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Exploration of Supportive Care in Advanced Disease Prostate Cancer Survivors

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Table of Contents

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List of Tables

List of Figures

Abstract

According to the National Cancer Institute, in 2019, there were approximately 17 million cancer survivors in the United States, of whom 3.7 million were prostate cancer (PC) survivors. Due to an increase in life expectancy, extensive screening, and novel therapies, this number is expected to continue rising in the coming years. PC survivors in advanced stages (III, IV, or recurrent) are particularly prone to experience a wide range of harmful effects that stem from cancer and the many treatments they undergo during this cancer's long trajectory. Past research has highlighted the importance of implementing supportive care as a standard for cancer survivors due to its multiple benefits, such as reducing morbidity and improving both quality of life (QOL) and health outcomes. However, little is known about supportive care needs and implementation among this subset of survivors. This information is vital to inform future patient-centered, holistic supportive care strategies that aim to optimize this population's QOL and rehabilitation.

This dissertation work found robust guidance from the Supportive Care Framework for Cancer Care due to its comprehensive taxonomy and holistic view of the cancer continuum. The first manuscript explored the supportive care interventions available to men with advanced prostate cancer. Next, a holistic needs assessment in American advanced disease PC survivors was conducted using a mixed-methods approach in order to provide a more comprehensive picture of their perceived supportive care needs. Finally, an exploration of the existing barriers and facilitators to supportive care implementation was performed before taking the next step in this line of research.

The results of the three manuscripts included in this dissertation reported that advanced disease PC survivors suffer from unmet needs that affect every dimension of the individual. Existing supportive care interventions were promising but limited, focusing primarily on specific domains of needs. Implementing supportive care can only become a

standard of care if researchers and clinicians find ways to minimize identified barriers while they maximize facilitators.

Introduction

Over the last few decades, research and implementation of new cancer treatments have led to an increasing number of cancer survivors.[1] However, the need for effectively addressing the unmet supportive care needs in advanced disease prostate cancer (PC) survivors still exists. The incidence of PC varies globally. In the United States specifically, it remains the leading type of cancer, accounting for 21% of all cancers detected in males. One in eight men will develop PC in the course of their lives, up to 30% of whom will suffer from a recurrence or progression.[2] This trend will continue its ascending trajectory as direct results of a higher life expectancy, improvements in screening, and innovative treatments.[3] As the number of survivors increase, advanced PC has subsequently become a significant health and economic challenge for the American society and healthcare system.[4] Given the fact that 3.7 million PC survivors currently live in the United States and that they will most likely deal with the advanced PC effects for the remainder of their lives, it is essential to provide them with more cost-effective, holistic, and patient-centered supportive care that meets their current and future needs.[5]

Advanced PC Cancer Survivor

There are multiple definitions in the existing literature of what constitutes a PC survivor. In the past, general definitions of "cancer survivors" focused primarily on individuals who had completed curative treatment and were in remission or cured.[6] However, in 2013, the National Cancer Institute (NCI) presented the National Coalition of Cancer Survivors' more inclusive definition along with some survivorship guidelines, that were later endorsed by the National Comprehensive Cancer Network (NCCN). According to this new standard, the term "cancer survivor" refers to any individual with cancer "from the time of diagnosis, through the balance of his or her life."[7] Advanced PC survivors are considered

1

men with a diagnosis of regionally advanced (III), metastatic (IV), or recurrent/refractory PC, no matter their treatment status or the years that have passed since the initial diagnosis.[8]

Debilitating Disease Effects on Advanced PC Survivors

PC may follow an indolent course and be asymptomatic at the early stages (I and II) of the disease remaining that way for long periods of time, contributing to its chronic nature.[3,9] Precisely because of this natural long-term trajectory, survivors usually undergo several types of treatment throughout the course of the illness to control progression or alleviate ongoing symptoms.[10] Prostatectomy, androgen deprivation therapy, radiation, chemotherapy, and cryotherapy are the most usual treatments for advanced PC. These therapies' harmful effects are varied and noteworthy, including toxicity, urinary and bowel dysfunctions, impotence, decreased libido, hot flushes, fatigue, pain, weight changes, anxiety, depression, cognitive decline, and even increased risk for suicide.[1,11,12] Since survivors must continuously live with these effects, they are more susceptible to suffer from a lower quality of life (QOL) and develop long term supportive care needs that will require continued access to multidisciplinary supportive care.

Supportive Care Needs and Supportive Care

Although supportive care needs can be diverse, they are often needs arising from chronic illnesses such as cancer, the treatments, and the follow-up, at any time between the initial diagnosis and end of life.[13] Greater number of supportive care needs are often associated with an increased risk for morbidity and distress. Since the diagnosis of advanced cancer can affect the physical, psychological, spiritual, and social dimensions of the being, it can lead to more complex and overlapping supportive care needs in these survivors. In addition, the survivor may experience lack of information and practical issues that can make coping with this illness even more dismal.[13,14]

Supportive care has been used as a euphemism for palliative care in past literature.[15] While both are important aspects of cancer care, there are some differences between them. Palliative care refers to a subspecialty that focuses on issues that are frequently seen at the end of life.[15,16] According to the Multinational Association of Supportive Care in Cancer supportive care attempts to prevent and manage the adverse effects and associated needs of the cancer and treatment.[16,17] It is a patient-centered and holistic approach that ensures the provision of all necessary interventions to prevent further deterioration and optimizes both, rehabilitation and QOL.[13,14]

During the last decades, supportive care in cancer has gained momentum among researchers and healthcare providers alike. Several factors have contributed to accepting supportive care as the new benchmark to improve health outcomes and QOL in cancer survivors. Its multiple benefits—improved treatment-related health outcomes and QOL, reduced morbidity and mortality, and decreased healthcare resource usage—have made this approach an indispensable component of high-quality standard cancer care. Furthermore, the integration of supportive care services has been progressively regarded favorably as part of modern oncology.[17-19]

Quality of Life in Cancer Survivorship

There is no accepted definition of QOL. The World Health Organization defines QOL as the self-report of the individual's position in life in relation to their life expectations, goals, standards, and concerns.[20] It is a broad, multifaced, and subjective construct. Despite the variations, there is a consensus that QOL must include domains such as physical health, emotional/psychological functioning, social life, roles, and overall quality of life.[21] Specific to cancer survivorship, achieving a good QOL often means finding wholeness after the life-changing experience, which in turn restores a sense of purpose in life.[22]

Due to the steady rise in prostate and other cancer survivors, there has been an increasing interest in researching QOL in these populations.[23] QOL research emphasizes *how well* these survivors are living instead of how long.[21] Among its multiple important applications, QOL research data may be used to assess the needs and quality of supportive care received by advanced PC survivors who experience persistent or late effects of diverse treatments to guide patient-centered, holistic interventions.[21]

