansion** The quantitative analysis in both groups indicated that approximately 50% of the patients in the PSA group and 70% of the patients in the Stockholm3 group considered the information provided by their GP as sufficient. The patients described large differences in the quality of the information they received. The received information affected their ability to participate in making decisions about their diagnostic test and left them unprepared for further diagnostic investigations. **Confirmation** The qualitative analysis confirmed that the Stockholm3 group received more satisfactory information from their GP than did the PSA group.

Key topics	Perceptions of information provided by healthcare providers at the urological outpatient clinic
Quantitative	**Study II** Were you told what you thought was necessary regarding how examinations would be conducted? (item 4): Over 75% of the patients in both groups responded either "to a large extent" or "to a very large extent". The Stockholm3 group found the information they received regarding further examination more sufficient than did the PSA group (OR = 1.85; 95% CI = 1.10 to 3.11; p = 0.020).
Qualitative	**Study I** **Theme 1: Different needs and perceptions of information** *I was happy with the information given in writing. I don't have, well, I am a bit like I take things as they come, I don't need to know absolutely all there is to know about everything* (PSA, ID38). *Absolutely nothing [of information] has come through the system. No, the biopsy… when I came in for a biopsy, I came in and they took a sample, and that was that [participant's prior perception of a prostate biopsy], but then time went on and on and on, and I thought, heavens! – By now they must be finished! Because no one had told me what it was actually all about; sure, I could perhaps have found out for myself, but I think the information was not as good as I had expected (PSA, ID30).* **Study II** **Theme 2: Stepping into the world of the healthcare system** Trying to keep track of the diagnostic process *Well, so actually it is quite impressive that, uh, uh, I don't know, so it is based on me Well, so actually it is quite impressive that, uh, uh, I don't know, so it is based on me being involved in research [Stockholm3] or something like that. I come to the doctor and get information: You will be examined and first there is the MRI [magnetic resonance imaging], it takes no more than 14 days, actually. And it didn't. Then I went to have an MRI and the next day, then I got a phone call from the hospital, can you come and have an ultrasound today, quarter past one? Nothing further, but in fact am I seriously ill? What is it that makes that I, uh, that it happens so fast?* (Stockholm3, ST226). Receiving information and care at the urological outpatient clinic: *I feel that I am being extremely well looked after by the people [healthcare providers] who organise this and I think that inspires confidence and so I can relax and think: "Yeah, yeah, they know what they are doing and know their job"* (PSA, ID38).
Mixed methods	**Confirmation** The quantitative analysis in study II showed that over 75% of the patients in both groups found the information from the urological outpatient clinic sufficient to a (very) large extent. The qualitative analysis in studies I and II revealed that the patients generally found the information satisfactory and the healthcare providers caring and proficient. Episodes of confusion and insufficient information about the biopsy were described in both groups, which could cause psychological distress. Some patients were puzzled about the rapid diagnostic process and had speculations about being seriously ill. **Discordance** The quantitative analysis in study II demonstrated that the Stockholm3 group found the information received regarding how examinations would be conducted more sufficient than did the PSA group (OR = 1.85). The qualitative analysis revealed no differences between the groups regarding information. However, some patients thought that the rapid diagnostic process was related to the Stockholm3 test. Both groups described similar experiences with examples of sufficient and insufficient information received

Key topics	Experiences of psychological distress
Quantitative	**Study II** Approximately 14% of the patients in the PSA group had an HADS-A score of ≥8. Approximately 15% of the patients in the Stockholm3 group had an HADS-A score of ≥8. Approximately 4% of the patients in the PSA group had an HADS-D score of ≥8. Approximately 7% of the patients in the Stockholm3 group had an HADS-D score of ≥8. There was no significant difference in these scores between the two groups (p = 0.30). **Study III** (single group) Approximately 14.7% of the patients had an HADS-A score of ≥8. Approximately 5.3% of the patients had an HADS-D score of ≥8. HADS-A score: median = 3.0, IQR = 1.0–6.0 HADS-D score: median = 1.0, IQR = 0.0–3.0 Correlation between ageing and symptoms of anxiety: rho = −0.21, p = 0.001 Correlation between self-reported health and symptoms of anxiety: rho = 0.16, p = 0.015 Correlation between self-reported health and symptoms of depression: rho = 0.30, p < 0.001
Qualitative	**Study I** **Theme 3: Worries about cancer and mortality** Feelings of uncertainty towards cancer: *I did not worry over the MRI [magnetic resonance imaging] scan, but when I heard that there was something there, then your stress level goes up, and when you get closer to the biopsy, then it goes up even further, and when you are anxiously waiting for the answer, then I was at the peak emotionally. At that point you have come a whole step closer to somewhere you would rather not be* (PSA, ID43). *Conflicting feelings:* *No, I did not think about it at all [PCa]. Well, yes, at the time I am a bit like, I think a little bit, well, I think a little bit like, if I think scary thoughts, then my thoughts tend to focus on cancer, you know, in a way that, well that's how it is, you know* (PSA, ID36). **Study II** **Theme 3: Periodical feelings of distress** *Clearly, when you have gone to bed a short while before the wife comes up [to bed], then you have thought: "Goodness, what if it is the beginning of the end, like?"* (Stockholm3, ST233).
Mixed methods	**Confirmation** The quantitative analysis showed that 14–15% and 5% of the patients in both groups experienced mild to severe symptoms of anxiety and depression, respectively. The qualitative analysis revealed that the diagnostic phase of PCa was not associated with overwhelming or persistent feelings of psychological distress. **Expansion** The qualitative analysis indicated that the feelings of psychological distress among the patients were complex and appeared to fluctuate during the diagnostic phase of PCa. The patients described episodes of distress and fear of death. The emotional impact related to the diagnostic phase of PCa was considered as something underlying that could not be entirely ignored.

Key topics	Applied coping strategies during the diagnostic evaluation of PCa
Quantitative	**Study III** RWCCL Problem-focused coping: median = 0.7, IQR = 0.3–1.1 Social support: median = 0.8, IQR = 0.2–1.7 Blamed-self: median = 0.0, IQR = 0.0–0.3 Wishful thinking: median = 0.4, IQR = 0.1–0.8 Avoidance: median = 0.4, IQR = 0.2–07 Correlation between ageing and wishful thinking: rho = −0.15, p = 0.024 Correlation between self-reported health and social support: rho = 0.16, p = 0.013 Correlation between self-reported health and wishful thinking: rho = 0.14, p < 0.028 Correlation with the HADS-A and HADS-D scores (p < 0.001) * (p = 0.002) HADS-A score: rho (95% CI) Problem-focused coping: 0.32 (0.18, 0.44) Social support: 0.26 (0.12, 0.39) HADS-D score: rho (95% CI) Problem-focused coping: 0.24 (0.11, 0.36) Social support: 0.22 (0.08, 0.35)* HADS-A score: rho (95% CI) Blamed-self: 0.34 (0.21, 0.46) Wishful thinking: 0.59 (0.49, 0.68) Avoidance: 0.43 (0.31, 0.54) HADS-D score: rho (95% CI) Blamed-self: 0.31 (0.18, 0.43) Wishful thinking: 0.44 (0.32, 0.54) Avoidance: 0.29 (0.17, 0.41)
Qualitative	**Study I** **Theme 2: A discovery of not being alone** Not a secret but not for everyone to know: *I have been fortunate; in the first place I have a buddy who is slightly ahead of me, and who has told me a lot, and that has also meant that I can go online [the Internet] and read for myself, but not everyone has that option (PSA. ID43).* *In the course of time, I have spoken to 2–3 of my closest friends, and I see it is good for me, really it is. It is not something I blurt out to all and sundry, but I talk to my nearest and dearest. So, I am not anxious about that actually… no (PSA, ID38).* One of many: *But then I also read what is online, and almost 40 percent of those over 75 have had problems with their prostate, so I am one of many. But then, most of them have a good outcome (PSA, ID38).* **Theme 3: Worries about cancer and mortality** Feelings of uncertainty toward cancer: *As a human being, you often imagine the worst possible outcome, it is easier to think the worse than the best. You hope for the best but prepare for the worst… It's a human weakness, I guess* (PSA, ID40)

	Study II **Theme 2: Stepping into the world of the healthcare system** Receiving information and care at the urological outpatient clinic: *Yes, I remember, I believe I read [the information], I believe that I probably read it through, so browsed it and then read a little ... (sighs), but I remember nothing now (chuckles)* (PSA, ID36).
Mixed methods	**Expansion** The quantitative analysis indicated that greater use of problem-focused coping was associated with more symptoms of anxiety and depression. During the interviews, the patients explained that they found additional information on the internet. Social support seeking was the most commonly applied coping strategy (median = 0.8). Social support was positively correlated with symptoms of anxiety and depression. The qualitative analysis indicated that most patients chose a few confidants to confide in. The patients often had relatives or men in their circle of acquaintances from whom they could get support and information about PCa. These patients considered social support as an advantage, which enhanced their emotional well-being. Increased use of avoidance was positively correlated with symptoms of anxiety and depression. The qualitative analysis showed that some patients explained that they avoided seeking additional information from the internet or others. Some argued that they wanted to protect themselves from unnecessary psychological distress. They also believed that healthcare providers would tell them what they needed to know. Some patients claimed not to read the information from the hospital prior to the biopsy. Some wanted to focus on good things in life. The strongest correlation was noted between the HADS-A score and wishful thinking (rho = 0.59). The interview data disclosed that the realisation of being one of many affected by PCa combined with the low mortality of PCa seemed to comfort the patients. Most patients perceived PCa as a non-aggressive cancer that they could live with for a long time or die with and not from. This perception may be an expression of wishful thinking, reducing the potential severity of the situation.

Key topics	Appraisals of suspected PCa
Quantitative	**Study III** Appraisal Benign: 27% Challenge: 60% Threat/loss/harm: 13% Appraisal ($p < 0.001$) Benign HADS-A score: median = 1.0, IQR = 0.0–3.0 HADS-D score: median = 0.0, IQR = 0.0–1.0 Challenge HADS-A score: median = 4.0, IQR = 1.0–6.0 HADS-D score: median = 1.0, IQR = 0.0–3.0 Threat HADS-A score: median = 9.0, IQR = 6.3–12.8 HADS-D score: median = 4.0, IQR = 1.3–8.0 The patients who appraised their situation as a threat or challenge applied problem-focused coping strategies more often than did those who appraised their situation as benign. There was no significant difference between the patients who appraised their situation as a threat or challenge and those who applied problem-focused coping strategies. The patients who appraised their situation as a threat applied emotion-focused coping strategies (Blamed-self, wishful thinking, and avoidance) more often than did both patients who appraised their situation as a challenge and benign.
Qualitative	**Study I** **Theme 3: Worries about cancer and mortality** Feelings of uncertainty toward cancer: *When it comes down to it, it is the not-knowing and the uncertainty that can be the most tiresome, more than getting a clear message that you have cancer, this is until death (ID5 p8).* **Theme 2: A discovery of not being alone** *One of many:* *I think to myself that I am not the first person to go through this, and not the last either (PSA, ID38).* ***Study II*** **Theme 3: Periodical feelings of distress** *Well, it is straight to the little white box [casket], isn't it? To me, cancer means death, you know, but of course it is not. So, "of the bat", what cancer means to me, it means 'game over'. I mean, doesn't it?* (PSA, ID36)
Mixed methods	**Expansion** Most patients appraised their situation as a challenge (60%). During the interviews, the patients explained that they believed that many men became diagnosed with PCa, and most of them were fine. They had an expectation that modern medicine can provide numerous opportunities for treatment. The minority of the patients appraised their situation as a threat (13%). The patients who appraised their situation as a threat commonly applied emotion-focused coping strategies (blamed-self, wishful thinking, and avoidance). The qualitative analysis revealed that

	some men associated the word 'cancer' with death and described how the uncertainty could cause psychological distress.

6 Discussion

The aim of this thesis was to develop knowledge concerning patients' perceptions of information, psychological distress, and coping during the diagnostic phase of PCa. The main findings revealed that a subgroup of patients experienced symptoms of psychological distress that suggested a need for additional information and support. Symptoms of psychological distress seemed to fluctuate, and emotions could be difficult to express. The Stockholm3 group received more satisfactory information during the diagnostic phase than did the PSA group. A negative correlation was found between ageing and symptoms of anxiety. Poorer self-reported health was associated with increased symptoms of both anxiety and depression and increased use of social support and wishful thinking. All five coping strategies correlated positively with symptoms of anxiety and depression. The majority of the patients appraised their situation as a challenge. The patients who appraised their situation as a threat showed the most symptoms of anxiety and depression and applied emotion-focused coping the most.

6.1 Perceptions of information provided by general practitioners

Both international and national guidelines emphasise the importance of adequate information about the potential benefits and harms prior to the PSA test (European Association of Urology, 2023). The meta-inferences drawn from the findings of this thesis indicate that patients experience a substantially different quality of information from their GPs before and after receiving their diagnostic findings (PSA level/Stockholm3 score). The patients who perceived the information provided by their GPs as insufficient experienced uncertainty about the implications of their diagnostic test and the further course of diagnostic evaluation. This finding is in line with a previous research that patients generally experience low levels of communication with their GP, limiting their involvement in making decisions about the PSA test (Bhuyan et al., 2017). General practitioners have been identified as important facilitators of prostate health management, but when patient communication appears insufficient, the likelihood of patients choosing the most beneficial decision is reduced (Kannan et al., 2019). An important consideration is that GPs are faced with a difficult task when deciding when the PSA test is appropriate. General practitioners may experience uncertainty and conflicting feelings regarding conducting the PSA test in asymptomatic men, and cancer and overdiagnosis can be difficult topics to discuss (Pickles et al., 2015). Furthermore, GPs have identified time, financial, and clinical constraints as barriers to shared decision-making (Nyamapfene et al., 2023).

This thesis adds new insights into perceived information in relation to diagnostic tests for PCa. The analyses indicated that the Stockholm3 group received more satisfactory information from their GP than did the PSA group. Approximately 47% of the patients in the PSA group and 28% of the patients in the Stockholm3 group responded that they had not received satisfactory information from their GP regarding the diagnostic phase of PCa. In comparison, a Norwegian national survey among patients with cancer revealed that less than 50% of patients evaluated for cancer within the last 12 months responded that they had received satisfactory information from their GP regarding the diagnostic phase of cancer (Iversen & Bjertnæs, 2020). Information has been determined to be a major factor in patients’ evaluation of care. In addition, patient involvement and the context also seem to influence patients’ evaluation of care (Appleton et al., 2019). It is conceivable that the initial mandatory questions included in the Stockholm3 test may support the dialogue between patients and GPs before the test is conducted, thereby increasing patients’ awareness of the test and its implications (study II). Among the patients who did not comprehend the association between an elevated PSA level and PCa, the need for further diagnostic evaluation was unexpected (studies I and II). These findings are supported by previous reports that patients are not always aware of the reason for performing a DRE and the PSA test (Kannan et al., 2019). In the study by Biddle et al. (2017), uncertainty in terms of future health and the risk of PCa was common among men after receiving an elevated PSA test finding. Information about the inaccuracy of the PSA test and future options has been found critical in providing patients with the opportunity to make individualised, informed, and value-consistent decisions (Leyva et al., 2016). Kuss et al. (2021) established that patients want to be informed about possibilities in regard to the PSA test, and insufficient information can be perceived as being deprived of a choice. They identified test (in)accuracy, benefit–harm balance, and awareness of subsequent procedures/consequences as important key points for facilitating an informed choice about the PSA test.

The thesis uncovers unmet information needs, and although the Stockholm3 group perceived the information from their GP as more satisfactory than did the PSA group, there seems to be an overall need for more sufficient information among a considerable proportion of patients. In contrast, some patients expressed a desire for information to be short and concise. According to Timmins (2006), some patients might prefer less information to manage psychological distress, which is an important point when defining the actual information need. To meet individual information needs, Kuss et al. (2021) recommended a set of core information that should be offered to patients before the decision of the first PSA test; additional information should be provided only on request.

6.2 Perceptions of information provided by the urological outpatient clinics

The Stockholm3 group was more likely to state that they had received satisfactory information regarding examinations at the hospital than the PSA group. However, the qualitative findings did not indicate similar differences. Instead, it became evident that the patients in both groups had different information needs and preferences and expressed varying degrees of satisfaction with the provided information (study II). Extensive information needs often arise during the early phase of the cancer trajectory, including the diagnostic evaluation. Hence, it has been suggested that an early intervention aimed at patients' individual information needs may lead to fewer supportive needs later in the cancer trajectory (Tran et al., 2019). Aunan et al. (2021) argued that consultations under the auspices of urological outpatient clinics constitute an early phase, in which information and support are crucial to establish trust in healthcare providers during the diagnostic evaluation of PCa. Sufficient information may reduce psychological distress and increase patient satisfaction (Davison & Breckon, 2012; Goerling et al., 2020).

In this thesis, general satisfaction with the information provided at the urological outpatient clinics was reported. Yet, some patients requested more detailed information. Correspondingly, Goerling et al. (2020) reported that the majority of patients with cancer felt well-informed at the time of a cancer diagnosis. It is important to target patients' actual knowledge gaps rather than providing information that is determined appropriate by healthcare providers. Inaction regarding information needs may lead to dissatisfaction and increased symptoms of psychological distress (Timmins, 2006). In this thesis, the biopsy experience and its possible sequels were pinpointed as a specific situation that deviated from what some patients expected (studies I and II). Wade et al. (2015) suggested that inconsistency between patients' expectations and the actual biopsy experience could result in increased symptoms of anxiety and frustrations with the pre-biopsy information. The quantity, duration, site, colour, and intermittent pattern of bleeding after biopsy were associated with increased symptoms of psychological distress. Patients identified the biopsy experience as a focal point where more detailed information should be directed at.