Theoretical Frameworks

Advanced PC survivors suffer from a wide variety of unmet supportive care needs that affect every dimension of the person. Although multiple theoretical foundations have been used in past cancer needs assessments, this dissertation work found robust guidance from Fitch's Supportive Care Framework for Cancer Care (SCFCC). This framework outlines a comprehensive taxonomy of seven domains of needs (i.e., physical, emotional, social, spiritual, informational, practical psychological), formulated to ensure that cancer survivors were cared for in a holistic manner from the time of diagnosis to the end of life (Figure 1).[13] This multidomain framework has a successful record of assessing the unmet needs of several advanced cancer survivors' populations, including breast and gynecological.[25,26] It has also guided supportive care intervention development in studies from the United States and abroad.[26]

The SCFCC domains of needs provided guidance for the three manuscripts of this dissertation in several ways: (1) defining the criteria for the article selection during the integrative and the scoping reviews, (2) selecting a validated instrument to measure the comprehensive set of unmet SC needs for the mixed methods study, (3) informing the qualitative interview guide development, (4) organizing the data of all three manuscripts, and (5) categorizing and interpreting the findings according to the framework seven domains of needs.
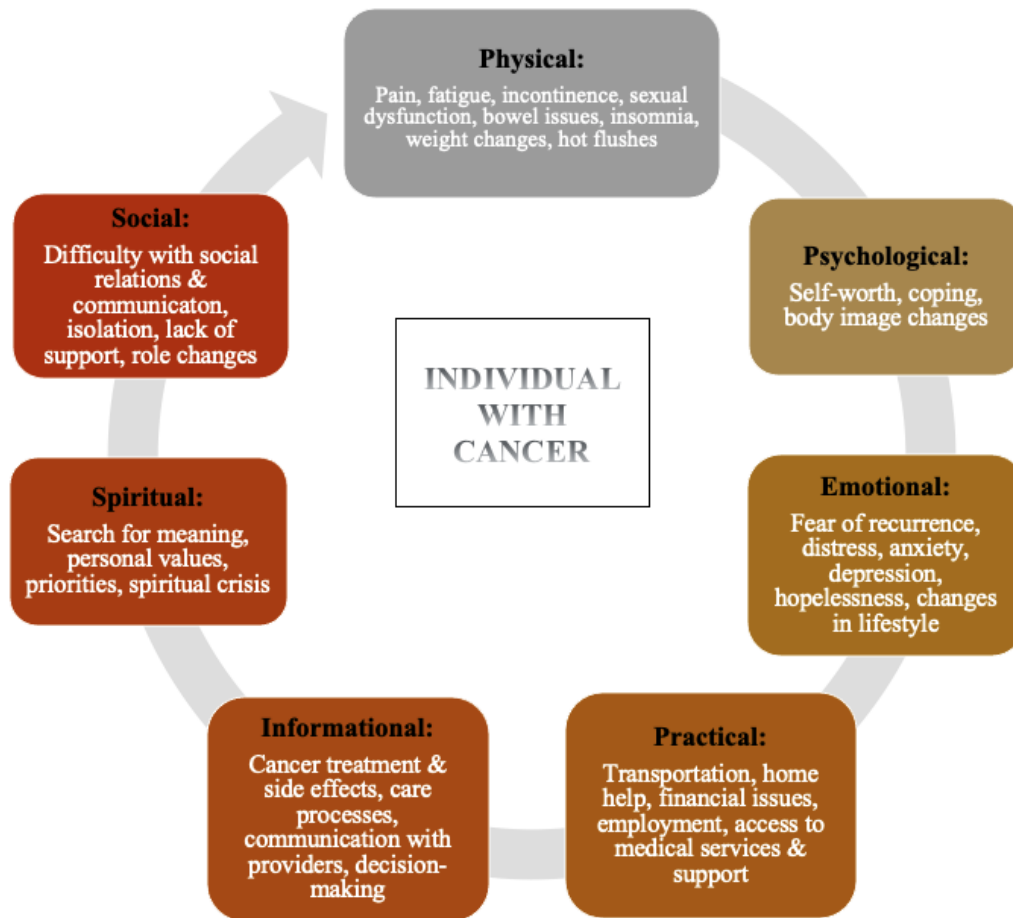
Figure 1: SCFCC Diagram Applied to Advanced PC Survivors (with permission)[15]

To complement the application of the SCFCC, this work also used the Theoretical Domains Framework (TDF) to explore the barriers and facilitators to supportive care implementation (manuscript 3). The TDF includes a schema derived from theory that assists with identifying behavioral factors that may affect the implementation of supportive care. This schema classifies the factors in 14 different domains: *Knowledge*; *Skills*; *Memory, Attention, and Decision Processes*; *Behavioral Regulation*; *Social/Professional Role and Identity*; *Beliefs About Capabilities*; *Optimism*; *Beliefs About Consequences*; *Intentions*; *Goals*; *Reinforcement*; *Emotions*; *Environmental Context and Resources*; and *Social Influences*. This theoretical foundation was appropriate for manuscript 3 because it has been

used in multiple previous literature reviews investigating barriers and facilitators of care implementation. The TDF structured the analysis and the categorization of the existing barriers and facilitators in implementing supportive care interventions among advanced PC survivors.[27-29]

Research Gaps

Following the recent publications of the American Society of Clinical Oncology survivorship agenda and the American Cancer Society survivorship guidelines, Jacobsen et al. reported that more research focusing on optimal supportive care for cancer survivors was needed.[10] This dissertation attempts to address several research gaps. First, current literature on supportive care interventions for advanced PC survivors is limited as most focuses on PC localized disease. Therefore, there was a need to synthesize the existing evidence with regards to the availability and effectiveness of these interventions in addressing the unmet supportive care needs and QOL in advanced PC survivors. Second, most reports on advanced PC have focused primarily on describing the survivors' experiences with the disease or on the results of piloting diverse psychosocial and exercise interventions.[12,30,31] Several holistic supportive care needs assessments have been conducted, reporting a wide range of unmet needs in a large proportion of advanced PC survivors.[1,16,32-34] However, none has been performed in American men specifically. Since many of these U.S. survivors are also at risk for a wide array of long-term needs, this was a necessary step to inform future design, development, and implementation of individualized, multidimensional, cost-effective supportive care interventions. And third, to better understand why supportive care is not being consistently delivered, it was essential to investigate the primary barriers and facilitators potentially affecting its implementation.[35,36] Altogether, these gaps have formed the premise for this dissertation work. The conclusions of the manuscripts have expanded the state of the science on supportive care for advanced disease PC survivors, directing special

attention to specific areas that have been recognized as essential to be addressed by future studies: common cancers aside from breast cancer, older populations (>65 years), long-term survivors, and QOL during survivorship.[10]

Manuscripts

This dissertation comprises three interrelated manuscripts contributing to supportive care in advanced PC survivors. The first manuscript, *Supportive Care Interventions and Quality of Life in Advanced Disease Prostate Cancer Survivors: An Integrative Review of the Literature,* initiated this work by critically appraising and characterizing the evidence-based supportive care interventions and their effects on QOL in this subset of survivors. The conclusion was that these types of interventions were needed but scarce. This conclusion led to the second manuscript, *Unmet Supportive Care Needs in Advanced Disease Prostate Cancer Survivors: A Mixed-Methods Exploration of the Prevalence and Association with Quality of Life,* which explored the unmet supportive care needs in advanced PC survivors living in the United States. Part of the study also identified a preliminary association between the prevalence of those unmet needs and QOL in this population. This work enhanced the understanding of supportive care needs and represents a necessary step before embarking on developing new holistic, patient-centered supportive care interventions. The third and last manuscript, *Barriers and Facilitators to Supportive Care Implementation in Advanced Disease Prostate Cancer Survivors: A Theory-Informed Scoping Review,* achieved a dual purpose. First, it helped identify commonly implemented supportive care interventions for advanced PC survivors in the sample of reviewed studies. Second, it synthesized the main barriers and facilitators to implementing those supportive care interventions among this subset of survivors in practice. This information is vital for continuing with this line of inquiry successfully. Developing and implementing novel supportive care interventions will

significantly depend on the ability to focus on the most prevalent needs, overcoming existing

barriers while maximizing facilitators.

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Manuscript 1

12

Supportive Care Interventions and Quality of Life in Advanced Disease Prostate Cancer Survivors: An Integrative Review of the Literature.

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Abstract

Background: Supportive care interventions can improve quality of life and health outcomes of advanced prostate cancer survivors. Despite the high prevalence of unmet needs, supportive care for this population is sparse.

Methods: The databases PubMed, SCOPUS, CINAHL, and ProQuest were searched for relevant articles. Data were extracted, organized by thematic matrix, and categorized according to the seven domains of the Supportive Care Framework for Cancer Care.

Results: The search yielded 1678 articles, out of which 18 were included in the review and were critically appraised. Most studies were cross-sectional with small, non-diverse samples. Supportive care interventions reported for advanced prostate cancer survivors are limited with some positive trends. Most outcomes were symptom-focused and patient self-reported (e.g., anxiety, pain, self-efficacy) evaluated by questionnaires or interview. Interventions delivered in group format reported improvements in more outcomes.

Conclusions: Additional supportive care intervention are needed for men with advanced prostate cancer. Because of their crucial position in caring for cancer patients, nurse scientists and clinicians must partner to research and develop, patient-centered, culturally relevant supportive care interventions that improve this population's quality of life and health outcomes. Efforts must concentrate on sampling, domains of needs, theoretical framework, guidelines and measurement instruments.

Prostate cancer (PC) is the most commonly diagnosed non-cutaneous malignancy in men, with more than 1.2 million new cases diagnosed every year worldwide. Due to favorable prognoses and advances in treatment, the number of PC survivors has progressively grown, amounting to more than 3.6 million in the United States alone (ASCO, 2019). Presently, there are variations in defining cancer survivors. According to the National Comprehensive Cancer Network, PC survivor refers to any man with a history of PC, from the time of the initial diagnosis until the end of life (Delinger et al., 2015). While the 5-year survival rate for early-stage PC is exceedingly high, once the disease has spread, the survival rate decreases to 30%, with higher illness-related mortality and morbidity than men with early-stage PC (Dickey & Ogunsanya, 2018; NCI, 2015). Most PC survivors receive the diagnosis in earlier stages of the disease, but up to one third will progress into regionally advanced (stage III) or metastatic (stage IV) disease, remaining treatable but no longer curable (Holm et al., 2018; PCEC, 2019). Men with stage III or IV PC are identified as "advanced disease survivors".

Men surviving PC report an array of overlapping supportive care needs associated with the debilitating effects of the various treatment modalities. These needs stem from pain, urinary incontinence, bowel and sexual dysfunction, fatigue, hot flashes, depression, and distress (Crawford-Williams, 2018). Advanced disease survivors are often treated with chemotherapy, androgen-deprivation therapy (ADT), or participation in clinical trials to slow progression or control disease (Jacobsen et al., 2017). While these treatments prolong life, they are associated with additional physical effects, such as treatment toxicity, deteriorating bone health, increased fat mass, and reduced vitality. Also, the treatment impacts can also increase the susceptibility for certain psychological problems, such as risk for suicide and cognitive decline. Altogether, these challenges affect advanced PC survivors' quality of life

(QOL) and functional well-being beyond their physical needs (Chambers et al., 2018; Darwish-Yassine et al., 2014).

In 2005, the Institute of Medicine recommended consistent, quality survivorship care for all cancer survivors (NRC, 2005). In 2014, the American Cancer Society published a set of PC survivorship guidelines, later endorsed by the American Society of Clinical Oncology to assist clinicians in caring for these survivors. The guidelines ensure uniformity and coordination of care through individualized interventions to meet the specific and often complex needs of PC survivors (Handberg et al., 2018; Noonan et al., 2016; Skolarus et al., 2014). Supportive care is a holistic, patient-centered approach to prevent and manage the side effects of the cancer and its therapies, with the goal of optimizing rehabilitation and QOL (Fitch, 2008). Despite the reported benefits, supportive care is delivered inconsistently due to reduced clinician time, insufficient evidence on optimal care delivery modes, and providers' lack of knowledge about survivors' specific needs (Post & Flanagan, 2016).

Literature on PC survivors covers diverse topics, such as available psychosocial interventions or unmet supportive care needs while undergoing specific treatments (Holm et al., 2018; McIntosh et al., 2019; Parahoo et al., 2013). A systematic review and qualitative synthesis by King et al. (2015) that explored men' experiences of and needs for supportive care, reported that more patient-centered, nurse-led supportive care is required. A separate systematic review by Crawford-Williams et al. (2008) identified that survivorship interventions did not address the real needs of this vulnerable population. Recent studies show that 33% to 81% of PC survivors report inadequate support for their unmet needs (King et al., 2015; Watson et al., 2016).

Due to the high prevalence of unmet needs among PC survivors, an apparent lack of adequate supportive care, and the underrepresentation of the topic in the literature, a synthesis of the available supportive care interventions and their effect on QOL is needed. Thus, the

15

aim of this integrative review was to critically appraise and characterize existing evidence-based supportive care interventions and their effects on QOL for advanced disease PC survivors through the lens of the Supportive Care Framework for Cancer Care (SCFCC) (Fitch, 2008). Results of this review may assist clinicians caring for this population and better inform future intervention development according to the current practice guidelines and recommendations.