An important finding illustrated by the qualitative analysis in studies I and II is that the diagnostic phase of PCa is multifaceted and contains several challenges in terms of timing and content of information. Ormandy (2011) emphasised that information needs are temporally changing over time and often directed at several challenges simultaneously. Sometimes, a hierarchy exists between different information needs, resulting in some information needs being more urgent or relevant at a certain time and others being ignored until later. These priorities depend on personality and context. International and national guidelines emphasise that diagnostic evaluation should be based on a standardised PCa care pathway, but with individual adaptations that ensure patients and their next of kin sufficient information and involvement (Mottet et al., 2023; The Norwegian Directory of Health, 2023a). Despite agreement that personalised information constitutes an important part of good cancer care, unmet information needs remain a recurrent finding of research into the trajectory of PCa (Appleton et al., 2019; Aunan et al., 2021; Schildmeijer et al., 2019)

In this thesis, nurses were identified as a flexible source of additional information that could facilitate contact to urologists if needed. This aspect should be further investigated to uncover the potential for targeted support and information that may lie within the domain of nursing. Clinical nurse specialists have been proven to be skilled at patient-centred communication, which may enable the provision of individualised information to patients during the different phases of PCa (Lopes & Higa, 2014). Clinical nurse specialists within cancer care have been established as essential and valuable members of the multidisciplinary team. Nonetheless, a clear role definition and allocation of resources are necessary to further the development of the tasks and responsibilities of clinical nurse specialists at urological outpatient clinics (Kerr et al., 2021).

6.3 Experiences of psychological distress during the diagnostic phase of prostate cancer

The thesis identified that some patients may be particularly vulnerable to symptoms of psychological distress during the diagnostic phase of PCa. A minor proportion of patients experienced mild to severe symptoms of anxiety and depression at the time of biopsy (studies II and III). These findings are consistent with some previous studies, however, combined, present an ambiguous overview of the measurement of psychological distress during the diagnostic phase of PCa (Awsare et al., 2008; De Sousa et al., 2012; Macefield et al., 2010; Sarchi et al., 2021; Sharp et al., 2018). Despite previous research presenting findings on a continuum from a small group of patients to a significant proportion of patients experiencing psychological distress, there is consensus that certain patients would benefit from additional support from healthcare providers. Different scales, cut-off scores, cultures, and times of data collection may explain some of the existing discrepancies (Awsare et al., 2008; Dillard et al., 2017). The joint display (Table 2) in this thesis revealed that although only a minor proportion of patients experienced symptoms of anxiety and depression, which indicated a need for further assessment, some emotional strain seemed to be common. Psychological distress during the diagnostic phase of PCa appeared to be both complex and context-bound, with fluctuating and different emotional responses noted. The definition of psychological distress encompasses a broad range of symptoms, extending from common feelings of fear and worry to more severe symptoms of anxiety and depression (Riba et al., 2019). The qualitative findings in studies I and II offered a deeper insight into the nature and versatility of the emotions experienced by patients during the diagnostic phase of PCa. The TMSC describes the relationship between emotions such as anxiety and depression and coping as multidirectional and changeable over time (Lazarus & Folkman, 1984). The process is affected by individual differences, and the importance of including aspects of context and life story should therefore not be neglected when healthcare providers assess psychological distress among patients (Hammen, 2016; Lazarus, 2006a).

Study III showed that increased age was associated with decreased symptoms of anxiety, while poorer self-reported health was associated with increased symptoms of both anxiety and depression. Esser et al. (2020) suggested that different coping strategies between age groups and disease-specific symptoms may generate more anxiety in younger men who are more sexually and socially active. The qualitative findings in studies I and II further expanded the understanding of the quantitative findings in studies II and III regarding psychological distress, emphasising that the experience of stress is highly personal. According to Fink (2016) what is experienced as a stressful encounter for one patient may have minimal effect on others. Early identification of patients experiencing symptoms of psychological distress should be prioritised before prostate biopsy because it may predict experiences of psychological distress later in the PCa trajectory (Oba et al., 2017).

6.4 Applied coping strategies during diagnostic evaluation of prostate cancer

Social support seeking was the most commonly applied coping strategy among the patients (study III). The qualitative findings in studies I and II indicated that patients often chose a few confidants to entrust in, especially other men with similar experiences. These patients considered social support as an advantage, enhancing their emotional well-being (studies I and II). Similarly, Spendelow et al. (2018) reported that patients with PCa may rely on support from their spouse, close family members, or other men with direct knowledge of PCa. Patient network has been designated an important role in managing needs for social support and information. Patients may use flexible networks to foster individual preferences by selecting people who meet those needs (Brown & Oetzel, 2016). The qualitative findings in studies I and II also revealed that information seeking was a regularly used problem-focused coping strategy. Most patients wanted information and browsed the internet for information about PCa. Some patients also contacted healthcare providers for additional information. Several sources of information have been identified for patients who engage in information seeking to manage uncertainty in relation to an elevated PSA level. These sources include the internet, media, friends with direct experience, and additional healthcare services (Biddle et al., 2017; Saab et al., 2018). According to Lazarus and Folkman (1984), information seeking is often the most commonly applied coping strategy in response to a stressful situation wherein information about the outcome is limited.

The relationship between, anxiety, depression, and coping is well established (Lazarus, 2006b). The presumption that certain ways of coping are more effective than others in promoting emotional well-being constitutes the rationale for healthcare providers' efforts to address issues that may cause psychological distress (Folkman & Moskowitz, 2004). Stress alone does not determine the effect on personal well-being; it is rather the way people cope with stress that needs to be addressed (Lazarus, 2006a). Study III revealed that all five coping strategies were associated with increased symptoms of anxiety. Previous research has indicated that patients who apply more emotion-focused coping experience higher levels of anxiety than patients who use both emotion- and problem-focused coping more well balanced (Otto et al., 2022). According to Lazarus and Folkman (1984), patients apply both emotion- and problem-focused coping in stressful situations, with the two strategies being mutually dependent. The composition between thoughts, wants, emotions, actions, and environments must be well balanced in successful coping (Lazarus, 2012). A primary focus of psychological supportive care interventions is the development of skills to cope with illness-related stressors; however, a lack of effective interventions has been reported in PCa care (Calvo-Schimmel et al., 2021).

Emotion-focused coping strategies such as avoidance, denial, and wishful thinking may provide emotional relief in situations perceived as uncontrollable, especially when existing resources are too limited for engaging in problem-focused coping strategies (Biggs et al., 2017). Nevertheless, these coping strategies have also been associated with long-term reduced well-being. Effective emotion-focused coping may reduce distress, possibly enabling problem-focused coping (Carver, 2019). The way emotion- and problem-focused coping strategies complement each other during the diagnostic evaluation of PCa appears complex, indicating the need for more knowledge.

6.5 Primary appraisal of suspected prostate cancer

In this thesis, the majority of the patients appraised the diagnostic evaluation of PCa as a challenge, while the minority appraised it as a threat (study III). Similar findings have been previously reported among men diagnosed with PCa (Ahmad et al., 2005). This thesis neither differentiated nor identified specific threats during the diagnostic phase of PCa. However, in studies I and II, the patients described various emotions in response to the suspicion of PCa. These emotions ranged from spontaneous catastrophic thoughts including thoughts about death to perceptions about PCa being a mild and treatable illness. These thoughts also seemed to individually fluctuate during the diagnostic phase. According to Biggs et al. (2017), people often juggle several appraisals simultaneously in relation to a stressor. Other previous studies have proposed that men who perceive PCa as an identity threat experience more psychological distress (Groarke et al., 2020; Orom et al., 2015). Another interesting point is that ageing has been associated with less negative illness appraisal in men with PCa (Kershaw et al., 2008; Kessler, 2020). The median age at PCa diagnosis among men is 70 years in Norway (Cancer Registry of Norway, 2022). Thus, PCa primarily affects older men, which can potentially influence the evaluation towards a less negative appraisal. The prognosis and long-term survival after diagnosis have also been suggested to direct men's appraisal of PCa towards a challenge (Ahmad et al., 2005).

In study III, the patients who perceived their situation as a threat experienced more symptoms of anxiety and depression than did those who perceived their situation as a challenge and benign. According to the coping theory, the intensity of a stress reaction is determined through cognitive appraisal, and a threat appraisal implies a potential for provoking negative emotions (Biggs et al., 2017). A negative appraisal of PCa, characterised by an assumed degree of threat, may predict a poorer quality of life within several months after diagnosis. Targeting threat appraisal by altering the appraisal towards a more manageable challenge appraisal is suggested as an intervention aiming at improving the quality of life of men with PCa (Song et al., 2016). In this thesis, the patients who appraised their situation as a threat applied emotion-focused coping strategies (blamed-self, wishful thinking and avoidance) more often than did those who perceived their situation as a challenge and benign (study III). Ahmad et al. (2005) presented similar findings but also found that patients who perceived their situation as a challenge applied more problem-focused coping strategies. This is in contrast to the findings in study III, which revealed no significant difference between challenge and threat appraisals and the use of problem-focused coping.

The present findings indicate that assessing the primary appraisal of patients may assist healthcare providers in identifying patients at risk of psychological distress during the diagnostic phase of PCa. Cognitive appraisal has previously been suggested as a target point for interventions to improve the quality of life of patients diagnosed with cancer. Informing healthcare providers about the changing nature of appraisal and its significance for patients' well-being may improve the support given to patients and guide their appraisal to a more beneficial direction (Kessler, 2020).

6.6 Strengths and limitations

This section presents the strengths and limitations of this thesis. A convergent mixed methods design including quantitative and qualitative methods was chosen. This design was applied to develop knowledge about information needs, psychological distress, and coping in patients during the diagnostic phase of PCa.

The mixed methods design provided a deeper understanding of the phenomenon studied, and the quantitative and qualitative data complemented each other, which is considered the main strength of this thesis (Cresswell & Clark 2018). Studies I and III were performed separately with a single method design, while study II was conducted using both quantitative and qualitative methods. Finally, the findings of the three studies were integrated to accommodate the overall aim of this thesis.

Data collection was conducted during the transition phase from the PSA test to the Stockholm3 test. The GPs in the catchment area of the target university hospital were recommended to replace the PSA test with the Stockholm3 test when conducting risk stratification for PCa (Viste et al., 2020). Studies II and III implied a passive role for the research team regarding the implementation of the Stockholm3 test and evaluation of its diagnostic performance. The focus was on the evaluation process of the participant experiences in real time. These conditions presented a challenge during data collection, resulting in the intended time schedule not being met. The quantitative data collection for the PSA group had to be expanded to include two more clinics. Despite the use of identical diagnostic pathways for PCa, individual and local differences between the clinics were expected, which may have influenced the homogeneity of the PSA group. The semi-structured interviews in both groups were conducted at clinic I. In retrospect, a different strategy could have improved the qualitative data collection for the PSA group by also conducting semi-structured interviews at clinics II and III. This could have strengthened the integration of the quantitative and qualitative data.

Although parametric tests usually have greater statistical power, non-parametric tests were utilised in studies II and III due to the non-normal distribution of data, the ability to analyse ordinal and ranked data, and because they are more robust to outliers (Nahm, 2016).

The choice of the theoretical perspective that guided this thesis could be considered both a strength and a limitation. The theoretical perspective guided the aim of this thesis. The variables included in the quantitative strand of the research were consistent with the theoretical perspective utilised. The questions in the interview guide were also designed to encompass the theoretical perspective. Finally, a theory was used as a reference in the interpretation of the findings in study III and the synthesis (Creswell & Clark, 2018). The use of an established coping theory to guide this thesis is considered a strength. Although the TMSC has been utilised in studies among patients affected by cancer, context is important; this aspect may have limited the theory's appropriateness in this thesis. Another limitation that cannot be entirely ignored is the possibility that the theoretical framework may have narrowed the perspective during the different phases of the thesis, consequently preventing nuances from being recognised (Passey, 2020).

7 Conclusion

This thesis contributes to the knowledge base of patients' perception of information, psychological distress, and coping during the diagnostic phase of PCa. Further, this thesis was conducted in the context of the implementation of the Stockholm3 test and thereby offers new knowledge for healthcare providers caring for this patient group in addition to policymakers and the public.

In this thesis, some patients had unmet information needs during the diagnostic phase of PCa. The patients displayed varied emotions towards the suspicion of PCa, including psychological distress. The patients who underwent the Stockholm3 test were more likely to be satisfied with the information provided by their GP than those who underwent the PSA test. This finding could be explained by the mandatory questions included in the Stockholm3 test. These questions may facilitate communication about diagnostics and PCa between patients and their GPs. Although the Stockholm3 group reported receiving more satisfactory information from their GP than did the PSA group, a significant proportion of the patients in both groups received insufficient information.

A large number of men in Norway undergo diagnostic evaluation of PCa each year, which entails a period characterised by uncertainty, potentially causing psychological distress. The thesis revealed that the majority of the patients appraised the diagnostic evaluation as a challenge, and the minority experienced symptoms of anxiety and depression within the clinical range (studies II and III). Nevertheless, psychological distress manifested as a wide range of emotions, affecting the patients' well-being. In addition, a subgroup of patients was affected by symptoms of anxiety and depression to an extent that measures needed to be initiated. The patients who appraised their situation as a threat experienced more symptoms of anxiety and depression and applied more emotion-focused coping strategies than did their counterparts. Poorer self-reported health and younger age were also related to increased symptoms of anxiety and depression. This thesis contributes to the literature by pinpointing focal points for healthcare providers to address when identifying patients in need of additional support and information.

7.1 Implications for practice

The findings of this thesis are applicable to healthcare providers who conduct diagnostic evaluations of PCa. The findings revealed challenges and potentials for clinical practice, highlighting important issues that healthcare services must acknowledge. The initial questions in the Stockholm3 test may be a contributor in facilitating patient–provider communication. The following strategies are recommended to improve healthcare for patients during the diagnostic phase of PCa:

- Development of routines that ensure more sufficient initial information about the PSA or Stockholm3 test and the potential benefits and harms;
- Development of an information chain between primary and specialist healthcare services to ensure that sufficient information is provided to patients throughout the diagnostic evaluation;
- Greater attention to factors that aid in the identification of individual information preferences;
- Development of the role of cancer nurses at urological outpatient clinics and exploitation of the potential of providing accessible and additional support and information; and
- Provision of education among healthcare providers on the relationship between patients' appraisal of their situation and psychological distress and on applied coping strategies to understand how patients may have different reactions to the diagnostic evaluation of PCa.

7.2 Implications for future research

This thesis could serve as a foundation of knowledge concerning patients' perceptions of information, psychological distress, and coping during the diagnostic phase of PCa. However, the findings are limited, and there is an established ambiguous overview of men's perception of psychological distress during the diagnostic evaluation of PCa. This section presents suggestions for future research based on the findings of this thesis.

A more comprehensive understanding of psychological distress during the diagnostic phase of PCa is needed. Repeated data from longitudinal studies on symptoms of anxiety and depression during the diagnostic phase of PCa could further bridge the knowledge gap in the literature.

A measurement tool directed at distress related to PCa could detect nuances that cannot be identified by the HADS. An example of a PCa-specific measurement tool is the Memorial Anxiety Scale for Prostate Cancer (MAX-PC), which appears to be a valid and reliable tool for measuring anxiety in men with PCa (Roth et al., 2003). However, unlike the HADS, a Norwegian validated version of the MAX-PC has not yet been developed.

Future research on appraisal and coping strategies with a mixed methods design is encouraged. The processes of appraisal and coping are complex, indicating the need for exploring the interplay between multiple cognitive appraisals and different coping strategies. The presumption that healthcare providers can influence and direct coping towards adjustment and eventually improved well-being should be investigated in relation to the diagnostic phase of PCa.

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Part II

List of papers

Paper I

Juul Søndergaard, M. E., Lode, K., Kjosavik, S. R., & Husebø, S. E. (2021). Men's perception of information and descriptions of emotional strain in the diagnostic phase of prostate cancer-a qualitative individual interview study. *Scandinavian journal of primary health care*, *39*(4), 476–485. https://doi.org/10.1080/02813432.2021.2004734

Paper II

Søndergaard, M.E.J., Lode, K., Husebø, S.E., Dalen, I. & Kjosavik, S. R. Men's perception of information and psychological distress in the diagnostic phase of prostate cancer: a comparative mixed methods study. *BMC Nurs* **21**, 266 (2022). https://doi.org/10.1186/s12912-022-01047-1

Paper III

Søndergaard, M.E.J., Kjosavik, S. R., Husebø, S.E., Dalen, I. & Lode, K. Associations between patient characteristics, psychological distress, and coping in the diagnostic phase of prostate cancer: A cross-sectional multicentre study. Submitted to The European Journal of Oncology Nursing. In review 10.01.2024

Paper I

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Men's perception of information and descriptions of emotional strain in the diagnostic phase of prostate cancer—a qualitative individual interview study

Maja Elisabeth Juul Søndergaard[a,b,c], Kirsten Lode[b,c], Svein Reidar Kjosavik[c,d] and Sissel Eikeland Husebø[a,b,c]

[a]Department of Surgery, Stavanger University Hospital, Stavanger, Norway; [b]Research Group of Nursing and Healthcare Sciences, Stavanger University Hospital, Stavanger, Norway; [c]The General Practice and Care Coordination Research Group, Stavanger University Hospital, Stavanger, Norway; [d]Faculty of Health Sciences, University of Stavanger, Stavanger, Norway

ABSTRACT

Objective: To explore mens̀ perception of information and their possible emotional strain in the diagnostic phase of prostate cancer.

Design, setting, patients: A qualitative explorative research design was employed. Data were collected from June to November 2017. The study was set at a urological outpatient clinic at a university hospital in Norway. Semi-structured interviews were conducted with ten men who had been examined for prostate cancer. Interviews were analyzed using Systematic Text Condensation (STC).

Results: The analysis revealed three themes. The theme 'Different needs and perceptions of information' illustrated that information should be personalized. Despite different information needs, insufficient information about prostate cancer may prevent some men from being involved in decisions. The theme, 'A discovery of not being alone', indicated that a sense of affinity occurs when men realize the commonality of prostate cancer. Some men benefited from other men's experiences and knowledge about prostate cancer. The last theme 'Worries about cancer and mortality' showed that the emotional strain was affected by men's knowledge of cancer and the received information. Men expressed conflicting feelings toward prostate cancer that could be difficult to express.

Conclusions: The findings indicate that men in the diagnostic phase of prostate cancer are not a homogeneous group, but need personalized information. Some men may benefit from other men's experiences and support. Men's emotional strain can affect their communication about prostate cancer, which should be acknowledged. Procedures that identify patients' information needs early on should be an integrated part of the diagnostic phase of prostate cancer.