Methods

Theoretical Framework and Application to Population

The SCFCC was initially formulated as a tool to help healthcare providers ensure that cancer patients' supportive care needs were being met throughout the various stages of illness, including survivorship (Fitch, 2008). The framework outlines a comprehensive taxonomy of seven domains of needs. The physical domain encompasses an absence of physical symptoms and the ability to carry out normal daily activities (ADL) (Fitch, 2008). Common adverse effects of advanced PC, measured as outcome indicators within this domain, include body composition, physical activity, fatigue, and urinary dysfunction, which impact QOL negatively (Dickey & Ogunsanya, 2018; Park et al., 2017; Shakeri et al., 2015). For example, up to 38.5% of advanced disease PC survivors report clinically relevant fatigue affecting overall well-being (Antolin et al., 2019).

The emotional domain relates to a sense of reassurance in times of distress (Fitch, 2008). Advanced disease PC survivors face many emotional unmet needs, including depression, anxiety, distress, fear of recurrence, or lifestyle changes due to the illness and the various treatments, which can lead to a lower overall QOL (Paterson et al., 2015). The need for information relates to improving decision-making and decreasing misunderstanding between survivors and providers (Fitch, 2008; Freire et al., 2014).

Cancer affects not only the patient but also the family and the community, potentially leading to higher levels of social withdrawal, a commonly reported unmet need. Positive social roles and support are indicators of higher health-related QOL in many cancer survivors, including PC (Shakeri et al., 2015). The same is true for the practical domain. Leaving practical needs unattended can reduce the survivors' overall QOL as they are a supporting vehicle to perform their usual ADL (Fitch, 2008; Park et al., 2017).

Advanced PC can often generate spiritual distress, leading to despair, suffering, and existential crises. The spiritual domain relates to a sense of purpose in life (Fitch, 2008). Unmet spiritual needs could lead to a loss of dignity and values, as the spiritual dimension of QOL is commonly a priority in people s' lives (Freire et al., 2014). The psychological domain relates to coping with the disease (Fitch, 2008). Past evidence has outlined the relationship between coping styles and psychological-related QOL (Park et al., 2017).

This multidomain framework has been used successfully in past studies assessing the unmet needs of breast and gynecological cancer survivors (Fitch & Steel, 2010; Fitch, 2012). It has also guided supportive care and educational oncology interventions in the U.S. and abroad (Busolo & Woodgate, 2016; Cheah et al., 2016). The SCFCC guided criteria for article selection, extraction and organization of data during analysis, and presentation of findings for this review, according to the framework domains of needs.

Design and Search Strategy

To ensure the highest rigor, this integrative review followed the five-stage process proposed by Whittemore and Knafl (2005). This process includes problem identification, literature search, data evaluation, data analysis, and presentation. The search strategy was designed after consulting with an expert research reference librarian. A comprehensive literature search was performed in the following electronic databases: PubMed, SCOPUS, CINAHL, and ProQuest, following an identical format. Key words included: (*advanced-*

disease OR *advanced-stage* OR *late-disease* OR *late-stage* OR *metastatic* OR *stage III* OR *stage IV)* AND (*prostate cancer* OR *prostate neoplasm* OR *prostate tumor)* AND (*interventions* OR *intervention).* Hand searching of studies' reference lists identified additional records for evaluation.

Inclusion and Exclusion Criteria

Studies were eligible if they were peer-reviewed, and reported quantitative, qualitative, or mixed methods original research focused on supportive care interventions for advanced PC, and included reported outcomes corresponding with one or more SCFCC domains. Exclusion criteria addressed studies targeting other types of neoplasms, solely localized PC, and unrelated subjects such as purely pharmacological or surgical interventions with curative or palliative intent. The search was limited to studies published in English from 2009 to 2019 to capture the most relevant articles. The PRISMA statement and flow chart (2015) guided the screening and selection of the relevant publications (Figure 1).

Data Extraction and Methodological Quality Assessment

During the first electronic database search, a total of 1678 articles were initially identified. Hand searching identified ten additional articles. After duplicates were removed (n=466), the first author (AS) independently screened 1,222 titles and abstracts for eligibility, with 1,190 articles excluded because they did not meet the inclusion criteria. A final count of 32 articles underwent a thorough full-text review by the first author, with 14 studies excluded because they did not report the full study results, were single-case studies, or involved an instrument validation or a palliative care intervention (care for those with a time limiting cancer). Twenty percent of the title, abstracts, and full-text were reviewed by a second reviewer (SQ) for validity and trustworthiness of the studies selected. All authors agreed on the final 18 studies that met the criteria for inclusion.

Data analysis proceeded through the development of a comprehensive evidence table, which included authors, year, purpose, design, setting, sample, intervention, outcomes, results, domain, and MMAT number of "Yes" (Table 1). Data on the reported intervention components and outcomes were extracted and categorized according to the domains of the SCFCC framework (Laughery & Woodgate, 2015). The findings were organized from the most to the least prevalent SCFCC domains. The methodological quality of the studies was appraised using the Mixed Methods Appraisal Tool (MMAT). The MMAT provides checklists that guide the concurrent appraisal of quantitative, qualitative, and mixed-methods studies in systematically conducted reviews (Hong et al., 2018). It is rooted in an extensive systematic literature review posing seven questions according to the study design: randomized-controlled trial, non-randomized, descriptive, mixed-methods, and qualitative (Hong et al., 2018). Methodological are evaluated as "Yes", "No", or "Can´t tell". More "Yes" responses indicate greater methodological quality. The final evidence table was reviewed by all authors to ensure accuracy of the findings.

Results

Overall Characteristics of the Sample Studies

The sample of selected studies (n=18) reported on original intervention research. Sixteen used quantitative designs and two studies used a qualitative or mixed-methods methodology. Twelve of the quantitative studies were randomized controlled trials (Table 1). The remaining used a quasi-experimental, a prospective observational cohort, and a retrospective descriptive design. Overall, sample sizes across studies were moderately small, ranging from 19 to 189 participants, with the exception of one study including 859 subjects (Beydun et al., 2014). All studies included advanced stage PC survivors (III, IV), either exclusively or in combination with earlier stage PC. The majority of studies included only White participants; only three included Black participants (Badger et al., 2011; Yanez et al.,

2015; Yennurajalingam et al., 2012). Studies were conducted in Turkey (n=1), United States (n=4), Canada (n=1), Europe (n=6), and Australia/New Zealand (n=6). The methodological quality of the reviewed studies was high: 44.4% of the studies met all criteria (5/5 "Yes" out of 5 in the MMAT tool), while the remaining 55.6% met 4 out of 5 criteria. None of the studies ranked lower than 4.

Addressing the multidomain supportive care needs is an essential part of the therapeutic management of cancer to maintain QOL (Afiyanti et al., 2018; Comert et al., 2013). All the studies included supportive care interventions that aimed to support QOL, improve coping with the disease and the side-effects, and maintain their dignity by addressing one or more SCFCC domains (Fitch, 2008). Three major intervention categories emerged from the studies: 1) exercise; 2) cognitive-behavioral/psychosocial; and 3) educational (Table 2). Two studies combined psychosocial counseling and educational components and one combined a physical activity intervention with daily life education (Badger et al., 2011; Beydun et al., 2014; Huri et al., 2015). One study included all three categories (Bourke et al., 2014). Interventions that were delivered face-to-face or were supervised, reported improvements in a greater number of study outcomes compared to interventions delivered using technology or teleconferencing. Four interventions were unsupervised or used mixed delivery methods (some components delivered in person and components unsupervised) (Table 1).

The number of outcomes measured in the studies ranged from one to 13. All studies reported various primary outcomes, typically more than three (Tables 1 & 2). Over half of the outcomes assessed a wide array of symptoms and perceptions (e.g., anxiety, pain, QOL, self-efficacy), were patient self-reported, and were measured either by questionnaires or individual interviews. The remaining outcomes were objectively measured (e.g., biomarkers, blood pressure, weight). None of the studies reported the psychometric properties of the

20

measurement instruments. Only the physical domain was assessed using objective measures such as biomarkers (e.g., maximum oxygen consumption, resting heart rate).

Self-reported QOL was measured as an outcome in 12 studies using various instruments (e.g., FACT, EORTC, SF-36) (Table 1). The results across these studies reported that although there were no significant differences observed in the overall QOL total score, some improvements were noted on the physical, emotional, and social subscale scores.

Summary of Interventions by SCFCC Domain

Physical Domain

The physical domain encompasses physical comfort and the ability to carry out usual ADL (Fitch, 2008). This domain was represented most frequently in the selected evidence. Fourteen studies reported on interventions aiming to alleviate ongoing effects pertaining to the physical domain (Tables 1 & 2). The most frequent primary outcomes included fatigue, body composition changes, physical activity function, muscle strength, and urinary symptoms. Additional outcomes associated with the physical domain included pain, vitality, and survival. Overall, most studies representing this domain reported a moderate degree of improvement in one or more of the outcomes measured.

Fatigue: Ten studies attempted to decrease fatigue, but only 5 reported statistically significant improvements (Badger et al., 2011; Bourke et al., 2014; Paterson et al., 2018; Taaffe et al., 2017; Yennurajalingam et al., 2012). Interventions included several modalities of health education, exercise training programs (impact loading, aerobic, or resistance), bladder rehabilitation, individual needs assessment, interpersonal counseling, or a combination of these. One study testing a multimodal supportive care intervention reported a 7% reduction in fatigue after 3 months (Paterson et al., 2018). Another study evaluating two exercise modalities (impact loading and aerobic with resistance training) reported a reduction of 5 points in the fatigue module of the measuring instrument (Taaffe et al., 2017). The

interventions occurred in three different settings: hospital, exercise clinics, or at home via telephone. The intervention adherence ranged from 67% to 94%. Some interventions were supervised, and some were independently managed. The duration of the interventions ranged from 8 weeks to 12 months.

Body Composition: One of the most effective advanced PC treatments is ADT. However, changes in body composition including gains in fat mass and losses in bone health have been often reported by PC survivors (Comert et al., 2013; Mina et al., 2013). Six studies evaluated interventions by measuring body composition through body weight, body mass index (BMI), waist and hip circumference, body fat mass, whole-body and appendicular lean mass, and certain biomarkers (e.g., leptin and insulin-like grown factors 1,3) (Table 1). Only one study that tested combined resistance and aerobic exercise with an education program reported a statistically significant reduction in waist and hip circumference ($p<0.0001$) (Beydun et al., 2014). A home-based aerobic versus resistance exercise training intervention showed a decrease in body weight and BMI associated with a non-significant reduction in leptin (Mina et al., 2013). An unsupervised exergaming intervention (exercise through videogames) reported numerical reduction in fat mass and increase in lean mass, though these were also not statistically significant (Villumsen et al., 2019). All other exercise interventions with or without an educational component reported modest or no changes in body composition. The interventions were implemented at home or in exercise clinics and had a duration from 10 weeks to 12 months. When reported, adherence was high, ranging from 70 to 91%.

Muscle Strength and Physical Activity: Five studies tested interventions that targeted muscle strength. Measures included resistance, muscular power, and chest and leg extension muscle strength. All interventions reported a significant improvement in the measures, were supervised, and shared common components, such as aerobic, impact, and resistance training.

A resistance exercise intervention resulted in an 11% improvement in muscle strength when measuring leg extension (Cormie et al., 2013). Regarding physical activity, the majority of the studies assessing physical activity measures reported a positive improvement favoring the intervention group, three of them with statistical significance ($p<0.001$). Measurements included ambulation, exercise behavior, chair rise time(s), 6-Minute Walking Ability Test (6MWT), Godin Leisure-Time Exercise score, and self-reported physical function. An intervention testing resistance exercises improved ambulation by 12% (Cormie et al., 2013). A home-based exergaming intervention reported a 4.2% improvement in physical activity function by assessing the 6MWT (Villumsen et al., 2019). The interventions targeting muscle strength and physical activity were all delivered at a hospital, exercise clinics, or were home-based. All interventions ranged from 10 weeks to 12 months.

Urinary Symptoms: One study involved a progressive urinary rehabilitation program with the purpose of reducing prostate-related urinary symptoms, resulting in a moderate reduction of difficulty, frequency, and nocturia (Serda et al., 2010). Four other studies tested interventions measuring the prostate-specific QOL, including urinary symptoms, via a self-administered instrument (FACT-P, UCLA PC Index, or EORTC-QOQ-30 PR25) but did not include urinary-specific outcome measures (Badger et al., 2011; Bourke et al., 2014; Huri et al., 2015; Villumsen et al., 2019).

Social Domain

The social domain addresses needs related to relationships, communication, and support systems within the family and the community (Fitch, 2008). This domain was the second most frequently represented within the body of evidence based on the nature of the intervention delivery. Thirteen studies delivered the intervention in a group format either face-to-face or via technology (Table 1). Outcomes included social well-being, social support, social functioning, sense of belonging, peer learning, and socialization. These

outcomes were secondary in all studies except in one, which measured social well-being and social support with instruments (Social Well-Being scale & PSS-FA) (Badger et al., 2011).