KEY POINTS

- Knowledge about men's information needs and possible emotional strain in the diagnostic phase of prostate cancer are limited.
- Men with suspected prostate cancer have different preferences and information needs; however, insufficient information prevents men from participating in decisions.
- Men experience a sense of affinity with other men affected by prostate cancer, and some men benefit from exchanging experiences.
- Men consider prostate cancer as a less aggressive type of cancer but may experience emotional strain.

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Diagnostic phase; emotions; information; patient experience; prostate cancer; qualitative research

Introduction

Prostate Cancer (PCa) is the second most common cancer, with 2.3 million new cases worldwide in 2018 [1]. Prostate cancer is usually suspected based on prostate-specific antigen (PSA) levels and/or a digital rectal exam, but a definitive diagnosis depends on a biopsy that verifies adenocarcinoma in the prostate gland [2,3]. The European Assosiation of Urology (EAU) PCa Guidelines recommend that men are not subjected to PSA testing

CONTACT Maja Elisabeth Juul Søndergaard majson@sus.no Department of Surgery, Stavanger University Hospital, Postboks 8100, Stavanger, 4068, Norway

Supplemental data for this article can be accessed here.

without being well-informed on potential risks and benefits [3].

Norway is among the countries with the highest incidence and mortality of PCa, with about 5000 annual incidents [4,5]. In Norway, general practitioners (GPs) perform an important function as a gatekeeper in selecting men for further diagnostic evaluation. There is consensus that a decision to have a PSA test should be made by patients in consultation with their GP who can explain the risks and benefits of the test, as well as risk factors and symptoms of PCa [6,7]. According to the Norwegian Directorate of Health, a large number of men without symptoms undergo PSA testing. They state that more information about the advantages and disadvantages of PSA testing will provide a better foundation for men's decisions about the test [8].

Lack of information about cancer treatment and its adverse effects has been described as a common experience for patients during the process of PCa care [9]. In addition, studies have reported that men with PCa requested more timely and accurate information. Information on treatment and side-effects provided simultaneously with the diagnosis was considered too late [10,11]. Altered masculinity and sexuality, urinary incontinence and bowel changes have been identified as some of the challenges that men are confronted with after treatment [9,12,13]. A meta-synthesis of qualitative studies found that treatment of PCa represented a threat to masculinity due to a changed body and the challenged sense of being a man [14]. Evidently, information and emotional challenges are important focal points related to the trajectory of PCa.

Whilst several studies address men's information needs and emotional challenges after a PCa diagnosis, few studies have focused on these aspects before a PCa diagnosis [15,16]. Little is known regarding men's perception of the possible emotional strain in the diagnostic phase. Both Appleton et al. [17] and Biddle et al. [18] found that men experienced uncertainty and sometimes anxiety throughout the diagnostic pathway and information was identified as central to help manage these emotions [17,18]. Research shows that men are generally aware that PCa can pose an important health issue [19]. However, a systematic review of qualitative research found that the understanding of causes, symptoms, anatomy, and diagnosis of PCa is limited among undiagnosed men [15]. Studies have reported that men experience uncertainty when confronted with an elevated PSA level and future management plan [18,20].

A qualitative approach may contribute important knowledge about the diagnostic phase of PCa from a patient perspective. Therefore, this study aims to explore mens̀ perception of information, and describe the possible emotional strain in the diagnostic phase from an elevated PSA test result was recognized and until they received the biopsy result.

Materials and methods

A qualitative, explorative descriptive design was employed [21]. This study adhered to the Standards for Reporting Qualitative Research checklist [22]. Semi-structured individual interviews were used as a data collecting method [23]. An interview guide was developed based on the aim of the study, the diagnostic pathway of PCa [6], and previous research. Interview data were analyzed using Systematic Text Condensation (STC) [24] to facilitate the descriptive and explorative approach, presenting participants' experiences as expressed by the participants themselves [25].

Setting and participants

The study was conducted at a urological outpatient clinic staffed by urologists and nurses at a university hospital located in an urban setting in the southwestern part of Norway. The interviews took place in consultation rooms located at the hospital close to the urological outpatient clinic, or a satellite clinic within the same health trust; others were held in conference rooms at the hospital. The first author and participants decided upon the interview locations together based on convenience for the participants. For example, some men wished to combine the interview with other appointments at the hospital. The hospital environment may have affected the participants' descriptions of their experiences [23]. A purposive sampling strategy was used, which included variation in age and PSA level at the time of referral [21]. Eligible participants received the invitation to participate together with the study information from the first author while they awaited a prostate biopsy at the urological outpatient clinic. Participants who considered participating received further information about the interview in a consultation room. The following inclusion criteria were used: men scheduled for a prostate biopsy, first episode of PCa, ≥40 years of age, and able to provide informed consent. Men with cognitive impairment were excluded. Participants were re-contacted by the first author after they received their biopsy result, i.e.

~2 weeks after the biopsy. None of the participants chose to withdraw from the study.

Data collection

Data were collected between June 2017 and November 2017. Demographics were obtained from the participants before the interviews. All interviews were audiotaped. To begin each interview, the participants were asked to tell about their experience from the time of their PSA test and during the diagnostic phase of PCa. Some participants had taken several PSA tests and they also spoke about the information they had received at the time of their first PSA test. The first author asked elaborating questions based on the participant's own story. Further, the interview guide was used to ensure that common themes were reflected upon according to the aim of the study (see Supplementary Appendix 1). This included their experience with the PSA test, received information, their experiences with information about the medical procedures at the urological outpatient clinic, and their thoughts, emotions, and possible worries. The interviews lasted between 25 and 52 minutes. After ten interviews, the research team agreed not to perform any further interviews based on the study aim, sample specificity, the quality of the dialogues, and our analysis strategy [26].

Data analysis

The recorded interviews were transcribed verbatim and analyzed thematically using STC [24]. The method consists of four steps: (1) total impression, from chaos to themes; (2) identifying and sorting meaning units, from themes to codes; (3) condensation, from code to meaning; and (4) synthesizing, from condensation to descriptions and concepts [24,25]. The first step was performed by the first author and, after gaining an overall impression, six preliminary themes were identified. In the second step, each transcript was systematically reviewed by the first author, and meaning units were sorted and classified into code groups related to the preliminary themes. The full transcripts were distributed within the research team and the preliminary analysis was discussed among the authors at an analysis seminar. The preliminary themes and codes were adjusted to ensure that they reflected the narratives and the aims of the study. Analysis benefits from being conducted by more than one researcher to create a wider analytic space. The first author performed the third step, which involved the abstraction of meaning. The content of each theme was reduced into a condensate reflecting the meaning of the text [25]. The research team then reduced and renamed the preliminary themes into three final themes. The fourth step required the condensates to be synthesized into generalized descriptions by the first author. The descriptions were then evaluated by the research team, ensuring that they reflected the original context.

This research team consisted of an experienced GP, two researchers in nursing with experience in conducting qualitative studies, and one specialist nurse, all of whom had previous experience with patients affected by cancer. The first author is a Ph.D. fellow and a former cancer coordinator for bladder and kidney cancer but also served as a PCa coordinator on various occasions. This position was located at the hospital and involved some acquaintance with the urological outpatient clinic. The multidisciplinary composition of the research team strengthened the process of reflexivity during the analysis. Selected parts of the analysis process are shown in Table 1.

Ethical considerations

The study was approved by the Norwegian Regional Committees for Medical and Health Research Ethics (REK no. 2017/71) and the hospital administration. The participants received both oral and written information about the study and were guaranteed anonymity. Participation was voluntary and participants were informed that they had the right to withdraw from the project at any time. All participants signed a letter of consent before the individual interview started.

Results

Ten men ranging from 50 to 80 years old participated in the study; six of them were diagnosed with PCa, while the remaining four participants had benign biopsies (Table 2). Participants with benign biopsies received no PCa diagnosis but had to continue to monitor their PSA level regularly with their GP. They expressed satisfaction with being monitored for safety reasons. Three themes with related subthemes emerged from the analysis (Figure 1): (1) Different needs and perceptions of information, (2) A discovery of not being alone, and (3) Worries about cancer and mortality.

Theme 1: different needs and perceptions of information

The first theme addressed the participants' perception of the received information from healthcare providers

Table 1. Examples of the analysis (selected parts).

Meaning units (selected)	Codes	Subthemes	Themes
I knew that he had taken a blood sample, but I did not know that he had examined the PSA and neither had he done a finger exam of the prostate gland. (ID40 p2)	Different information and patient involvement throughout the diagnostic phase		Different needs and perceptions of information
He [GP] was saying that there [at the hospital] they go in and examine the prostate, but he did not say anything more specific as far as I can recall, so after this first consultation or a couple of consultations, I had no clear idea of what follows. (ID5 p3)	Different information and patient involvement throughout the diagnostic phase		Different needs and perceptions of information
I think to myself that I am not the first person to go through this, and not the last either. (ID38 p3)	Different experiences with social support	One of many	A discovery of not being alone
As a human being, you often imagine the worst possible outcome, it is easier to think the worse than the best. You hope for the best but prepare for the worst… It's a human weakness, I guess. (ID40 p3)	Different experiences and psychological reactions	Feelings of uncertainty toward cancer	Worries about cancer and mortality

Table 2. Sample demographics.

Variables	$n = 10$
Age (years)	
51–60	1
61–70	6
71–80	3
People in the household (*n*)	
1 person	3
2 persons	6
≥3 persons	1
Education, after primary school (years)	
1–3	1
4–5	6
7–9	3
Occupation status (*n*)	
Employed	4
Retired	5
On rehabilitation	1
Prostate cancer (*n*)	
Yes	6
No	4

during the referral process and consultations at the outpatient clinic. The theme reveals that men have different needs for information and involvement in decisions. Being unaware that the GP had ordered a PSA test was a common experience among the participants. They described that their GP ordered the blood sample without giving further information about the actual reason for the test. A participant explained that he had consulted the GP because of pain in the groin area. The GP suggested that the pain could be caused by an enlarged prostate gland. After a pause of thinking, the participant explained that he was unsure if the GP had mentioned the word 'cancer'. The participant had not received any information regarding the PSA test; therefore, he had not understood the relationship between the blood test and PCa.

> *Just now I was thinking what the reason might be … I have not felt that he did it behind my back, since he is a really nice and open-hearted person and I don't think he tried to hide anything from me. So why this value [PSA] was measured, whether it was by chance or not, I don't know. (ID5 p2)*

Whether the GP ordered the PSA test with or without the participants' knowledge, the participants perceived the GP's decision as a result of his/her competence and care. Participants were unprepared when receiving the PSA results without being aware of the PSA test in the first place. A participant described how his GP had called him and explained about the PSA test and the possibility of PCa:

> *He [my GP] said it indicates that it may be cancer that was what he said, so I … but he also said it can be an indication that you have an infection. I didn't know that PSA was to indicate prostate cancer, I had no idea. (ID30 p4).*

The cancer had not been discussed before the blood test so he thought the blood test was only related to an infection. He expressed a concern that healthcare providers assumed that ordinary people were familiar with medical terms and procedures, which he believed was a general problem during the diagnostic phase of PCa.

Insufficient knowledge and information seemed to produce uncertainty and reduce predictability, and thereby possibly diminishing participants' will and opportunity to be involved in decisions about their own health. However, some participants stated that they preferred to refrain from being included in medical decisions and avoid unnecessary information.

> *I was happy with the information given in writing. I don't have, well, I am a bit like I take things as they come, I don't need to know absolutely all there is to know about everything. (ID38 p5).*

These participants seemed certain that the healthcare providers possessed the necessary competence and should be allowed to perform their job without

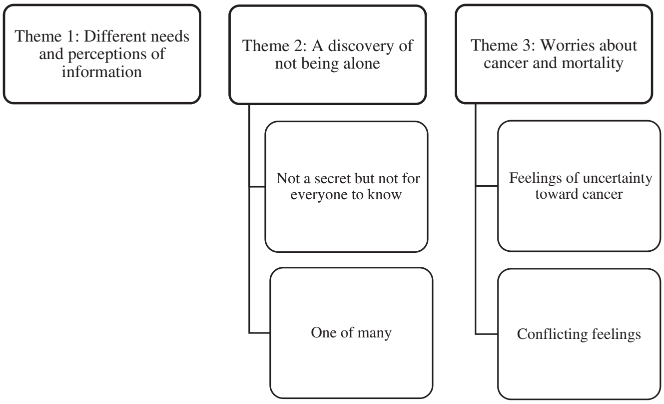

Figure 1. Main themes with associated subthemes.

them interfering or questioning their actions. Information provided together with the results of the elevated PSA test or the prostate biopsy may have caused this attitude. Participants did not feel prepared for a co-responsibility, because the decision itself could lead to pondering and feelings of uncertainty and guilt.

The results demonstrated variation related to the biopsy-based on their perception of the information, their expectations, and subsequent sequelae. A participant explained that the healthcare providers were friendly and caring, but failed to provide predictability:

> *Absolutely nothing [of information] has come through the system. No, the biopsy… when I came in for a biopsy, I came in and they took a sample, and that was that [The participant's prior perception of a prostate biopsy], but then time went on and on and on, and I thought, heavens! – By now they must be finished! Because no-one had told me what it was actually all about; sure, I could perhaps have found out for myself, but I think the information was not as good as I had expected. (ID30 p3)*

Participants who requested more information felt poorly prepared both before and after the biopsy. They expected information to prevent them from wondering about normal bodily reactions. Consequently, they searched the Internet for information, which should have been communicated by the healthcare providers. For instance, insufficient information regarding unsuspected prolonged bleeding after the biopsy seemed to arouse unpleasant feelings of worry and disgust.

Theme 2: a discovery of not being alone

The second theme, 'A discovery of not being alone', consisted of two subthemes: 'Not a secret but not for everyone to know' and 'One of many'. This theme highlights how relations could be an important source of support and information, especially men with similar experiences who were valued. The commonality of PCa created a sense of affinity for other men affected by PCa.

Not a secret but not for everyone to know

Participants were selective in whom they confided concerning the suspicion of PCa. The decision to inform the nearest family, friends, and coworkers often depended on a wish for support and honesty. Some participants described these conversations as beneficial due to increased emotional well-being when they shared their personal concerns and received support. A participant who lived alone exemplified this:

> *In the course of time, I have spoken to 2–3 of my closest friends, and I see it is good for me, really it is. It is not something I blurt out to all and sundry, but I talk to my nearest and dearest. So, I am not anxious about that actually… no. (ID38 p2)*

For participants who needed more information and support, family members or friends with previous PCa experience contributed to a more understandable and participatory picture of the diagnostic phase. A participant explained:

> *I have been fortunate; in the first place I have a buddy who is slightly ahead of me, and who has told me a lot, and that has also meant that I can go online [the Internet] and read for myself, but not everyone has that option. (ID43 p7)*

In contrast, participants exposed to what they explained as emotional overreactions or scary stories, tended to avoid discussing the subject with others, allegedly because it interrupted their perception of their current situation. Being reluctant to share the suspicion or diagnosis of PCa was apparently also based on an intention not to be a burden. In general, participants expressed that conversations with friends about PCa were related to practical issues because they rarely discussed feelings with each other nor felt the need. Conversations about feelings seemed to be reserved for their significant other.

One of many

Participants expressed a feeling of not being alone when they realized the commonality of PCa among their acquaintances. The acknowledgment of being one of many appeared to generate a feeling of affinity, which was unaffected by whether the participants had discussed the topic with others or not. The Internet and the media also contributed to this feeling, as a participant said:

> *But then I also read what is online, and almost 40 percent of those over 75 have had problems with their prostate, so I am one of many. But then, most of them have a good outcome. (ID38 p3)*

This insight of being one of many may represent a significant contribution to how participants perceived themselves during the diagnostic phase of PCa as well as after a confirmed diagnosis. The realization seemed to direct their feelings toward hope and acceptance of the situation.

Theme 3: worries about cancer and mortality

The third theme, 'Worries about cancer and mortality', consisted of the two subthemes: 'Feelings of uncertainty toward cancer' and 'Conflicting feelings'. In this theme, participants expressed their emotional strain related to the suspicion of PCa. The information they received about PCa seemed to affect their emotions toward PCa.

Feelings of uncertainty toward cancer

The period leading up to a possible PCa diagnosis could be perceived as demanding, and uncertainty about the disease and the future was difficult to reconcile with. Participants' prior knowledge and the information they received appeared to influence their emotional response to the suspicion of PCa. A participant described himself as anxious by nature, though the information and conversations with the healthcare providers had convinced him that there was little suspicion of PCa. However, before the first consultation at the outpatient clinic, he felt paralyzed with fear.

> *When it comes down to it, it is the not-knowing and the uncertainty that can be the most tiresome, more than getting a clear message that you have cancer, this is until death. (ID5 p8)*

Participants spontaneously associated cancer with death, as they knew someone who had died from cancer. On second thought, however, the participants expressed beliefs that modern medicine provided many treatment opportunities that could possibly cure cancer. Prostate cancer was considered a less aggressive cancer illness but was nevertheless a reminder that life was fragile. Physical discomfort, such as abdominal pain and tension, difficulty sleeping, and catastrophic thoughts were described as reactions related to the suspicion of PCa. For some, concerns and stress became more prominent as the results of the biopsy approached. Participants assessed both the meaning and the impact of a potential PCa diagnosis:

> *I did not worry over the MRI [magnetic resonance imaging] scan, but when I heard that there was something there, then your stress level goes up, and when you get closer to the biopsy, then it goes up even further, and when you are anxiously waiting for the answer, then I was at the peak emotionally. At that point you have come a whole step closer to somewhere you would rather not be. (ID43 p7)*

This was described as a process of sorting out one's thoughts and included reflections on life and death, but also finding acceptance.

Conflicting feelings

It was common that participants appeared to experience conflicting feelings when describing their thoughts about PCa. This was expressed in reluctant and ambiguous statements during the interviews. For example, a participant stated that he had not spent time speculating; however, during the interview, he expressed anxiety about the illness and tried to avoid thinking about it:

> *No, I did not think about it at all [PCa]. Well, yes, at the time I am a bit like, I think a little bit, well, I think a little bit like, if I think scary thoughts, then my thoughts tend to focus on cancer, you know, in a way that, well that's how it is, you know. (ID36 p3)*

After receiving a negative biopsy result, some participants described themselves as feeling surprisingly relieved and more energetic.