The interventions that included a psychosocial component such as group counseling, cognitive-based occupational therapy, or stress reduction reported an improvement in social well-being among the participants in the treatment group (Badger et al., 2011; Huri et al., 2013; Yanez et al., 2015). Group mindfulness sessions delivered by teleconference provided an increased sense of social belonging to the participants (Chambers et al., 2017; Chambers et al., 2012). There were also interventions evaluating various exercising modalities, such as aerobic, impact loading, or resistance training conducted in groups (Beydun et al., 2014; Bourke et al., 2014; Cornie et al., 2013; Galvao et al., 2014; Serda et al., 2010; Taaffe et al., 2017; Winters-Stone et al., 2015). Despite a lack of social-specific outcomes, all group exercising programs resulted in better social functioning and group interaction by encouraging socialization among participating survivors. Additionally, one study evaluating a multimodal supportive care intervention that included group seminars reported an improvement in social support (Primeau et al., 2017). All interventions took place at home via teleconference, at a hospital, or at exercise clinics. They were implemented for periods of 8 weeks to 12 months and demonstrated high adherence rates (65%-100%).

Informational Domain

Fitch's SCFCC associates the informational domain with adequate information regarding the disease trajectory, treatments, care processes, and available resources (2008). Although every type of intervention can be considered "educational" to some degree, 10 studies included interventions that represented the informational domain, by presenting resources to the participants and/or the caregivers; educating on diet; exercise, relaxation and self-management; or by informing them about symptom-related burdens (Table 1). No specific informational outcomes related to informational supportive care needs were

measured in any of the studies. Three studies included nutritional education. One intervention contained nutrition advice seminars and reported a non-statistically significant reduction in total fats consumption (Bourke et al., 2014). A polyamide-reduced diet proved its safety and suggested an increase in the participants' median cancer-specific survival time to 36 months, versus 17 months in the control group (Cipolla et al., 2010). The health promotion group in the study by Yanez et al. (2015) was provided with health educational information on sleep, nutrition, and physical fitness, proven to be "somewhat" helpful.

One commonality across studies was that the majority of the information disseminated in these interventions was about cancer treatments or supportive care. After an educational intervention about the effects of the ADT, 98% of the participants reported a positive impact from this information on physical fitness level and no further deterioration from the adverse effects of ADT (Yennurajalingam et al., 2012). A web-assisted group intervention with education on stress awareness and reduction resulted in better coping skills regarding prostate-related symptomatology (Yanez et al., 2015). The two studies that included an educational seminar about ADT side effects, self-management, emotion and stress control, nutrition, exercise, and financing reported fewer unmet informational needs about treatment choices and disclosure of test results (Paterson et al., 2018; Primeau et al., 2017). In addition, an early outpatient palliative care consultation addressing symptom burden resulted in an increased sense of general well-being and an increased lifespan (Yennurajalingam et al., 2012). Despite not having a direct effect on QOL, the interventions including an informational component had a positive effect on some of the outcomes measured, such as fat intake, mindfulness, survival, and overall well-being.

Emotional Domain

The emotional domain relates to the need for comfort and reassurance when adjusting to stressful situations (Fitch, 2008). Eight studies assessed an intervention with at least one

component addressing emotional needs (Table 1). Intervention methods included interpersonal counseling, occupational therapy, stress reduction, or mindfulness. Depression, anxiety, stress, and cancer-specific distress were the most commonly measured primary and secondary outcomes. The duration of the interventions averaged between 8 weeks and 12 months. Half were delivered via telephone and half were face-to-face at the hospital.

Two studies tested mindfulness-based cognitive therapy in groups using self-help materials and meditation CD delivered via teleconference (Chambers et al., 2012; Chambers et al., 2017). Although not statistically significant, one reported improved levels of anxiety, fear of recurrence, and avoidance in the subscales of the distress-measuring instruments (Chambers et al., 2012). An 8-week telephone intervention combining interpersonal counseling and cancer education reported a statistically significant reduction in depression and disease-related stress ($p<0.001$) (Badger et al., 2011). A multimodal supportive care intervention (ThriverCare) demonstrated no improvement in reducing stress, anxiety, or depression in the treatment group, but did report lower prevalence of fear and worries (Paterson et al., 2018). A technology-assisted psychosocial intervention to reduce stress also reported better scores in relaxation and fewer depressive symptoms upon completion (Yanez et al., 2015). One additional study evaluating the impact of an outpatient palliative care consultation on symptom burden in advanced PC survivors improved seven out of the 10 symptoms, including depression and anxiety (Primeau et al., 2017). Despite the mixed results of some of the interventions, several reported a statistically significant improvement in the emotional needs (e.g., depression, anxiety) of the study participants ($p < 0.05$).

Practical Domain

Practical needs associated with the cancer journey include supports that reduce the demands on the person's life at home (e.g., finances), facilitate transportation to the care center, and access to supportive care and resources, childcare, and shopping (Fitch, 2008).

Across multiple studies, intervention accessibility was facilitated through alternatives to in-person participation (e.g., telephone, teleconference or Web-assisted) (Table 1). The majority of these technology-assisted interventions were psychosocial in nature, such as interpersonal counseling, mindfulness, or stress reduction, and reported no significant differences in most primary outcomes (e.g., fatigue, QOL, physical function, psychological well-being) despite the degree of "feasibility and helpfulness."

The practical domain was addressed by one study that explored the relationship between ADL and consequences of the PC treatments (Huri et al., 2015). The intervention included a combination of individualized ADL training, group recreational activity, and education about PC and relaxation. Practical issues that were negatively affected by advanced PC included: personal activities such as grooming, driving, bathing, or dressing; productive activities such as typing, storing groceries, home repair, leisure, walking the pet, moving after rest, using the phone, or reading the newspaper in bed. Participants reported some improvement in functioning upon completion of the intervention. A web-based exergaming intervention, implemented in the participants' home using devices that can be acquired inexpensively in any technology-selling store, indicated modest, non-significant improvement of the physical activity outcomes (Villumsen et al., 2019). Overall, interventions representing the practical domain were limited to facilitating study participation. Despite being helpful, they did not report any specific practical outcomes.

Spiritual Domain

The spiritual domain relates to finding a personal sense of meaning in life and the need to practice some sort of spirituality, whether in the form of a religious or alternative beliefs (Fitch, 2008). Only one study addressed the spiritual domain as a secondary outcome (Badger et al., 2011). The study compared an 8-week interpersonal counseling via teleconference with education (interventional group) and 8-weeks of health education by

telephone using written materials regarding nutrition, exercise, resources, and quitting smoking (control group). The influence of the participants' illness on spiritual well-being was measured with the 8-item spiritual well-being subscale of the Quality-of-Life Breast Cancer version questionnaire. The study reported a statistically significant improvement in spiritual well-being in the health education by telephone group ($p<0.01$).

Psychological Domain

The primary feature of the psychological domain is the development of skills to cope effectively with illness-related stressors (Fitch, 2008). One study testing web-based group sessions for stress reduction, coping skills, and social network (CBSM) addressed the psychological domain (Yanez et al., 2015). The intervention included stress awareness development, learning stress reduction skills, changing negative stressor appraisals, and developing effective coping skills. The retention rate was 85%. Despite not having outcomes for those targets, results reported high interventional endorsement and feasibility. Statistically significant intervention effects were consistent with medium effect sizes on the health-related QOL scale domains (measured with the Functional Assessment of Cancer Therapy–General scale and subscales of the Measure of Current Status) favoring the intervention.

Discussion

This integrative review confirms that supportive care interventions for advanced PC exist but they remain limited in number and scope despite the disease's uncurable nature, its growing prevalence, and the most current supportive care guidelines. Advanced PC is often associated with long-term challenges leading to greater levels of unmet needs and decreased QOL (Chambers et al., 2012; Cockle-Hearne et al., 2013). Evidence indicates that supportive care interventions are an acceptable and potentially efficacious way to improve some aspects of PC and other cancer survivors' QOL (Chambers et al., 2018; Forbes et al., 2019; Young et al., 2020).

The majority of interventions in this review focused on supportive care needs from the physical domain, such as fatigue, muscle strength, or body composition changes. Despite the mixed results in reducing fatigue, physical outcomes such as muscle strength, specific anthropometric measures (waist circumference), and physical function improved across all studies. Possible explanations for the mixed results in fatigue could be that the studies considered different outcomes, utilized various measuring instruments, or that the interventions lacked implementation fidelity (intervention dose, intensity, or frequency). This finding is consistent with past studies that have reported supportive care interventions being ineffective in improving QOL in diverse cancer populations due to inadequate doses or variable timeframes (Carey et al., 2012). Supervised interventions with adequate dosages and frequency to increase functional capacity, QOL, and ability to conduct ADL, such as exercise, have shown effectiveness among advanced PC and other cancer survivors (Dickey & Ogunsanya, 2018). Moreover, all exercise interventions that were delivered in group formats motivated socialization, social support, and sense of belonging among participating survivors despite social well-being not being a specific outcome measured.

The high prevalence of emotional needs in this population is commonly associated with more advanced stages of the disease, uncertainty about the future, and the harmful effects of the treatments (Paterson et al., 2015). Interventions addressing emotional needs are limited and often lack demonstrated efficacy. Only five in this review reported significant improvements in outcomes, such as depression, anxiety, distress, or fear. The heterogeneity of these studies makes it difficult to draw conclusions about the most effective way to provide emotional supportive care. Barriers to emotional health may include traditional masculine stoic roles, a restricted emotional response, and embarrassment (Ettridge et al., 2018; Wood et al., 2017).

A similar situation was found within the spiritual, practical, and psychological domains. Evidence shows that despite 79% of Americans identifying with some spiritual doctrine, spiritual needs are the least represented in cancer research, and the studies reviewed are no exception (Busolo & Woodgate, 2016). Challenges in coping with advanced PC can lead to increased suffering, grief, and loss, contributing to a poorer overall QOL (Laughery & Woodgate, 2015). Educational interventions have showed promising results in enhancing study participants' spiritual well-being.

A study involving web-based group sessions of stress reduction, coping skills, and social network (CBSM) contributed to the psychological domain and reported improvements on the health-related QOL subscales (Yanez et al., 2015). However, the study did not use any exiting instrument to assess patients' coping such as the Cancer-Coping Questionnaire (Moorey et al., 2003). No studies specifically targeted practical needs, but one study described the impact of advanced PC on daily life, and other studies reported intervention delivery acceptability. Interventions using teleconferencing or the Web were implemented conveniently in the comfort of the home. The majority of those, predominantly psychosocial interventions, reported moderate acceptability and feasibility, with high compliance and retention rates. However, they had mixed results: only one resulted in significant decreases in anxiety, fear, and mindfulness abilities (Chambers et al., 2012). This result coincides with a study reporting that telemedicine care delivery was moderately effective in addressing survivorship symptomatology (Agochukwu et al., 2018). More extensive studies are warranted to demonstrate the usefulness of these delivery formats for advanced PC survivors.

All the studies included advanced disease PC survivors, exclusively or in conjunction with varying disease stages. However, there was a noteworthy lack of racial and ethnic diversity in the studies. Interestingly, the three studies with participants other than White were conducted in the U.S. The majority of the studies reviewed were exploratory with small

sample sizes. Also, studies used different outcome measures and the interventions varied in dose, frequency (ranging from 1 to 5 days per week), and length (8 to 24 weeks), making it difficult to determine which supportive care interventions were the most effective (Bossert et al., 2020; Carey et al., 2012). Despite some promising results, it is premature to generalize the findings to practice in all the settings caring for these survivors. Longitudinal confirmation of the most effective interventions that meet this group's unique and complex needs is needed from more rigorous, multicenter, blinded RCTs that are sufficiently and diversely sampled (Ross et al., 2020).

There were three noteworthy findings from this review. First, the interventions delivered in a group format, whether in person or via technology, resulted in significant improvements in social-related measures (social support, social well-being, or a sense of belonging). This finding supports conclusions from past reviews reporting that the social domain is positively associated with a better overall QOL in advanced PC and breast cancer survivors (Dickey & Ogunsanya, 2018; Post & Flanagan, 2016). Second, the intervention results do not appear to be dependent on the number of domains addressed by the intervention. Some interventions showed positive trends, whether they addressed only one or several of the SCFCC domains. Third, some of the SCFCC domain —social or the practical domains—were impacted by the intervention even when they were not explicitly targeted.

Limitations

Several methodological limitations may limit the generalizability of the findings. The majority of studies were of high methodological quality. However, none of the studies reported a theoretical framework guiding the intervention development or delivery. It is possible that relevant articles were missed since our focus was on supportive care interventions in advanced PC survivors. The search terms were narrow to reflect this specific interventional category, dropping other areas that may have produced additional relevant

evidence. Limiting studies to the English language and the last ten years could have resulted in the omission of relevant evidence.

Implications for Research

This review highlights several gaps. First, different sampling approaches need to be considered to advance research in this area. Future research must include racial and ethnic diversity to reduce health disparities and promote QOL across communities suffering from chronic illnesses such as advanced PC (NINR, 2016). Second, researchers must focus on studying interventions that combine several components addressing the maximum number of supportive care domains since those interventions can be more cost-efficient in the long run. Third, interventions need to be guided by a theoretical framework and align with the recommended guidelines for survivorship care (ASCO, 2019; CCO, 2019). An absence of theory makes it difficult to understand how and why the interventions were or were not successful in addressing this growing population's unmet supportive care needs (Nilsen, 2015). Finally, some of the mixed results may be attributable to the dissimilarities in psychometric properties of the instruments used across studies, making a comparison of the results very challenging. Future research must consider assessing the validation properties and quality of all measurement instruments as well as utilizing the same instruments to measure the same outcomes. Also, there is a need to diversify research methodologies and include more qualitative and mixed methods research studies. These methodologies can provide a more in-depth understanding of advanced disease PC survivors' experiences and perceptions of regarding supportive care interventions.