Discussion

The findings demonstrate that men in the diagnostic phase of PCa are not a homogeneous group but have different needs for information. Men experienced a feeling of affinity when realizing the commonality of PCa. The received information and their prior knowledge about PCa seemed to affect men's emotional response to the suspicion of PCa. However, the suspicion of PCa often evoked a sudden fear of death but was nevertheless perceived as a less dangerous type of cancer.

In general, participants in this study experienced information regarding the PSA test as inadequate or untimely to provide them a framework within which to act. These findings are in line with previous studies on shared decision-making in PSA screening, which found that the decision on the PSA test was not often patient-centered [27,28]. This clinical practice diverges from both Norwegian and European guidelines, which strongly recommend providing thorough information before a PSA test for men to participate in the decision-making [3,8]. However, the results of the current study emphasize variations in men's preferences for healthcare providers to make decisions. Participants expressed general confidence in their GPs, although the discussion about possible benefits and harm seemed insufficient. A recent study argues that shared decision-making during a diagnostic phase of an illness is very complex and should be considered from the perspective of the patient and family. The results emphasize the importance of context and acknowledge that although doctors are the most trusted source of health information, patients may obtain information from various sources. The decision-making is thereby expanded beyond the boundaries of the medical visit [29]. A previous study found that GPs' communication practice in relation to PSA testing vary, specifically about overdiagnosis of PCa. Difficulty in understanding the concept, being contradictory to existing health beliefs and the perception of cancer as dangerous has been identified as contextualizing factors that prevent communication [30].

Most participants in the present study expressed genuine confidence and humility towards the healthcare system. Although participants expressed that information about the diagnostic process and what to expect was important, some preferred the healthcare providers to make the decisions and keep the information at a basic level. Previous studies have found that not all patients desire to be involved in decisions about their treatment after being diagnosed with PCa [31,32]. Findings in the current study suggest that men will benefit from their individual information preferences and wishes for involvement being identified early in the diagnostic phase of PCa. In Norway, patients have a legal right to receive information to gain insight into their own state of health and treatment, as well as possible side effects. However, information should not be given contrary to the patient's own request unless an omission causes harm [33]. Patients may have different preferences for being involved in decisions but this preference should be informed rather than based on clinicians' presumptions [34]. Therefore, personalized information should be available for patients in the diagnostic phase of PCa.

Although some participants in our study were reluctant to tell others about the suspicion of PCa, most participants told their closest family and friends. Similarly, a review study found that men often place restrictions on the circle of people who know about the suspicion of PCa. The restraint was described as an attempt to maintain masculinity and protect themselves from any potential stigma. This behavior has been suggested as a final line of resistance against the dissemination of knowledge about PCa [35]. In contrast, most participants in the present study valued conversations and exchanges of knowledge with other men with similar experiences. This is in line with previous research on men's behavior after a PCa diagnosis, which showed that men with PCa seek different types of information. In addition to medical information, many men valued lived-experience information that came from sources with direct and personal connections to the information. This contributed to sympathy from others and helped to understand the different types of treatment [32]. Furthermore, previous research has revealed commonality as an important factor for whether men disclosed their PCa diagnosis. By recognizing others with similar experiences, men's desire to share their diagnoses and exchange knowledge was stimulated [36]. Our findings suggest that men in the diagnostic phase of PCa can combine information from healthcare providers with the experiences of others to understand their own situation and the possible consequences. Nevertheless, issues affecting emotions related to PCa were rarely discussed and often reserved for their significant other. Regardless of how much the participants chose to share about the suspicion of PCa, the commonality of men affected by PCa was experienced as comforting and contributed to a sense of affinity.

The findings in this study showed that the participants managed the suspicion of PCa in a continuum, from no worries to thoughts of death. Despite general anxiety about cancer, PCa was considered a less aggressive cancer. This assumption was often reinforced by other men's experiences or from information on the Internet. Some participants seemed to have conflicting feelings towards their own experiences and thoughts about PCa, which resulted in reluctant or ambiguous statements. According to a recent review, the construct of masculinity is a major barrier for men to seek prostate care because of a perceived prohibition of displaying weakness. The fear of being perceived as weak was found to limit health information seeking and communication about prostate issues. Existential fear could also be perceived as a sign of weakness. Eventually, this construct of masculinity made some men avoid situations that could make them appear weak [15]. This further emphasizes the importance of an approach that maps individual beliefs and experiences that affects their health behaviors [37].

Strengths and weaknesses of the study

Since men in the diagnostic phase of PCa are in the transition between primary- and specialist healthcare, this study may be valuable to healthcare providers at both levels. A qualitative method was used to meet the study's aim and to explore an area with limited knowledge. The research team contributed with different perspectives and experiences, which strengthened the analysis. The first author's previous close relation to the affected patients made it easier to elaborate on certain parts of the interview and obtain deeper descriptions. Nevertheless, this relation could also represent weakness, and therefore, uncovering preconceptions was highly prioritized to ensure objectivity and that the data represented the information given by the participants. In addition, we have presented a rich description of the participants, the setting, and the analysis to promote transferability. To establish confirmability, we have described the analytical process in which all the authors participated.

Due to the relatively broad aim, the number of participants who were recruited from one hospital is considered a limitation of the study. However, the analysis revealed a significant mutual influence between the participants' information needs and their emotional strain. This finding has been little described in previous studies and thus the research team decided it may be of importance to clinical encounters. Although our results are related to the specific context and cannot be generalized, they may serve as a base for further research. Six of the ten participants were between 61 and 70 years, which gave a slightly uneven distribution of participants according to the intended sampling strategy of a wide variation in age. However, due to the fact that the median age of men diagnosed with PCa in Norway is 70 [5], it was agreed to be acceptable. Additionally, the first author recruited all participants, which may have resulted in sample bias [24]. Directly applying to patients could have made it difficult to say no.

Conclusion and implications for research and practice

The findings in this qualitative individual interview study of men's perception of information, and their emotional strain in the diagnostic phase of PCa emphasize the need for a flexible and tailored information structure that meets individual requirements. By offering patients information that is adjusted to their individual preferences, healthcare providers might reduce uncertainty and worry in the diagnostic phase of PCa. More research on how to address or screen patients' information needs is required. The findings elaborate that some men value exchanging practical knowledge with other men with similar experiences. These experiences helped participants navigate the diagnostic phase and enhanced the feeling of being 'one of many'. The recognition of not being alone added a sense of affinity, which applied to all participants regardless of where they obtained this knowledge. Healthcare providers should address this subject and direct men to patient organizations or the like if needed.

This study also offers new insight into how men experience the diagnostic phase of PCa and highlights that men may experience emotional strain that can be considered difficult to communicate, which may affect the dialogue between patients and healthcare providers.

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ORCID

Maja Elisabeth Juul Søndergaard http://orcid.org/0000-0003-4610-1651
Kirsten Lode http://orcid.org/0000-0001-8322-9457
Svein Reidar Kjosavik http://orcid.org/0000-0002-7004-5533
Sissel Eikeland Husebø http://orcid.org/0000-0001-5053-5730

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Paper II

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RESEARCH **Open Access**

Men's perception of information and psychological distress in the diagnostic phase of prostate cancer: a comparative mixed methods study

Maja Elisabeth Juul Søndergaard[1,2,3*], Kirsten Lode[2,3], Sissel Eikeland Husebø[1,2,3], Ingvild Dalen[4] and Svein Reidar Kjosavik[3,5]

Abstract

Background: Previous studies indicate that men experience frustration and uncertainty when confronted with an elevated prostate specific antigen (PSA) test and during further diagnostics for prostate cancer. The novel Stockholm3 test is an algorithm-based test that combines plasma protein biomarkers, genetic markers and clinical variables in predicting the risk of PCa. The test was introduced in a western part of Norway as a new tool for detecting prostate cancer. This study aimed to explore and compare men's perception of information and possible experience of distress between a PSA group and a Stockholm3 group during the diagnostic phase of prostate cancer.

Methods: This study is a part of the trailing research evaluating the impact of the change from PSA to Stockholm3. It is a multicenter study using a comparative mixed method design. Data were collected in a PSA group ($n = 130$) and a Stockholm3 group ($n = 120$) between 2017 and 2019. Quantitative data were collected using questionnaires and qualitative data were collected using semi-structured interviews ($n = 20$). The quantitative and qualitative data were analysed and compared separately and then merged in a side-by-side discussion. The study adheres to the GRAMMS guidelines for reporting mixed-methods research.

Results: Compared with the PSA group, men in the Stockholm3 group reported that the information from the general practitioners was better. Similarly, men in the Stockholm3 group were more likely to indicate that they had received sufficient information regarding how examinations would be conducted. No differences were found between the groups regarding waiting time and distress. Three themes emerged from the qualitative analysis of the two groups: "Information affects the experience of comprehension", "Stepping into the world of the healthcare system", and "Periodically feelings of distress".

Conclusion: The Stockholm3 test may facilitate the provision of information to patients. However, some patients in both groups experienced distress and would benefit from more information and additional support from healthcare professionals. Routines that ensure sufficient information from the interdisciplinary healthcare team should be of

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*Correspondence: majson@sus.no

[1] Department of Surgery, Stavanger University Hospital, Postboks 8100, 4068, Stavanger, Norway
Full list of author information is available at the end of the article

priority during the diagnostic phase of prostate cancer in order to provide patients with predictability and to avoid unnecessary distress.

Keywords: Diagnostic phase, Distress, Information, Patient experience, Prostate cancer

Introduction

Globally, prostate cancer (PCa) is the second most common cancer in men and accounts for about 15% of all cancer in men [1]. A patient's referral to specialized health care for diagnosing PCa is usually based on an elevated prostate-specific-antigen (PSA) test and/or a digital rectal examination. Using PSA for screening has been evaluated by long-term randomized controlled trials and overdiagnosis has been estimated to occur in 21% to 50% of PCas detected [2]. International and national guidelines strongly recommend adequate information on potential risks and benefits to men before they undergo PSA testing [3, 4]. The health authorities in Norway do not recommend PSA screening for the general male population and the health services has a responsibility to limit overdiagnosis and unnecessary treatment. PSA tests are recommended for men with genetic predispositions, symptoms and/or palpation findings and only after sufficient information [5]. However, there is widespread unsystematic testing of men with PSA in Norway [6].

Previous studies suggest that men experience frustration and uncertainty regarding the limitations of the test and the further diagnostic process when confronted with an elevated PSA [7, 8]. The diagnostic phase of PCa refers to the period that consist of initial blood tests, clinical examination, possible prostate imaging and biopsies, as defined by the Norwegian health authorities [9]. According to the Essential Requirements for Quality Cancer Care (ERQCC), the diagnostic evaluation should be organized as an interdisciplinary collaboration in a standardized patient cancer pathway (SCP) in order to secure good patient-centred care. As a part of an interdisciplinary team, nurses have versatile and pivotal functions throughout the SCP, including being a key contact for patients and providing information, care, and support [10]. However, recent studies have found that men in the SCP of PCa require personalized information and that some men are in need of additional psychological support beyond the scope of the SCP [11, 12] (Fig. 1).

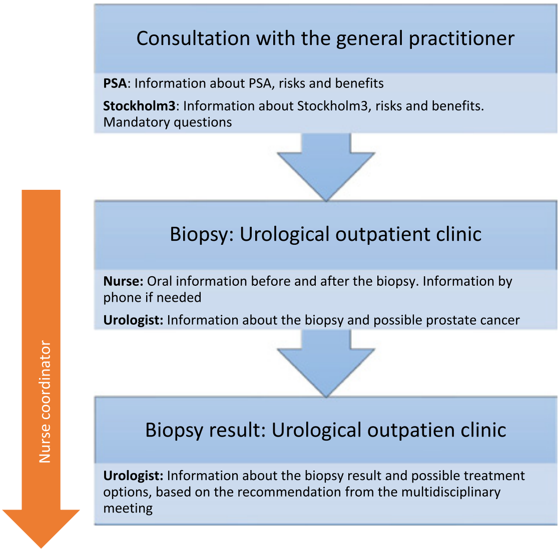

Fig. 1 Flowchart of information points during diagnostic evaluation for prostate cancer

Background

The interdisciplinary project "From PSA to Stockholm3" aims to improve the accuracy of PCa diagnostics, i.e. improve the diagnosis of clinically significant cancer while reducing overdiagnosis. The purpose of implementation was that all general practitioners (GPs) in the catchment area were recommended to change from PSA to Stockholm3 when conducting a risk-stratification for PCa [13]. The Stockholm3 test is an algorithm developed at the Karolinska Institute in Sweden. Based on blood tests (including PSA) and some clinical information, it aims to increase both sensitivity and specificity compared with the PSA, and thereby reduce the number of biopsies required without compromising the ability to diagnose clinically significant PCa (Gleason score of at least 7) [13–15]. The Stockholm3 test contains mandatory preliminary questions about three issues that should be discussed with the patient prior to the test, These questions are a part of the algorithm that determines the risk score and pertain to family history of PCa, use of medication related to the prostate, and any previous prostate biopsies [13].

Previous research may imply that PSA testing can be initiated by GPs and without patients being aware that PSA has been ordered along with other blood tests [16, 17]. Furthermore, the monitoring practices of patients with a raised PSA may leave uncertainty about further stages of the process [16]. Although men may be aware of the PSA test, insufficient knowledge about what the test entails has been reported [7, 18, 19]. For example, men were often unfamiliar with the limitations of the test (20). Patients have experienced lack of information during the trajectory of PCa, and the process of diagnostics and treatment was perceived as long and complex [12]. Furthermore, inadequate information can cause distress in patients with suspected PCa [7, 20]. Lower levels of knowledge about PCa and treatment options has shown to be associated with anxiety prior to diagnosis [21]. However, the patient's perception of information received and possible distress during the diagnostic phase of PCa have not yet been thoroughly explored [19, 22]. Distress has been defined as "a multifactorial unpleasant experience of a psychological, social, spiritual, and/or physical nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment" [23]. Distress ranges from common feelings, such as sadness and fear, to depression, anxiety, and panic [23]. Previous research shows mixed findings concerning distress during the diagnostic phase of PCa. Some studies have found a low incidence of clinically significant anxiety in men with an elevated PSA, and that only a small group of men evaluated for PCa had significant psychological distress [24, 25]. In contrast, a review reported that 30–40% of men with suspected PCa reported that anxiety affected their day-to-day life [26]. Distress has been reported in 49% of men after attending for a prostate biopsy [27]. Different scales, cut-off scores, cultures, and times of data collection may explain some of the existing discrepancies in the research examining distress in the diagnostic phase of PCa [24]. However, it also reveals a need for a more comprehensive understanding of patients' perception of the provided information and the possible experience of distress in the diagnostic phase of PCa. Comparing and synthesizing quantitative and qualitative data may add an important contribution to the existing literature [28]. Furthermore, the implementation of the Stockholm3 test may lead to changes in how patients experience the diagnostic evaluation for PCa. It may have consequences for how healthcare providers should approach and care for this group of patients.

The current study is a sub-study of the larger project "From PSA to Stockholm3", and is characterized as trailing research because the research team took on a passive role regarding the implementation of the Stockholm3 test and its diagnostic performance. Instead, the research team engaged in the evaluation process of the participant's experiences, which is the focal point of this study. This involved a scientific approach and a critical distance to actual action, in order to intercept changes that the Stockholm3 test may entail for patients regarding information and potential distress [29].

To our knowledge, there are no studies to date that have explored the patient perspective regarding the Stockholm3 test. Therefore, the aim of this study was to explore and compare men's perception of information and possible experience of distress between a PSA group and a Stockholm3 group during the diagnostic phase of PCa.

Methods

Design

In this study, we used a trailing research design as an approach to study changes in real time without the research team acting as an agent of change. The objective was to generate insight about the change initiated by the implementation of the Stockholm3 test, by following academic procedures to analyze the process and to produce new knowledge while balancing with care to the practical context [30]. The Design implied a constant attention to our role as a research team, which was discussed throughout the entire process [31] (Fig. 2).

The two participant groups underwent similar diagnostic evaluation at the urological outpatient clinics, apart from being assigned an initial diagnostic test using either PSA or Stockholm3 procedures. There was no other special attention given to the Stockholm3 group.

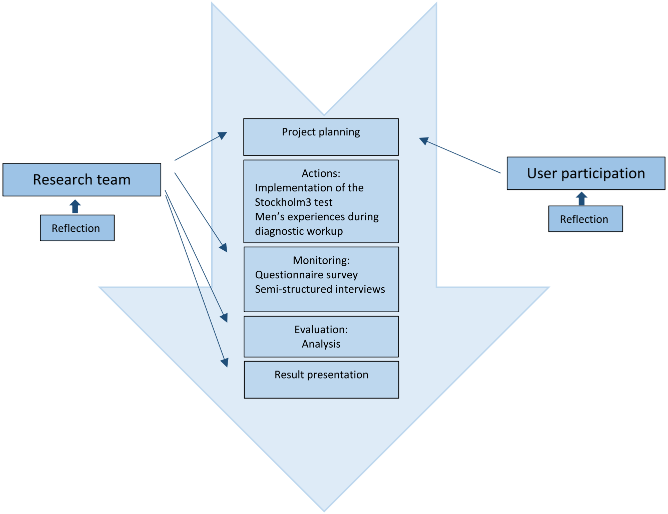

Fig. 2 Flowchart of the study process using a trailing research approach

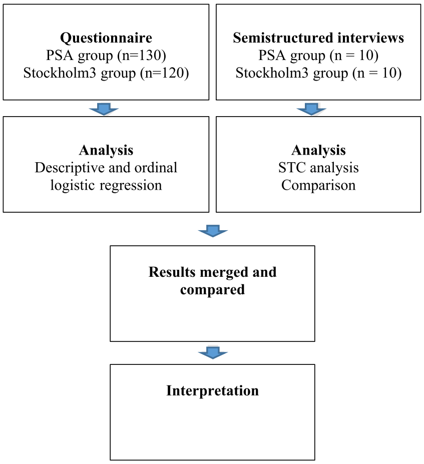

Fig. 3 A Convergent mixed methods design, presenting data collection and analysis process

A comparative study using a convergent mixed method design was employed (Fig. 3).

This design means that parallel strands of qualitative and quantitative data that are analysed individually and then brought together during interpretation [28]. The comparison between the quantitative data of each group and the comparison between the qualitative data for the two groups constitutes an intermediate step that extended the core design to a more advanced design. After conducting the intermediate analysis, the quantitative and qualitative results were merged and interpreted in adherence with the core design [32]. The qualitative and quantitative methods were given equal priority. The study design was considered appropriate because existing knowledge is limited, and our aim was to enable a comparison of quantitative and qualitative results to produce a more detailed and complete understanding of the topic [28]. The Good Reporting of A Mixed Methods Study (GRAMMS) checklist was applied to enhance validity in the study [33] (see Additional file 1).

Setting and sample

The study was conducted in the western part of Norway in three different settings. According to the original protocol, all data was supposed to be collected from a single clinic (Clinic I); however, the Stockholm3 test was implemented in Clinic I before the PSA data collection was completed, resulting in two more clinics being added (Clinic II and Clinic III). The three urological outpatient clinics were selected because they belonged to the same health trust and had similar procedures and routines during the diagnostic phase of PCa in accordance with the national SCP for PCa. However, Clinic I and Clinic II were affiliated with university hospitals in urban settings while Clinic III was affiliated with a hospital in a less urban setting. At Clinic I, both PSA and Stockholm3 data were collected, while at Clinic II and III only PSA data were collected because the Stockholm3 test was only implemented in Clinic I. Due to the geographical proximity of the research team, the individual semi-structured interviews were conducted at Clinic I. The interviews took place in suitable private rooms at the outpatient clinic, at an affiliated satellite clinic, or in a conference room at the hospital.

At all three clinics, patients were invited to participate in the study after they had received antibiotics and oral information and were awaiting the prostate biopsy at the clinics. A nurse or a study nurse who provided oral information about the biopsy invited patients to participate in the study. A convenience sample, based on accessibility and that met the inclusion criteria [34]. Inclusion criteria were: patients referred based on an elevated PSA test or an elevated Stockholm3 test, over 18 years of age, no prior diagnosis of PCa, and able to provide informed consent. Patients with cognitive impairment were excluded. Participants completed the questionnaire at one of the three urological outpatient clinics after receiving antibiotic and while they were awaiting their biopsy. Participants were also given the option of completing the questionnaire at home, and received a stamped envelope to return later. When patients agreed to participate in the questionnaire survey in Clinic I, the first author informed potential participants about the individual follow-up interview. A purposive sampling strategy was used in the individual interviews to ensure a variation in age and PSA or Stockholm3 value at the time of referral [35]. From the patients who completed the questionnaire at Clinic I, 10 patients with an elevated PSA test (PSA group) and 12 patients with an elevated Stockholm3 test (Stockholm3 group) were invited to participate in semi-structured interviews. The first author contacted the 22 patients that had been willing to participate in the interview by phone after they had received the biopsy result. Two patients from the Stockholm3 group declined to participate, one because of severe PCa, the other due to lack of time. Finally, 20 patients agreed to participate in the semi-structured interviews, distributed with 10 men in each group. The interviews were scheduled and conducted during the two weeks following their biopsy result.

Data collection

Data were collected between September 2017 and November 2019. The recruitment of eligible participants for the survey was performed by different nurses at the three clinics. The first author assisted in the recruitment and data collection at Clinic I. All semi-structured interviews were conducted by the first author.

Quantitative measurement

Demographics

Demographic information such as patients' age, the number of people in their household, educational level, and occupation was gathered at the beginning of the survey.

Patient experience items

Four items addressing patient experiences with the diagnostic evaluation of cancer were selected from a national survey previously conducted on the general population and cancer patients in Norway [36]. The national survey aimed to explore different conditions and challenges in the healthcare services for cancer patients. The items used were: 1. "Did you find that your GP gave you satisfactory information about what was going to happen related to the diagnostic evaluation of possible prostate cancer?", 2."Did you find the waiting time from hospital referral until first attendance acceptable?", 3."Did you find that the referring doctor/GP and the hospital worked well together?" and, 4."Were you told what you thought was necessary regarding how examinations would be conducted?" Participants responded on a five-point Likert scale (1 representing "not at all" and 5 representing "to a very large extent") with an additional option of "not relevant." A higher score indicated a more satisfying experience for each variable [36].

The hospital anxiety and depression scale

The Hospital Anxiety and Depression Scale (HADS) was developed as a screening instrument for assessing the likelihood of anxiety disorders and depression among patients in non-psychiatric hospital clinics. The scale consists of two subscales that each produce a score of 0–21. One scale assesses anxiety (HADS-A) while the other assesses depression (HADS-D). Together, the two subscales constitute HADS-T with a score from 0–42 [37]. The most optimal balance between sensitivity and specificity as a screening instrument for the two subscales was previously found to be a cut-off score of 8 + for patients with possible anxiety or depression [38]. Therefore, a cut-off score of ≥ 8 was used in the present study. HADS' ability to identify possible distress is well described in the literature [39]. The Norwegian version of the HADS has been validated by Leiknes et al. [39].

Qualitative interviews

An interview guide was developed by the research team to obtain an in-depth understanding of the patients' experiences with received information and possible distress in the diagnostic phase of PCa within both groups. The questions in the interview guide were designed to elaborate on the questions in the questionnaire, with three topics as focal points. These topics addressed consultations with the GP, consultations and communication with healthcare providers at the urological outpatient clinic, and possible distress (Table 1). At the beginning of each interview, the patients were encouraged to talk about their experiences from the time of the PSA test or Stockholm3 test until they received their biopsy result. The first author asked additional questions when elaboration was needed and only used the interview guide to ensure that all themes were discussed during the interview. The interviews lasted between 20 and 52 min.

Analysis

The quantitative data from the PSA group and the Stockholm3 group were statistically compared. The qualitative results for each of the two groups were subsequently compared before the results from both quantitative and qualitative analyses were merged.

Quantitative analysis

Initially, a power calculation was performed for an independent samples t-test and the required sample size was estimated to be 100 participants in each group to reach a power of 80% to detect a standardized difference of 0.4 with a two-sided significance level of 5%. The aim was increased to 120 in each group, to accommodate the ordinal nature of the outcomes and non-parametric testing [40].

The statistical analysis was performed using ordinal logistic regression. Descriptive methods were used to summarize the general characteristics of the participants and the distribution of the patient experience items using frequencies and percentages. Pearson's chi-squared test was used to assess whether there was a statistically significant difference between the PSA group and the Stockholm3 group with regard to the categorical variables. Ordinal logistic regression was employed to compare the PSA group and the Stockholm3 group for each of the four dependent variables concerning patient experiences, while adjusting for age, living alone (yes/no) and education. The resulting odds ratios represent the relative odds of answering in a higher rather than lower category on the scales, in the Stockholm3 group vs. the PSA group. The proportional odds assumption was checked for all ordinal regression analyses using a likelihood ratio test, and all *p*-values were > 0.05. Binary logistic regression was conducted to compare proportions of potential anxiety and/or depression in the two groups. All odds ratios are presented with 95% confidence intervals and *p*-values from Wald tests. *P*-values ≤ 0.05 were considered statistically significant. Descriptive statistics and plots were produced using SPSS v. 26 and regression analysis was performed in Stata v. 16.1.

Table 1 The semi-structured interview guide

Regarding contact with the general practitioner (GP)
What caused you to contact your GP?
What information did you receive from your GP about the tests and blood tests that were performed?
What information did you get from your GP if examinations were performed?
What information did you get from your GP about how examinations would be performed?
What information did you get from the GP of what would happen in the future?
What information did you get from your GP about your consultation at the urological outpatient clinic?
What information did you miss from your GP?
Regarding contact with the urological outpatient clinic
What information about your health condition have you received from a doctor/nurse at the urological outpatient clinic?
What information did you receive on examinations and blood samples that have been performed, possibly scheduled for you?
What information did you receive about examinations performed/possibly planned for you?
What information did you receive about what should happen in the future?
What information did you miss from the doctor/nurses at the urological outpatient clinic?
Experienced anxiety and worries during the diagnostic phase of prostate cancer
Why did you get a PSA[a]/Stockholm3 test?
How did you experience the time until you received the result of the PSA/Stockholm3 blood test?
How did you experience the time until the scheduled biopsy at the urological outpatient clinic?
How did you experience the time until you received the biopsy result?
What emotions arise when you think about prostate cancer?
What do you think of the future?

[a] *PSA* Prostate-specific antigen

Qualitative analysis

The interview data were analyzed using Systematic Text Condensation (STC) [41]. STC consists of four steps: 1) Read the material to gain an overall impression and evoke preliminary themes, 2) Establish code groups (CG) from preliminary themes and identify meaning units that reflect the participant's experiences of information, knowledge and distress, 3) Generate subgroups from the code groups and develop a condensate from the content in each subgroup and identify illustrating quotes, and finally 4) Synthesize condensates into conceptual descriptions [41]. The interview data from the two groups were analyzed separately.

Based on the notion that analysis benefits from collaboration, the full transcripts were distributed among the research team in order to create a wider analytic space [41]. After the team read the transcripts, preliminary themes and code groups were negotiated during several rounds of discussion. Each round was entered in an analysis journal. Subsequently, the first author identified meaning units and developed sub-categories, and categories, and after further negotiation in research team meetings, the final descriptions were presented to the research team. See Table 2 for a selected part of the analysis.

Comparison

After STC was performed separately for each participant group, the final step of comparing themes and identifying key similarities and differences between the two groups was conducted. These findings were based on relevance, prevalence, and perceived importance of the data [42]. Themes and descriptions from both groups were compared systematically and constantly balanced against aim and context. Matrixes were used to organize descriptions of themes in order to establish an overview while identifying similarities and differences [43]. After comparing themes, the similarities and differences were discussed within the research team and the description was further adjusted according to the aim of the study until consensus was reached.

Rigor

Comparison between groups in qualitative research can add rigor and transferability to findings and facilitate the identification of key ingredients in the change that makes a difference [43]. Establishing confidence in qualitative data depends on qualifications, experience, and reflexivity among the researchers [44]. The research team had a multidisciplinary composition, which strengthened the process of reflexivity during the analysis. The team consisted of two researchers in nursing science with extensive experience with qualitative research, a specialist nurse in a PhD fellowship, and an experienced former GP with quantitative research experience. All members of the research team had previous experience with patients affected by cancer. The first author had former experience as a cancer coordinator for bladder and kidney cancer in the urological department. This position was located on another floor, but involved some contact with staff in clinic I. This previous experience provided important insight into the diagnostic phase of PCa, but it was important for us to prioritize uncovering preconceptions throughout the whole process of inquiry.

Merging the results

The separate results from the quantitative analysis and the qualitative analysis are merged to form the discussion. This step includes identifying common concepts across the results to determine if the results from the two sets of analyses confirm, disconfirm, or expand on each other [31]. The first author did the preliminary merging of the results, and after several rounds of evaluation, an editing agreement was reached between all authors.

Results

In general, the PSA group and the Stockholm3 group were similar with respect to demographic characteristics, with no statistically significant differences (Table 3).

Demographic characteristics of the qualitative interview sample are presented in Table 4.

Quantitative results

Figure 4 summarizes the frequencies in percentages of the total for each of the four items. For item 1, 53.2% in the PSA group and 28.3% in the Stockholm3 group responded "not at all", "to a small extent", or "to some extent" satisfactory. For item 2, item 3, and item 4 over 75% of the patients in both groups responded "to a large extent" or "to a very large extent".

When comparing the two groups, the patients in the Stockholm3 group found the information provided by the GP more satisfactory than the PSA group (OR 2.61; 95% CI 1.59 to 4.28; $p < 0.001$) (item 1) (Table 5).

The Stockholm3 group also assessed the information they received regarding the further examination more sufficient (OR 1.85; 95% CI 1.10 to 3.11; $p = 0.020$) (item 4). No statistically significant differences were found regarding acceptance of waiting time from hospital referral until first attendance (item 2) ($p = 0.55$). Likewise, no statistically significant differences were found regarding how well the GP and the hospital worked together (item 3) ($p = 0.47$) (Table 5).

According to HADS, approximately 14% of the men in the PSA group and 15% of the men in the Stockholm3 group were at risk of developing anxiety (HADS-A). In the PSA group almost 4% of the men were at risk

Table 2 Selected parts of the qualitative analysis

Preliminary themes	Meaning units	Code groups (CG)	Condensate	Themes
Fluctuating quality and quantity of information during the diagnostic phase of PCa	But it was in relation to the fact that the GP could have been a little more [forthcoming] before, uh, before, uh, before we started to get the results. Like what they mean and such, for the only thing he said was "We will send a referral", and I did not ask very much either, because actually I did not really know exactly what I should ask about (Stockholm3, ST247)	The level of information about the PSA, the Stockholm3 test and PCa depends on the individual healthcare providers (CG1)	He told me it was a special blood test that was sent to Stockholm. My GP told me it was a more accurate and safe test, compared to the PSA test, so I was happy … I received my Stockholm3 test result in a letter, it was slightly elevated, but what does that mean, could it be serious? My GP just called me and Informed me that he would refer me for further examinations (Stockholm3)	Information affects the experience of comprehension
	I wondered a little about being called in [to have a CT scan], you know, I did not get, you know, the invitation letter, with contrast fluid. It was sent by post and it had the wrong address because they did not have the same system as the Ward here had (Stockholm3, ST301) Yes, they have been very accessible. Very good and, as I said, very informative. They have been approachable and very friendly all of them [health care providers] (Stockholm3, ST207)	Predictability and adequate information are important for men's satisfaction and sense of security (CG2)	At first, I was told that they would not do any examinations at the hospital, then suddenly I received an appointment for a MRI, it was a little contradictory. Then they scheduled a biopsy as if suddenly there was an opening it came a little abruptly. There was a glitch in the system it was as if the order did not quite add up (Stockholm3) The Healthcare providers have been very welcoming and nice. They have explained things to me so that I was well prepared before examinations and not left in ignorance. I feel that they have taken care of me in a very professional manner (Stockholm3)	Stepping into the world of the healthcare system
Periodic distress and potential anxiety	In my youth, cancer… cancer was of course synonymous with death then. Now I am quite old, but when I was in my younger years, then there was no help or assistance or drugs. Cancer cures were not very successful at that time. If you got cancer, then as a rule you died. So some of that stays in my old mind, even though I know that things are going the opposite way today with most forms of cancer (PSA[a], ID40)	Men's experience of distress varies individually. (CG3)	I was very anxious before my first appointment at the urological outpatient clinic. It was not just because of the suspected PCa but rather a fear of pain and the unknown. Thoughts about PCa never left my consciousness, but I was never that worried (PSA[a])	Periodically feelings of distress

Table 3 Demographic characteristics of the total survey sample and the individual distribution for each clinic

	Prostate specific antigen (PSA)								Stockholm 3		
	All included		Clinic I		Clinic II		Clinic III		Clinic I		
	N	%	N	%	N	%	N	%	N	%	P*
Included	130	100	47	36.2	37	28.5	46	35.4	120	100.0	
Age group	130		47		37		46		117[a]		0.189
41–50	4	3.1	0	0.0	2	5.4	2	4.3	1	0.9	
51–60	21	16.2	7	14.9	6	16.2	8	17.4	16	13.7	
61–70	66	50.8	23	48.9	23	62.2	20	43.5	61	52.1	
71–80	31	23.8	16	34.0	6	16.2	9	19.6	37	31.6	
81–90	8	6.2	1	2.1	0	0.0	7	15.2	2	1.7	
Living alone	130		47			37		46	118[a]		0.546
Yes	20	15.4	8	17.0	5	13.5	7	15.2	15	12.7	
No	110	84.6	39	83.0	32	86.5	39	84.8	103	87.3	
Education (higher degree)	117[a]		40[a]		36[a]		41[a]		110[a]		0.446
Yes	39	33.3	21	52.5	10	27.8	10	24.4	42	38.2	
No	78	66.7	19	47.5	26	72.2	31	75.6	68	61.8	
Occupation	130		47		37		46		118[a]		0.534
Employed	56	43.1	18	38.3	21	56.8	17	37.0	39	33.0	
Domestic worker	1	0.8	0	0.0	1	2.7	0	0.0	1	0.9	
Disability pension	3	2.3	2	4.3	0	0.0	1	2.2	3	2.5	
Rehabilitation	2	1.5	1	2.1	0	0.0	1	2.2	1	0.9	
Retired	63	48.5	25	53.2	15	40.5	23	50.0	72	61.0	
Under education	4	3.1	0	0.0	0	0.0	4	8.7	2	1.7	
Other	1	0.8	1	2.1	0	0.0	0	0.0	0	0.0	

[*] Pearson's chi-squared test

[a] Some data missing

of developing depression, while almost 7% in the Stockholm3 group were at risk of developing symptoms of depression (HADS-D). About 8% were at risk of both (HADS-T) (Additional file 3). No statistically significant differences were found between the PSA group and the Stockholm3 group in terms of anxiety and depression (Table 5).

Qualitative results

The STC analysis of the two groups resulted in three main themes with associated subthemes. The themes were systematically compared and the analysis reflected both differences and similarities between the two groups (see Table 6). The themes included "Information affects the experience of comprehension", "Stepping into the world of the healthcare system", and "Periodically feelings of distress". For the theme "Periodically feelings of distress", the analysis did not reveal any clear differences between the experiences of men in the Stockholm3 group compared to the PSA group. Accordingly, the results for this theme are presented together.

Theme 1: Information affects the experience of comprehension

The theme describes how patients in both groups experienced the information they received from their GP. The quality and amount of information affected how patients were prepared for the diagnostic process. The theme encompasses three subthemes: initial introduction, a more accurate test, and receiving the test result.

Initial introduction

The two groups described considerable differences in how the PSA and the Stockholm3 test were introduced to them. Most patients in the PSA group reported that they had received little or no initial information about PSA or the potential implications of a PSA test. A participant explained:

> *'He [the GP] took a blood sample, uh I had no idea of what he was going to do with it' (PSA, ID30).*

For some patients, the lack of information led to bewilderment and frustration. In contrast, other patients indicated that they respected the GP's decision about the PSA test. Regardless of the initial amount of information,

Table 4 Demographic characteristics of the interview sample

	Prostate specific antigen ($n = 10$)	Stockholm3 ($n = 10$)
Age group		
41–50	0	1
51–60	1	2
61–70	6	4
71–80	3	3
People in the household		
1 person	3	3
2 persons	6	6
≥ 3 persons	1	1
Education (year after primary school)		
0–3	1	7
4–5	6	3
7–9	3	0
Occupation status		
Employed	4	6
Retired	5	4
On rehabilitation	1	0
Prostate cancer		
Yes	6	7
No	4	3

the decision was interpreted as an expression of the GP's care and professionalism. Upon further reflection, the GP's choice of not including them in the decision about the PSA test was suggested as a natural consequence of the GP- patient relationship. Patients who had knowledge of elevated PSA over time reported repeated consultations with their GP where the subject had been discussed and that they had received sufficient information about PSA.

The Stockholm3 group said that they had received initial information about the Stockholm3 test and identified it as a diagnostic test. They expressed satisfaction with receiving initial information, which appeared to be considered a natural part of the consultation. Despite patients being aware of the test, it often seemed more like a recommendation than the GP providing sufficient information that enabled patients to make an informed decision.

Men's perception of the diagnostic test

The comparison between the PSA group and the Stockholm3 group revealed very different perceptions of the diagnostic blood test that had been conducted. The main difference between the two groups was that the Stockholm3 group frequently characterized the Stockholm3 test as a more accurate test than the PSA test. This perception appeared to be initiated by the information provided by the GPs, who described the test as an extended and more trustworthy test. This is illustrated by the following patient's response:

> *'I guess I received information that they would do, well, a Stockholm test instead of the PSA because the Stockholm test seemed to be more accurate. So, if there was something there, they could catch it, and if there was nothing, then you avoided going through the whole process of setting off a huge mechanism [further diagnostic evaluation] and all that stuff. So, that's what I got from my GP' (Stockholm3, ST207).*

Receiving the test result

For patients in the PSA group who did not have knowledge of the test being performed, the elevated PSA test result came as a shock. Meanwhile, all patients in the Stockholm3 group expected to receive the test result and had considered the possibility of it being elevated. The amount of information patients received when their test results were presented differed within both groups. The information varied between a short message about the referral to the urological outpatient clinic to more thorough conversations about the test result. A patient remembered that his GP announced the Stockholm3 test result without further explanation:

> *'No, nothing else except that he would refer me to this place [the hospital] so they could take a biopsy, quite simply' (Stockholm3, ST267).*

Another participant stated that he received information about potential side-effects of treatment simultaneously with the test result, and also explained that his GP had told him about the risk of overdiagnosis:

> *'Yes, it might be that you, I would almost say, would be sexually incapacitated and you could get [urine] leakage and some such unpleasantness that they did not want you to get, so he [the GP] explained that' (PSA, ID40).*

In both groups, variations in the quality of information provided resulted in varying dispositions before entering the diagnostic phase of PCa. Nevertheless, the initial awareness of the Stockholm3 test seemed to generate a more comprehensible and clarified situation compared to the PSA group, which one average expressed more uncertainty about their elevated PSA test result.

Theme 2: Stepping into the world of the healthcare system

This theme refers to how patients experience the encounter with the healthcare system. Two subthemes emerged: 1) trying to keep track of the diagnostic process and 2)

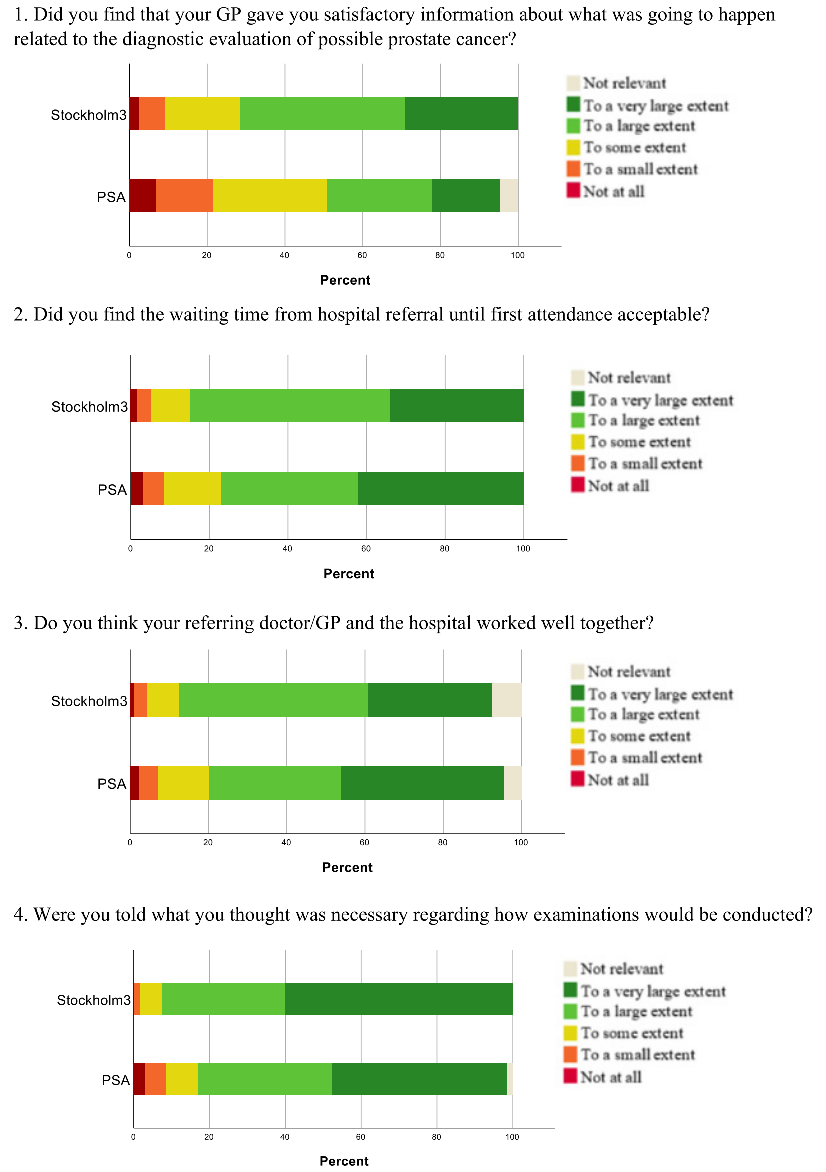

Fig. 4 The percentage distribution of the responses in each of the four items

Table 5 Results on the patient experience survey and HADS

	Unadjusted				Adjusted[a]			
	N	*OR*	95% CI	*P*	N	*OR*	95% CI	*P*
Did you find that your GP gave you satisfactory information about what was going to happen related to the diagnostic evaluation of possible prostate cancer?	244	*2.45*	1.54—3.90	< 0.001*	221	*2.61*	1.59—4.28	< 0.001*
In your opinion, were you given the information you needed regarding the examination and how it would be done?	248	*1.87*	1.15—3.05	0.011*	224	*1.85*	1.10—3.11	0.020*
Did you find that the referring doctor/GP and the hospital cooperated well?	235	*0.90*	0.47—1.40	0.66	211	*0.83*	0.49—1.38	0.47
Did you find the waiting time from hospital referral until first attendance acceptable?	250	*0.95*	0.60—1.51	0.83	226	*0.50*	0.28—0.89	0.55
Anxiety (HADS[b])	245	*1.11*	0.55—2.25	0.77	222	*1.05*	0.94—1.17	0.40
Depression (HADS[b])	246	*1.79*	0.57—5.63	0.32	223	*1.87*	0.58—6.02	0.30
Anxiety and depression (HADS[b])	246	*1.09*	0.44—2.73	0.85	223	*1.16*	0.45—2.98	0.76

* Wald tests, *p*-values ≤ 0.05

[a] Adjusted for age, education and living alone (yes/no)

[b] HADS = Hospital Anxiety and Depression Scale

receiving information and care at the urological outpatient clinic.

Trying to keep track of the diagnostic process

In general, patients in both groups appeared impressed or grateful to the Norwegian healthcare system, which they experienced as taking responsibility when it really mattered. However, patients in the PSA group seemed more inclined to report delayed or mixed up responses and consultations from the urological outpatient clinic. Patients in both groups referred to this as system errors in the communication pathway. The diagnostic phase of PCa was mostly considered to be well planned and without too much waiting time. Patients in both groups seemed somewhat puzzled because they did not know about the rapid diagnostic investigation, which could cause a discrepancy between the desire for diagnosis clarification and worries about a serious illness. They expressed that they were lucky when consultations were scheduled fast or they had received cancelled consultations. Furthermore, the patients had speculations about the fact that cancer was a serious illness and had to be given priority over less serious illnesses. In contrast to the PSA group, some men in the Stockholm3 group believed that their Stockholm3 test implied that the diagnostic process was accelerated:

> *'Well, so actually it is quite impressive that, uh, uh, I don't know, so it is based on me being involved in research [Stockholm3] or something like that. I come to the doctor and get information: You will be examined and first there is the MRI [Magnetic resonance imaging], it takes no more than 14 days, actually. And it didn't. Then I went to have an MRI and the next day, then I got a phone call from the hospital, can you come and have an ultrasound today, quarter past one? Nothing further, but in fact am I seriously ill? What is it that makes that I, uh, that it happens so fast?' (Stockholm3, ST226).*

Some patients in both groups recognized the rapid diagnostic process as a part of the SCP.

Receiving information and care at the urological outpatient clinic

Patients identified consultations with the urologists as important time points for gaining information, whereas nurses had a more flexible role with more contact points in terms of disseminating personalized information. For example, these contact points could be conversations by phone with the coordinating nurse or receiving information from a nurse before and after the biopsy. The nurses could also mediate additional contact between the patients and the urologist. The healthcare providers were generally described as helpful, friendly, and professional. More specifically, the urologists were referred to as proficient in their job and the nurses as caring and skilled in conveying information. These competencies were perceived as important to ensure a safe and trusting environment for patients. A patient from the PSA group stated:

> *'I feel that I am being extremely well looked after by the people [healthcare providers] who organise this and I think that inspires confidence and so I can relax and think: "Yeah, yeah, they know what they are doing and know their job" ' (PSA, ID38).*

The PSA and the Stockholm3 group received written information from the hospital that was sent by mail, as well as oral information from a nurse prior to the biopsy. The perception and need for written information varied

Table 6 Summary of thematic differences and similarities

Themes	Subthemes	Differences/ similarities	Prostate-specific antigen (PSA)	Stockholm3
1. Information affects the experience of comprehension	Initial introduction	Differences	Several patients reported that they had no initial information before the PSA test. Patients with several previous PSA tests often expressed that they had received sufficient information from their GP	All patientss reported that they had received some initial information before the Stockholm3 test
	Men's perception of the diagnostic test	Differences	Patients explained that an elevated PSA was not always to be trusted. Besides prostate cancer, an elevated PSA could be a sign of infection or an enlarged prostate gland	In general, patients perceived the Stockholm3 test as a more accurate test. It was described as a medical progress
	Receiving the test result	Differences	For some patients, the elevated PSA level came as a shock because they were unaware of the test in the first place	Patients were aware of the Stockholm3 test and were prepared to receive the test result
		Similarities	The information patients received varied from being informed about a referral for further diagnostic evaluation to more comprehensive information	
2. Stepping into the world of the healthcare system	Trying to keep track of the diagnostic process	Differences	Patients were more inclined to report errors and delayed responses from the hospital	Overall, men were satisfied with the communication with the hospital. However, they did report some errors and delayed responses Some men believed that the fast and well organized diagnostic process was because they had agreed to the Stockholm3 test
		Similarities	In general, patients described the diagnostic phase of prostate cancer as well organized and fast, without too much unnecessary waiting. Not all patients identified the fast process as a part of the standardized care pathway, which made some patients worry about being seriously ill	
	Receiving information and care at the urological outpatient clinic	Similarities	Most patients described the healthcare providers as professional and caring. However, patients had very different needs for information; some required more detailed written and oral information both before and after the biopsy. The healthcare providers did not always identify these needs	
3. Periodically feelings of distress		Similarities	Patients did not experience pervasive anxiety. However, most men described times with worries or anxiety. The word "cancer" was associated with death. For some, anxiety became more prominent when the results of the biopsy approached. Others described both physical and psychological discomfort. It seemed that some patients found it difficult to explain or identify their different emotions during the diagnostic phase of prostate cancer	

within patients in both groups. Patients considered the information to be short and precise without causing unnecessary anxiety and implied that they did not have a need for detailed information. Some even deliberately did not pay attention to the written information, while others just skimmed through it:

> *'Yes, I remember, I believe I read [the information], I believe that I probably read it through, so browsed it and then read a little ... (sighs), but I remember nothing now (chuckles)' (PSA, ID36).*

The reason for not reading the information carefully was that both groups believed that the healthcare providers told them what they needed to know regarding the biopsy. In contrast, some patients in both groups requested more detailed information and appeared less satisfied with the written information, which they believed failed to prepare them for what to expect during and after the biopsy. They also requested more oral information, especially about bowel leakage during the biopsy and prolonged bleeding after the biopsy. Patients in both groups requested more detailed information about sensitive issues, for example, blood in their semen.

Theme 3: Periodically feelings of distress

This theme relates to the emotions and distress that could arise during the diagnostic phase of PCa. The strength of different emotions seemed to vary between patients and depend on individual assumptions or knowledge about PCa. There were no differences in emotional reactions between the two test groups, but rather some variations within the whole group of patients, regardless of test type.

The cancer diagnosis confronted patients with an immediate possibility of death, which could manifest in episodes of fear of death or catastrophic thoughts. A patient spontaneously declared:

> *'Well, it is straight to the little white box [casket], isn't it? To me, cancer means death, you know, but of course it is not. So, "off the bat", what cancer means to me, it means "Game Over". I mean, doesn't it?' (PSA, ID36).*

Episodes of distress emerged in different situations, sometimes in solitude at night.

> *'Clearly, when you have gone to bed a short while before the wife comes up [to bed], then you have thought: "Goodness, what if it is the beginning of the end, like?" ' (Stockholm3, ST233).*

Regardless of periodic feelings of distress, it was a common perception that the diagnostic phase of PCa was not associated with anxiety, but rather was something underlying that could not be entirely ignored. Patients expressed that they had felt anxious right before receiving the biopsy result. It seemed that the emotions experienced in the diagnostic phase could be difficult to identify or separate and therefore also difficult to explain.

Discussion

In the present study, the quantitative and the qualitative results are merged and presented in a narrative discussion that organizes the quantitative and qualitative results side by side within a section of text [28]. The quantitative results showed that men in the Stockholm3 group were more likely to find the information from the GP more sufficient than men in the PSA group. These findings are supported by the qualitative results.

The Stockholm3 group was more than twice as likely (OR = 2.61) as the PSA group to find the information from the GP sufficient. During the interviews, several men in the PSA group explained that they had received little or no initial information about the PSA test. In contrast, patients from the Stockholm3 group had received initial information about the Stockholm3 test. Surprisingly, both groups seemed to find the GP's behaviour natural, which may indicate that the patients trusted their GP's judgement and his/her authority regardless of the initial information. The interaction between patients and doctors has previously been identified as complex and influenced by professional authority, which should be recognized during consultations [45]. Despite individual differences in information needs, none of the patients in the present study indicated having received too much information. This suggests that the information from healthcare providers was typically valued and appreciated and did not cause unnecessary distress.

Patients in the Stocholm3 group seemed more inclined to have confidence in the accuracy of their diagnostic test than men in the PSA group. This might suggest that the mandatory patient questions included in the Stockholm 3 algorithm supports more dialogue between the patient and the GP before the test is conducted. This is an important finding as previous research has shown that many patients are tested without having received adequate information or having made a shared decision as recommended [46]. A review found that public controversies regarding the PSA test caused some patients to feel confused and uncertain about the accuracy and reliability of the PSA test [47]. Kannan et al. 2019 reported that men in general did not fully understand what a PSA test entailed and some men were not familiar with the term PSA [19]. Another study found that less than 30% of patients received sufficient information about the accuracy of PSA and the risks and benefits of different PCa treatments [48].

There were no statistically significant differences between the groups regarding acceptance of waiting time from hospital referral until first attendance. This corroborates the qualitative results for the same theme. Errors that could cause delay and confusion were reported in both groups, while rapid diagnostic evaluations also made patients wonder about its urgency. This was in line with findings in a previous study, which found patients with suspected cancer may associate rapid diagnostic evaluation with individual diagnosis and prognosis and not as a part of the SCP, which possibly increased their worries [49].

The Stockholm3 group were more likely than the PSA group to state that they had received sufficient information regarding examinations when attending the outpatient clinic (OR = 1.85 [CI 1.10, 3.11], $p < 0.05$). However, the qualitative findings revealed no differences between the two groups. Patients in both groups expressed varied needs for information, from wishing as little information as possible to requesting detailed information. Wade et al. 2015 [50] found that when information about side-effects and sequelae differed from the actual experience, men tended to get more anxious and frustrated with the pre-biopsy information. Distress has been reported to be common after a prostate biopsy and is possibly caused by multiple factors, including the experience of the procedure, waiting for the result, uncertainty, and aspects of personality [27]. In the present study, the patients explained that nurses could be reached outside scheduled consultations and could thereby provide additional and more personalized information. Nurses also facilitated contact or information between the urologists and the patients if needed. Access to information has been identified as central for patients in order to manage uncertainty throughout the PCa pathway and in their evaluation of care. Good quality of care for PCa patients involves sufficient information, recognition of patients' feelings, and effective and timely communication between the different healthcare providers [51].

Our study found no statistically significant differences between the two groups in terms of anxiety and depression. Approximately 14% of the patients in the PSA and 15% in the Stockholm3 group, who were awaiting a prostate biopsy at the outpatient clinic, experienced anxiety. Patients in both groups reported very similar experiences and did not appear to experience any significant anxiety, but periodic distress was common. Our findings emphasize that patients' emotions and possible distress in the diagnostic phase are idiosyncratic, complex, of an inconsistent nature, and independent of the diagnostic test performed. The measurement of anxiety may be complicated further as patients may not define their emotions as anxiety or worry but still experience psychological distress that affects their wellbeing. Correspondingly, a review found that anxiety in patients affected by PCa appeared to vary over the clinical timeline [52]. Another study reported that 41% of men awaiting a biopsy result showed some degree of distress with anxiety being more dominant in those men [53]. Patients in the diagnostic phase of PCa are a group at risk of psychological distress, and some patients may benefit from additional support and information [24, 54]. Nurses and doctors have an important role to play in identifying patients affected by distress and providing tailored information and support.

Strengths and limitations

In this study, trailing research was found to be appropriate to study patients' experiences with the diagnostic phase of PCa. Furthermore, the design enables the use of different methods [29]. The intent of the convergent mixed methods design is that the quantitative and qualitative methods complement each other [28]. In this study, the qualitative results elaborated on the quantitative results. Therefore, the conclusions that are presented may be considered more robust than they otherwise would have been should only one analytic approach have been used in isolation [55]. Ideally, all data should have been collected from Clinic I, but due to the rapid introduction of the Stockholm3 test, two more clinics were added to complete the data collection. Although the three clinics had similar procedures according to the SCP and adhered to the same health trust, local differences must be expected, which could have affected the results at each clinic. In addition, the novelty of the Stockholm3 test may have affected the information provided by the GPs. Another limitation is that we have no report of how many patients declined to participate in the study. The results should be considered in the context of this limitation. In future research, one should attempt to repeat the data collection in a single clinic and in a larger scale.

When using comparison groups, homogeneity of demographics characteristics should be pursued as much as limitations allow [43]. The two groups differed in age and education, but were otherwise very similar. The composition of the two groups may have affected the findings. Since the comparison groups explore similarities and differences within a particular context and in the nature of qualitative research, the results may not be generalizable. In qualitative research, the researcher might influence the interview unconsciously, but the research team tried to avoid biases by uncovering preconceptions both before and after the interviews. Despite limitations of the study, the quantitative and qualitative results complemented each other, which enhanced the overall validity of the study.

Conclusion

We found that men who had a Stocholm3 test had received more sufficient information from their GP compared to men who had a PSA test. Therefore, patients in the Stockholm3 group felt more prepared when they received the result of their diagnostic test. However, information about potential risks and benefits regarding diagnostic testing and side-effects of treatment for PCa seemed insufficient in both groups. The Stockholm3 test may facilitate the provision of information to patients; however, further research is needed to explore ways to enhance the amount of information received prior to and after a Stockholm3 test. In both groups, nurses were identified as a source of additional and more personalized information. Nurses have a critical position for providing additional support and mediate contact between urologists and patients. Routines that ensure more sufficient information should be a priority in order to provide patients with greater predictability and to avoid unnecessary distress. Patients at risk of psychological distress or anxiety may experience particular benefits from early detection and initiated actions.

Abbreviations

PSA: Prostate specific antigen; GRAMMS: Guidelines for reporting mixed-methods research; PCa: Prostate cancer; ERQCC: Essential Requirements for Quality Cancer Care; SCP: Standardized patient cancer pathway; GP: General practitioner; HADS: The Hospital Anxiety and Depression Scale; STC: Systematic Text Condensation; CG: Code group.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12912-022-01047-1.

Additional file 1. Good Reporting of A Mixed Methods Study (GRAMMS*) Checklist.

Additional file 2. Counts and percentages of patients with different response categories to the four patient experience items in the PSA^{a}group (n=130) and the Stockholm3 group (n=120).

Additional file 3. Counts and percentages of patients with scores above threshold levels for the Hospital Anxiety and Depression Scale in the PSA^{a}group (n=130) and the Stockholm3 group (n=120).

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Authors' contributions

MEJS, SEH, KL and SRK contributed to the design, data analysis, and manuscript drafting. MEJS was involved in the data collection. ID contributed to statistical and analytical parts. All authors approved the final draft of the manuscript before submission.

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Availability of data and materials

The dataset analysed during the current study is available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Norwegian Regional Committees for Medical and Health Research Ethics (REK no. 2017/71) and the hospital administrations at the three clinics. The participants received both oral and written information about the study and were guaranteed confidentiality. Participation was voluntary and participants were informed that they had the right to withdraw from the project at any time. All participants signed an informed consent before completing the questionnaire and before the individual interviews started.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Author details

[1]Department of Surgery, Stavanger University Hospital, Postboks 8100, 4068, Stavanger, Norway. [2]Research Group of Nursing and Healthcare Sciences, Stavanger University Hospital, Postboks 8100, 4068, Stavanger, Norway. [3]Faculty of Health Sciences, University of Stavanger, Kjell Arholms Hus, postboks 8600, 4036, Stavanger, Norway. [4]Department of Research, Section of Biostatistics, Stavanger University Hospital, Postboks 8100, 4068 Stavanger, Norway. [5]The General Practice and Care Coordination Research Group, Stavanger University Hospital, Postboks 8100, 4068, Stavanger, Norway.

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Publisher's Note

Paper III

Title page

Title: Associations between patient characteristics, psychological distress, and coping in the diagnostic phase of prostate cancer: A cross-sectional multicentre study

Maja Elisabeth Juul SØNDERGAARD[a,b,c], MSc, RN; Svein Reidar KJOSAVIK[c,d], PhD, MD; Sissel Eikeland HUSEBØ[b,c], PhD, RN; Ingvild DALEN[e] PhD, Kirsten LODE[b,c], PhD, RN;

Authors affiliations:

[a]Department of Surgery, Stavanger University Hospital, Stavanger, Norway

[b]Research Group of Nursing and Healthcare Sciences, Stavanger University Hospital, Stavanger, Norway

[c]Faculty of Health Sciences, University of Stavanger, Stavanger, Norway

[d]The General Practice and Care Coordination Research Group, Stavanger University Hospital, Stavanger, Norway

[e]Department of Research, Section of Biostatistics, Stavanger University Hospital

Correspondence:

[1]Maja Elisabeth Juul Søndergaard, MSc, RN, Department of Surgery, Stavanger University Hospital, Postboks 8100, 4068 Stavanger, Norway. Telephone: +4552701820 (MEJ_Sondergaard@outlook.dk)

ORCID

Maja E.J. Søndergaard http://orcid.org/0000-0003-4610-1651

Svein Reidar Kjosavik http://orcid.org/0000-0002-7004-5533

Sissel Eikeland Husebø http://orcid.org/0000-0001-5053-5730

Ingvild Dalen https://orcid.org/0000-0002-8160-3211

Kirsten Lode http://orcid.org/0000-0001-8322-9457

This paper is not included in the repository, because it is still in review.

Appendices

Appendix 1 – Interview guide used in studies I and II

Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

HELSE STAVANGER
Stavanger universitetssjukehus

Intervju guide for doktorgradsprosjektet

«Pasienters erfaring og tilfredshet ved utredning av mulig prostatakreft ved urologisk poliklinikk»

En delstudie i forskningsprosjektet fra PSA til STHLM3

Vedrørende kontakt med fastlege/allmennlege:

- Hva var årsaken til at du tok kontakt med fastlegen?
- Hvilken informasjon fikk du av fastlegen om prøver og blodprøver som ble utført?
- Hvilken informasjon fikk du av fastlegen om resultatet av prøver og blodprøver?
- Hvilken informasjon fikk du av fastlegen dersom undersøkelser ble utført?
- Hvilken informasjon fikk du av fastlegen om hvordan undersøkelser skulle foregå?
- Hvilken informasjon fikk du av fastlegen av hva som skal skje fremover?
- Hvilken informasjon fikk du av fastlegen angående din konsultasjon ved urologisk poliklinikk?
- Hvilken informasjon savnet du fra fastlegen din?

Vedrørende kontakt med urologisk poliklinikk / spesialisthelsetjenesten:

- Hvilken informasjon om din helsetilstand har du mottatt av lege/sykepleier ved urologisk poliklinikk?
- Hvilken informasjon fikk du om prøver og blodprøver som er tatt, evt. er planlagt for deg?
- Hvilken informasjon fikk du om undersøkelser som er utført/evt. er planlagt for deg?
- Hvilken forklaring har du fått på hva som skal skje fremover?
- Hvilken informasjon savnet du fra urologisk poliklinikk fra lege/sykepleier?

Erfaring med engstelse og bekymring under utredningen for prostatakreft

- Hvorfor fikk du tatt en PSA/STHLM3 blodprøve?
- Hvordan opplevde tiden frem til svaret på PSA/STHLM3 blodprøven kom?
- Hvordan opplevde du tiden frem til timen på poliklinikken og en eventuell biopsi ble tatt?
- Hvordan opplevde du tiden frem til biopsisvar?
- Hvilke følelser oppstår når du tenker på prostatakreft?
- Hva tenker du om fremtiden?

Appendix 2 – Questionnaire studies II and III

Spørreskjemaundersøkelsen

«Pasienters erfaringer og mestring ved utredning av mulig prostatakreft ved urologisk poliklinikk»

HELSE STAVANGER
Stavanger universitetssjukehus

Bakgrunnsdata

Sett ett kryss

1. Hvor mange personer bor i husstanden din?

Jeg bor alene	☐ 1
Vi er 2 personer	☐ 2
Vi er 3 personer eller flere	☐ 3

2. Stort sett, vil du si at din helse er:

Utmerket	☐ 1
Meget god	☐ 2
Nokså god	☐ 3
God	☐ 4
Dårlig	☐ 5

3. Hva gjør du til daglig?

Er yrkesaktiv	☐ 1
Er hjemmearbeidende	☐ 2
Er uføretrygdet	☐ 3
Er sykemeldt – på attføring	☐ 4
Er pensjonist	☐ 5
Er under utdanning	☐ 6
Annet	☐ 7

4. Hvor mange år har du gått på skole/tatt utdanning etter at du var ferdig med obligatorisk grunnskole?

(Obligatorisk grunnskole = 0, alle årene etter grunnskolen legges sammen)

Antall år ____

5. Hvem hadde du time hos da du besøkte poliklinikken?

Lege	☐ 1
Sykepleier	☐ 2
Fysioterapeut	☐ 3
Ernæringsfysiolog	☐ 4
Vet ikke	☐ 5

6. Hvor gammel er du?

Under 31 år	☐ 1
31-40 år	☐ 2
41-50 år	☐ 3
51-60 år	☐ 4
61-70 år	☐ 5
71-80 år	☐ 6
81-90 år	☐ 7
91 år eller mer	☐ 8

Spørsmål om erfaringer med utredning av mulig prostatakreft

Nedenfor følger noen spørsmål om egne erfaringer med utredning av mulig prostatakreft. Vennligst sett ett kryss for hvert spørsmål.

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
7	Opplevde du at fastlegen ga deg tilfredsstillende informasjon om hva som skulle skje i forbindelse med utredning for mulig prostatakreft?						
8	Var ventetiden fra du ble henvist til sykehus og til du møtte der første gang akseptabel?						
9	Opplevde du at henvisende lege/fastlege og sykehuset samarbeidet bra?						
10	Opplevde du at samarbeidet internt på sykehuset var bra?						
11	Fikk du vite det du syntes var nødvendig om hvordan undersøkelser skulle foregå?						

Her kommer noen spørsmål om hvorledes du føler deg. For hvert spørsmål setter du kryss for ett av de fire svarene som best beskriver dine følelser den siste uken. Ikke tenk for lenge på svaret – de spontane svarene er best.

1. Jeg føler meg nervøs og urolig	**7. Jeg kan sitte i fred og ro og kjenne meg avslappet**
☐ 3 Mesteparten av tiden ☐ 2 Mye av tiden ☐ 1 Fra tid til annen ☐ 0 Ikke i det hele tatt	☐ 0 Ja, helt klart ☐ 1 Vanligvis ☐ 2 Ikke så ofte ☐ 3 Nesten ikke i det hele tatt

2. Jeg gleder meg fortsatt over tingene slik jeg pleide før	**8. Jeg føler meg som om alt går langsommere**
☐ 0 Avgjort like mye	☐ 3 Nesten hele tiden
☐ 1 Ikke fullt så mye	☐ 2 Svært ofte
☐ 2 Bare lite grann	☐ 1 Fra tid til annen
☐ 3 Ikke i det hele tatt	☐ 0 Ikke i det hele tatt
3. Jeg har en uroføelse som om noe forferdelig vil skje	**9. Jeg føler meg urolig som om jeg har sommerfugler i magen**
☐ 3 Ja, og noe svært ille	☐ 0 Ikke i det hele tatt
☐ 2 Ja, ikke så veldig ille	☐ 1 Fra tid til annen
☐ 1 Litt, bekymrer meg lite	☐ 2 Ganske ofte
☐ 0 Ikke i det hele tatt	☐ 3 Svært ofte
4. Jeg kan le og se det morsomme i situasjoner	**10. Jeg bryr meg ikke lenger om hvordan jeg ser ut**
☐ 0 Like mye som før	☐ 3 Ja, jeg har sluttet og bry meg
☐ 1 Ikke like mye nå som før	☐ 2 Ikke som jeg burde
☐ 2 Avgjort ikke som før	☐ 1 Kan hende ikke nok
☐ 3 Ikke i det hele tatt	☐ 0 Bryr meg som før
5. Jeg har hodet fullt av bekymringer	**11. Jeg er rastløs som om jeg stadig må være aktiv**
☐ 3 Veldig ofte	☐ 3 Uten tvil svært mye
☐ 2 Ganske ofte	☐ 2 Ganske mye
☐ 1 Av og til	☐ 1 Ikke så veldig mye
☐ 0 En gang i blant	☐ 0 Ikke i det hele tatt
6. Jeg er i godt humør	**12. Jeg ser med glede frem til hendelser og ting**
☐ 3 Aldri	☐ 0 Like mye som før
☐ 2 Noen ganger	☐ 1 Heller mindre enn før
☐ 1 Ganske ofte	☐ 2 Avgjort mindre enn før
☐ 0 For det meste	☐ 3 Nesten ikke i det hele tatt
13. Jeg kan plutselig få en følelse av panikk	**14. Jeg kan glede meg over gode bøker, radio og TV**
☐ 3 Uten tvil svært ofte	☐ 0 Ofte
☐ 2 Ganske ofte	☐ 1 Fra tid til annen
☐ 1 Ikke så veldig ofte	☐ 2 ikke så ofte
☐ 0 Ikke i det hele tatt	☐ 3 Svært sjelden

Måter å mestre på

Hensikten med dette spørreskjemaet er å finne ut hvor belastende det er for deg å utredes for mulig prostatakreft.

Opplever du din nåværende situasjonen som: (Sett bare ett kryss)

☐ Truende

☐ Tap

☐ Skadelig

☐ Utfordring

☐ Godartet

Når du tenker på din nåværende situasjon der du utredes for mulig prostatakreft, er dette vanligvis en situasjon som:
(Dersom du setter flere kryss sett en ring rundt det som du mener best beskriver situasjonen)

a. du kan gjøre noe med?	☐ JA	☐ NEI
b. bare må godtas eller som en må vende seg til?	☐ JA	☐ NEI
c. du trenger å vite mer før du kan handle?	☐ JA	☐ NEI
d. du må avstå fra å gjøre det du har lyst til?	☐ JA	☐ NEI

Nedenfor står en rekke setninger som hver beskriver forskjellige måter å mestre belastninger på som det å være under utredning for mulig prostatakreft. Ut fra hver enkel setning bes du om å sette en sirkel rundt det tallet som passer best i din situasjon.

	Passer ikke, ikke brukt	Brukt en del	Brukt ganske mye	Brukt svært mye
1. Du prøver å inngå en slags avtale eller overenskomst for å få noe positivt ut av situasjonen.	0	1	2	3
2. Du snakker med noen for å finne ut mer om situasjonen.	0	1	2	3
3. Du klandrer deg selv.	0	1	2	3
4. Håper at det vil skje et under.	0	1	2	3
5. Later som om ingenting har hendt.	0	1	2	3
6. Prøver å se det positive i det hele; aldri så galt at det ikke er godt for noe.	0	1	2	3
7. Skulle ønske du var sterkere,- mer optimistisk og hadde mer krefter.	0	1	2	3
8. Syntes det var synd at du ikke kunne unngå problemet.	0	1	2	3
9. Forsøker å ikke brenne alle broer, men lar flere muligheter stå åpne.	0	1	2	3
10. Tar imot sympati og forståelse fra noen.	0	1	2	3
11. Ønsker at du kunne forandre det som har skjedd.	0	1	2	3
12. Forsøker å holde følelsene dine for deg selv.	0	1	2	3
13. Forandrer deg eller vokser som menneske på en god måte.	0	1	2	3
14. Ønsker du kunne forandre måten din å føle på.	0	1	2	3
15. Legger en handlingsplan og følger den.	0	1	2	3
16. Får hjelp av fagfolk.	0	1	2	3
17. Kritiserer eller sier til deg selv hva du burde ha gjort.	0	1	2	3
18. Godtar det som er det nest beste i forhold til det du egentlig hadde ønsket.	0	1	2	3
19. Dagdrømmer eller tenker deg inn i en bedre tid eller til et bedre sted enn den/der du er nå.	0	1	2	3
20. Kommer sterkere og bedre rustet ut av hendelsen enn du gikk inn i den.	0	1	2	3
21. Sover mer enn vanlig.	0	1	2	3

	Passer ikke, ikke brukt	Brukt en del	Brukt ganske mye	Brukt svært mye
22. Har fantasier eller ønsker om hvordan det skal gå til slutt.	0	1	2	3
23. Forsøker å la være å handle overilt eller følge din første innskytelse.	0	1	2	3
24. Snakker med noen som kan gjøre noe med problemet	0	1	2	3
25. Tenkte på noe fantastisk eller utrolig som kunne skje (slik som hevn eller at du vant en million) som fikk deg til å føle deg bedre.	0	1	2	3
26. Gjør en forandring slik at det vil gå bra til slutt.	0	1	2	3
27. Blir sint på den, det eller de som er skyld i problemet.	0	1	2	3
28. Tar en ting av gangen.	0	1	2	3
29. Forsøker å glemme det hele.	0	1	2	3
30. Du vet hva som må til og øker innsatsen ytterligere for at alt skal ordne seg.	0	1	2	3
31. Spør en slektning eller en venn du respekterer om råd.	0	1	2	3
32. Forsøker å få det bedre ved å spise, drikke, røyke, ta medisiner e.l.	0	1	2	3
33. Finner fram til flere forskjellige løsninger på problemet.	0	1	2	3
34. Innser at du selv har skapt problemet.	0	1	2	3
35. Unngår å være sammen med andre mennesker.	0	1	2	3
36. Godtar følelsene mine, men forsøker å unngå at de virker for mye inn på andre ting.	0	1	2	3
37. Ønsker at situasjonen skulle bli borte eller på et eller annet vis gå over av seg selv.	0	1	2	3
38. Lar ikke andre få vite hvor ille det er.	0	1	2	3
39. Forandrer noe ved deg selv så du takler situasjonen bedre.	0	1	2	3
40. Snakker med noen om hvordan du har det.	0	1	2	3
41. Nekter å tro at det har hendt.	0	1	2	3
42. Står på ditt og kjemper for det du vil.	0	1	2	3

Takk for at du tok deg tid til å delta på denne undersøkelsen!

Appendix 3 – Ethical approval

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK vest	Camilla Gjerstad	55978499	01.03.2017	2017/71/REK vest
			Deres dato:	
			10.01.2017	

Vår referanse må oppgis ved alle henvendelser

Svein Reidar Kjosavik
Kompetansesenter for aldersmedisin og samhandling

2017/71 Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

Forskningsansvarlig: Karolinska Institutet, Helse Stavanger HF - Stavanger universitetssjukehus
Prosjektleder: Svein Reidar Kjosavik

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK vest) i møtet 09.02.2017. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale
I dag brukes i hovedsak PSA som grunnlag for videre henvisning til utredning for prostatakreft. PSA har imidlertid lav sensitivitet og spesifisitet. STHLM3-testen er et nyutviklet testbatteri for oppdaging av prostatakreft. Forskning har vist at testen er mer sensitiv og mer spesifikk enn PSA alene. Helse Stavanger skal i 2017 endre praksis. Formålet med prosjektet er å analysere effektene av å innføre STHLM3-testen i ordinær klinisk praksis. Hovedstudien vil inkludere om lag 8000 menn mellom 50 og 69 år som har tatt STHLM3-testen. Studien vil sammenlikne pasientdata før og etter innføring av testen. For de historiske kontrollene vil man bruke aggregerte eller anonymiserte journaldata. En delstudie vil undersøke pasientenes erfaringer og tilfredshet (spørreskjema) og hvilke erfaringer pasienter har med veiledning (intervju) ved utredning før og etter innføring av STHLM3-test.

Vurdering
Forsvarlighetsvurdering
Komiteen mener at studien har et viktig forskningsformål og anser studien som forsvarlig å gjennomføre.

Informasjonsskriv
Det er utviklet tre ulike informasjonsskriv (til hhv. hovedstudien, intervju og spørreskjema). REK vest har følgende merknader til skrivet til hovedstudien:

- Skrivet må informere om dato for prosjektslutt og sletting av data.
- Komiteen forstår søknaden slik at deltakerne vil få et egen informasjonsskriv om lagring av prøvene i den generelle biobanken SolidTH. Informasjonsskrivet om biobanken må sendes til REK vest.

Fritak fra samtykke i hovedstudien, hfl § 35
For pasientgruppen som har tatt STHLM3 -test og som kun følges opp videre hos egen lege, søkes det opp til å benytte testresultater uten innhenting av samtykke fra pasientene. Studien ønsker videre å undersøke hvor mange pasienter den enkelte fastlege har tatt PSA-prøve av, både før og etter rutineendring. Opplysninger fra bl.a. sykehuslaboratoriet og uttrekk av data fra journal vil bli koblet. For de historiske data ønskes anonymiserte eller aggregerte data. Prosjektleder peker på at det er vanskelig å innhente samtykke og

at krav om samtykke kan gi stort frafall. For at helseopplysninger innsamlet i helse- og omsorgtjenesten skal kunne benyttes i forskning uten samtykke, må kravene i helseforskningsloven § 35 være oppfylt. Fritak fra samtykke kan kun innvilges dersom det er vanskelig å innhente samtykke, forskningen er av vesentlig interesse for samfunnet, og hensynet til deltakernes velferd og integritet er ivaretatt. Komiteen mener lovkravene er oppfylt i studien og innvilger fritak etter hft § 35, samt fritak fra informasjonsplikten, jf. personopplysningsloven § 20.

Biobank
Biologisk materiale (blodprøve, biopsi) som samles inn i studien vil bli lagret i en tidligere godkjent generell forskningsbiobank kalt SolidTH, ansvarshavende Emiel Janssen. REK vest forstår det slik biopsien innhentes uavhengig av studien som en del av diagnostikken, og at deltaker får et egen skriv om prøver til lagring i den generelle biobanken. REK vest har ingen merknader til dette.

Prosjektslutt
Kliniske data og analyseresultater vil bli anonymisert ved prosjektslutt 31.12.27. Prøver innsamlet i den generelle forskningsbiobanken vil bli oppbevart videre. REK vest har ingen innvendinger til dette.

Vilkår

- Informasjonsskrivet til hovedstudien må revideres og sendes til REK vest.
- Informasjonsskrivet til den generelle biobanken SolidTH må sendes til REK vest.

Vedtak
REK vest godkjenner prosjektet på betingelse av at ovennevnte vilkår tas til følge.

Sluttmelding og søknad om prosjektendring
Prosjektleder skal sende sluttmelding til REK vest på eget skjema senest 30.06.2028, jf. hfl. § 12. Prosjektleder skal sende søknad om prosjektendring til REK vest dersom det skal gjøres vesentlige endringer i forhold til de opplysninger som er gitt i søknaden, jf. hfl. § 11.

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

Med vennlig hilsen

Marit Grønning
Prof. dr.med
Komiteleder

Camilla Gjerstad
rådgiver

Kopi til:henrik.gronberg@ki.se; forskning@sus.no; biobankregisteret@fhi.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK vest	Anna Stephansen	55978496	24.05.2017	2017/71/REK vest
			Deres dato:	
			09.05.2017	

Vår referanse må oppgis ved alle henvendelser

Svein Reidar Kjosavik
Kompetansesenter for aldersmedisin og samhandling

2017/71 Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

Forskningsansvarlig: Karolinska Institutet, Helse Stavanger HF - Stavanger universitetssjukehus
Prosjektleder: Svein Reidar Kjosavik

Vi viser til søknad om prosjektendring datert 09.05.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatsleder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Vurdering
Ømsøkte endringer gjelder:

oppdatering av spørreskjema og intervjuguide samt et nytt skjema der pasienten blir bedt om å tegne en grafisk fremstilling av hvordan stress/bekymringsnivået har vært gjennom de ulike fasene av utredningen for mulig prostatakreft.

Tittelen på prosjektprotokoll ble omformulert til: 'Anxiety, stress and coping among men who receive a STHLM3-answer compared to those who receive a PSAanswer in screening for prostatic cancer'.

Vurdering
REK vest forstår det slik at det ikke er noen endringer i formålet med prosjektet dvs. at undersøkelse av tilfredsstillelse og erfaringer i søkerens forstand ligger nært hverandre. REK vest vurderer det slik at det er presiseringer og ikke endringer av tema for studien som beskrives i endringsmeldingen.

REK vest har merket seg at det er mer omfattende endringer i den nye prosjektprotokollen enn det som er merket i rødt og ber søkeren om å være presis på endringer som er gjort i dokumentet i fremtiden.

Vedtak
REK vest godkjenner prosjektendringen i samsvar med søknad.

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

Med vennlig hilsen,
Anna Stephansen
Kontorsjef

Kopi til: *henrik.gronberg@ki.se; forskning@sus.no*

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK vest	Camilla Gjerstad	55978499	01.12.2017	2017/71/REK vest
			Deres dato:	**Deres referanse:**
			15.11.2017	

Vår referanse må oppgis ved alle henvendelser

Svein Reidar Kjosavik
Kompetansesenter for aldersmedisin og samhandling

2017/71 Fra PSA til STHLM3, ny praksis for utredning av prostatakreft

Forskningsansvarlig: Karolinska Institutet, Helse Stavanger HF - Stavanger universitetssjukehus
Prosjektleder: Svein Reidar Kjosavik

Vi viser til søknad om prosjektendring datert 15.11.2017 for ovennevnte forskningsprosjekt. Søknaden er behandlet av nestleder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Prosjektendring
Det søkes om å utvide datagrunnlaget for delprosjektet som skal danne grunnlag for en PhD for sykepleier Maja Søndergaard. Man ønsker å kunne inkludere pasienter henvist på bakgrunn av PSA-svar til urologisk avdeling ved Haugesund sjukehus. Dette er for at man kan få et godt nok datagrunnlag for analysene.

Det søkes også om endring i skjemaene for visuell analog scoring av opplevd stess/angstnivå. Endringen består kun i en mer utfyllende tekst om hvordan skjemaene skal fylles ut. Ellers er skjemaene tilsvarende og med samme hensikt som det REK tidligere har godkjent.

Vurdering
REK vest har vurdert endringssøknaden og har ingen merknader.

Vedtak

REK vest godkjenner prosjektendringen i samsvar med forelagt søknad.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Ketil Joachim Ødegaard
dr.med. nestleder

Camilla Gjerstad
rådgiver

Kopi til: *forskning@sus.no*

Besøksadresse:
Armauer Hansens Hus (AHH),
Tverrfløy Nord, 2 etasje. Rom
281. Haukelandsveien 28

Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Camilla Gjerstad	55978499	11.06.2019	2017/71/REK vest
			Deres dato:	
			29.05.2019	

Vår referanse må oppgis ved alle henvendelser

Svein Reidar Kjosavik
Forskningsgruppe for allmennmedisin og samhandling

2017/71 Fra PSA til STHLM3, ny praksis for utredning av prostatakreft

Forskningsansvarlig: Karolinska Institutet, Helse Stavanger HF - Stavanger universitetssjukehus
Prosjektleder: Svein Reidar Kjosavik

Vi viser til søknad om prosjektendring datert 29.05.2019 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Prosjektendring
Endring i rekrutteringsprosedyre: Det har vært mer utfordrende enn forventet å få rekruttert tilstrekkelig antall pasienter til studien (100 tilsammen). Prosjektgruppen har derfor etablert et samarbeid med Urologisk poliklinikk ved Haukeland universitetssjukehus i tillegg. En har avtalt med HUS at de skal samle inn 40 spørreskjema fra pasienter som er under under utredning for prostatakreft hos dem. I opprinnelig søknad ble det estimert at man trenger minst 100 spørreskjema fra pasienter som utredes for prostatakreft for å kunne utføre nødvendige statistiske analyser. Siden diagnostiseringsrutinene for pasienter med prostatakreft ved SUS er endret til en Stockholm3 testen istedenfor PSA, er det ikke mulig å gjennomføre spørreskjemaundersøkelsen ved SUS.
Det er ingen andre endringer i prosjektplanene, dvs. alle andre forhold er som tidligere godkjent.

Vurdering
REK vest ved leder har vurdert endringssøknaden og har ingen merknader.

Vedtak
REK vest godkjenner prosjektendringen i samsvar med søknad, med hjemmel i helseforskningsloven § 11.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK vest. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK vest, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

Marit Grønning
Prof. dr. med
komitéleder

Camilla Gjerstad
rådgiver

Besøksadresse:
Armauer Hansens Hus (AHH), Tverrfløy Nord, 2 etasje. Rom 281. Haukelandsveien 28

Telefon: 55975000
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK vest og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK vest, not to individual staff

Kopi til: *post@sus.no*

Fra: <noreply@rekportalen.no>
Dato: 3. oktober 2019 kl. 14:38:48 CEST
Til: <svein.kjosavik@sus.no>
Emne: Svarbrev
Svar til: <noreply@rekportalen.no>

Alle skriftlige henvendelser om saken må sendes via REK-portalen
Du finner informasjon om REK på våre hjemmesider rekportalen.no

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK vest	Fredrik Kolstad Rongved	55978498	03.10.2019	25580
			Deres referanse:	

Svein Reidar Kjosavik

25580 Fra PSA til STHLM3, ny praksis for utredning av prostatakreft

Forskningsansvarlig: Helse Stavanger HF - Stavanger universitetssjukehus

Søker: Svein Reidar Kjosavik

REKs vurdering

Vi viser til søknad om prosjektendring datert 20.09.2019 for ovennevnte forskningsprosjekt. Søknaden er behandlet av sekretariatet for REK vest på fullmakt, med hjemmel i helseforskningsloven § 11.

Ønsket endring:

Prosjektleder ønsker å bytte sykepleiere som skal bistå prosjektgruppen med datainnsamling ved urologisk poliklinikk på Haukleland Universitetssjukehus. Nye medarbeidere er navngitt i endringsmelding datert 20.09.2019. Revidert informasjonsskriv med navn på de nye medarbeiderne er lagt ved.

Vurdering:

REK vest har ingen innvendinger mot ønsket endring.

Vedtak

Godkjent

REK vest godkjenner prosjektendringen i samsvar med forelagt søknad, med hjemmel i helseforskningsloven § 11.

Med vennlig hilsen
Fredrik Rongved
rådgiver

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

Appendix 4 – Information letter studies I and II

HELSE **STAVANGER**
Stavanger universitetssjukehus

Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKT

«Pasienters erfaring ved utredning av mulig prostatakreft ved urologisk poliklinikk» en delstudie i forskningsprosjektet fra PSA til STHLM3

Dette er et spørsmål til deg om å delta i et doktorgradsprosjekt ved Stavanger universitetssjukehus (SUS). Hensikten med dette arbeidet er å utforske hvilke erfaringer pasienter har med informasjon og veiledning i forbindelse med utredning for mulig kreftsykdom i prostata.

Siden du er blitt henvist til urologisk poliklinikk ved SUS håper vi at du er villig til vil bidra med dine erfaringer med mottatt informasjon og veiledning i utredningsfasen slik at vi får mer kunnskap om hvilke behov for informasjon og veiledning menn som utredes for prostatakreft har.

Forskningsansvarlig håper at funnene som fremkommer fra studien vil bidra til økt kunnskap om hvilken informasjon og veiledning menn som utredes for prostatakreft har behov for og at helsetjenesten vil forbedre sine helsetjenester på dette grunnlag.

HVA INNEBÆRER PROSJEKTET?

Velger du å delta vil du etter avtale bli intervjuet av en forsker. For å kunne gjengi intervjuet korrekt, vil det tas opp på en lydfil og lagres. Intervjuet vil deretter skrives ned og bearbeides til anvendelse i studien. Intervjuet vil ta ca. 1 time. Informasjon om tidspunkt for intervju vil avtales med forskningsansvarlig etter at du har samtykket til å delta i studien.

MULIGE FORDELER OG ULEMPER

Det er ingen spesielle fordeler for deg forbundet med denne studien, men du vil kanskje synes at det er litt slitsomt å svare på alle spørsmålene. Dersom du føler deg sliten og uopplagt, er det anledning til å ta en pause til du føler for å fortsette.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet og deltakelse i studien medfører ingen ekstra kostnader for deg og du får ingen betaling for å delta. Om du sier ja til å delta, undertegner du samtykkeerklæringen på siste side.
Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke uten at det vil ha konsekvenser for din nåværende eller fremtidige behandling ved sykehuset.

Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte
Maja Søndergaard på telefon 974 08 397 eller epost maja.elisabeth.juul.sondergaard@sus.no eller hennes veileder **Sissel E. Husebø på telefon 958 97 983 eller epost** sissel.i.husebo@uis.no

HVA SKJER MED INFORMASJONEN OM DEG?

Lydbåndopptakene av intervjuene blir behandlet konfidensielt og avidentifisert og vil bli lagret på eget område på sykehusets forskningsserver som er sikret med forskningsansvarlig sitt brukernavn og passord. Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Alle lydfiler og transkripsjoner av intervjuene vil bli slettet 31.12.2022.

Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk,
Referanse nummer REK (2017/71/REK vest).

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Tlf. nr.	Deltakers signatur

Sted og dato	Deltakers navn med trykte bokstaver

Appendix 5 – Information letter studies II and III

Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

HELSE STAVANGER
Stavanger universitetssjukehus

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKT

«Pasienters erfaring og mestring ved utredning av mulig prostatakreft ved urologisk poliklinikk» en delstudie i forskningsprosjektet fra PSA til STHLM3

Dette er et spørsmål til deg om å delta i et doktorgradsprosjekt ved Stavanger universitetssjukehus (SUS). Hensikten med dette arbeidet er å kartlegge pasienters erfaring og mestring ved utredning for mulig kreftsykdom i prostata ved urologisk poliklinikk.

Siden du er blitt henvist til urologisk poliklinikk ved SUS håper vi at du er villig til vil bidra med dine erfaringer i utredningsfasen slik at informasjon og veiledning av pasienter i denne fasen kan forbedres.

HVA INNEBÆRER PROSJEKTET?

Om du velger å delta ber vi deg om å fylle ut et spørreskjema mens du er på urologisk poliklinikk. Det vil ta ca. 15 minutter å besvare spørsmålene. Dersom du ønsker å ta med deg spørreskjemaet hjem for fylle det ut, er det vedlagt en frankert konvolutt som du kan bruke for å returnere spørreskjemaet til urologisk poliklinikk.

MULIGE FORDELER OG ULEMPER

Det er ingen spesielle fordeler for deg forbundet med denne studien, men du vil kanskje synes at det er litt slitsomt å svare på alle spørsmålene. Dersom du føler deg sliten og uopplagt, er det anledning til å ta en pause til du føler for å fortsette.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet og deltakelse i studien medfører ingen ekstra kostnader for deg og du får ingen betaling for å delta. Om du sier ja til å delta, undertegner du samtykkeerklæringen på siste side.
Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke uten at det vil ha konsekvenser for din nåværende eller fremtidige behandling ved sykehuset.

Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte
Maja Søndergaard på telefon 974 08 397 eller epost maja.elisabeth.juul.sondergaard@sus.no eller hennes veileder **Sissel E. Husebø på telefon 958 97 983 eller epost sissel.i.husebo@uis.no**

HVA SKJER MED INFORMASJONEN OM DEG?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Det vil ikke være mulig å identifisere deg i resultatene av doktorgraden når disse publiseres.

Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert.

Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Navnet ditt og kodelisten som kobler deg til spørreskjemaet oppbevares separat fra hverandre på Helse Stavanger sin forskningsserver.
Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten

Fra PSA til STHLM3, en ny rutine for utredning av prostatakreft

Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte. Perioden for lagring av data utgår 01.01.2022. Data lagret på PC vil da bli slettet, og alle data i papirform vil bli makulert sammen med de innsamlede spørreskjemaene.

GODKJENNING

Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk,
Referanse nummer REK (2017/71/REK vest).

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL Å DELTA I PROSJEKTET

Sted og dato	Deltakers signatur
	--
	Deltakers navn med trykte bokstaver