<div align="center">

Conclusion

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Supportive care in advanced PC remains underserved and overlooked. This review reveals valuable insights regarding available supportive care interventions that improve the QOL in this growing population. Findings suggest that the majority of the interventions

reported some effectiveness. However, no intervention can be recommended over another and the results must be interpreted with caution due to the existing limitations. This review supports the need for further interventional research, specifically longitudinal studies with larger, more racially diverse samples and methodologies. Future directions may include multi-domain designs and systematic use of theories and cancer survivorship guidelines. Finally, it also is critical to focus on the spiritual, practical, and psychological domains, as they can significantly enhance these survivors' overall QOL and sense of overall meaning.

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Table 1. Evidence Table of Selected Studies

Authors (Year)	Study Purpose	Study Design	Setting; Sample Description & Size (N)	Intervention	Primary Outcomes	Results	SCFCC Domain	MMAT (# of YES)
Badger TA, Segrin C, Figueredo AJ, et al. (2011)	To test the effectiveness of two 8-week telephone psychosocial interventions for maintaining and improving QOL	Randomized experimental design	Cancer and Veteran Affairs Centers, Arizona (USA) Prostate cancer survivors (all stages) **N=71** Survivors' caregivers **N=71**	TIP-C Arm (n=36): 8-week telephone interpersonal counseling + cancer education HEAC arm (n=35): 8-week telephone health education attention condition + written materials (nutrition, exercise, resources, quitting smoking)	**At baseline, 12 and 24 weeks** - Depression - Positive & negative affect - Stress - Fatigue - Prostate health QOL - Social well-being - Social support - spiritual well-being	**Differences between groups:** - Survivors in TIP-C did not exhibit any significant changes on any of the QOL outcomes. - Survivors in the HEAC showed significant changes in 5 outcomes: depression, negative affect, stress, fatigue, spiritual well-being, and in the 4 dimensions of the QOL	Physical Social Informational Emotional Practical Spiritual	4 out of 5
Beydun N, Bucci JA, Chin YS, et al. (2014)	To examine if a community-based centrally managed combined resistance and aerobic exercise + education program can ameliorate the adverse effects of androgen-deprivation therapy	Prospective cohort study	South New Wales (Australia) Survivors with relapsed or metastatic prostate cancer **N = 859**	Face-to-face (n=396): 10-week supervised group exercise sessions At-home (n=255): Video + resistance bands + coach calls for 6 months Man Plan (208): Phone line support, magazines and education on low-intensity exercise,	**At baseline and 10-weeks** - Height, weight, BMI, waist and hip circumference - BP - Resting HR - Resistance exercises	- Modest reduction in mean weight not statistically significant - Statistically significant reduction of mean waist & hip circumference - No change in BMI - Mean BP reduced from baseline - Not statistically	Physical Social Informational	4 out of 5

				diet and psychosexual function		significant lower resting HR - Significant decrease in mean time for the 400-m test - Statistically significant improvements in all measured variables - 98% reported a positive impact on their overall fitness + socialization - No further deterioration from treatment while on intervention		
Bourke L, Gilbert S, Hooper R, et al. *(2014)*	To assess the effects of a combined tapered supervised exercise training program with healthy eating advice on improving and sustaining changes in disease specific QOL, BP and fatigue	2-armed, single-blind randomized controlled trial	London & Sheffield, U.K. Survivors with locally advanced (n=20) or metastatic (n=80) prostate cancer **N = 100**	<u>Complex arm (n=50):</u> Supervised aerobic & resistance exercise twice/ week + behavioral component (barriers to exercise, goal setting, social support) + nutrition advice seminars <u>Usual care arm (n=50):</u> Care by oncology nurse	**At baseline, 12 weeks and 6 months** - Exercise behavior, adherence & biochemical safety - Disease-specific QOL - Fatigue - BP - BMI - Weight - Biomarkers: PSA, testosterone, free androgen index, & hormone-binding globulin	-Significant improvements in total exercise behavior maintained at 6 months -No differences in biochemical safety markers -Adherence 94% and 82% in supervised and independent exercise respectively -Significant, clinically relevant improvement in disease-specific QoL but not maintained after supervision	Physical Social Informational	5 out of 5

					- Dietary behavior:	-No changes in BP, weight or PSA -Significant clinically relevant improvements in fatigue at 12 weeks & 6 months -Reduction of fats intake, non-statistically significant		
Chambers SK, Newton RU. (2012)	To investigate feasibility and effectiveness of an 8-week intensive mindfulness-based cognitive therapy	Mixed-methods pilot study	Rural and urban healthcare centers, Queensland, Australia Advanced stage prostate cancer survivors **N = 19**	2-hour teleconference group session - weekly session handbook + self-help materials + meditation CD (daily 35 min session minimum)	**At baseline, after completion, and 3 months after** - Psychological distress - Cancer-specific distress - QOL - Perceived global QOL - Mindfulness skills - Program Evaluation: acceptability & frequency - Qualitative assessment: overall experience	- Improved anxiety, avoidance & fear of recurrence - No changes in QOL - Increased mindfulness over time - Ideal quotas in urban centers - 80% attended all 8-week sessions - At 3 months, 54% reported regular mindfulness meditation - Majority found it very helpful - Thematic analysis Group identification (belong); Diversity acceptance; Peer learning (new ways of dealing with challenges);	Social Emotional	5 out of 5

						Acceptance of disease progression		
Chambers SK, Occhipinti S, Foley S, et al. (2017)	To assess the effectiveness of MBCT in reducing psychological distress	2-armed randomized controlled trial	Griffin University, several hospitals Queensland, Australia Men with metastatic or castration-resistant prostate cancer **N = 189**	<u>MBCT arm (n=94):</u> 8 group MBCT sessions at weekly intervals via teleconference <u>Enhanced care arm (n=35):</u> Education on advanced PC, relaxation CD, nutrition, support services	**At baseline, 3, 6, and 9 months** - Psychological distress - Cancer-specific distress - Anxiety - QOL - Post-traumatic Growth Inventory - Mindfulness skills	- No significant changes or improvements in any of the measured outcomes - 72% rated the intervention as extremely helpful - No improvements in emotional distress over time - Intervention not efficacious	Social Emotional Practical	5 out of 5
Cipolla BG, Havouis R, Moulinoux JP. (2010)	To present results of observance, safety, and effect of PRD diet on QOL (performance status and pain control) To compare survival between PRD diet and control patients on normal diet	Prospective cohort study	Centre Hospitalier de Saint-Gregoire, France Consecutive metastatic HRPC patients **N = 42**	<u>PA reduced diet (n=26):</u> 5-day/week meals from food tables given to patients + partial intermittent intestinal tract cleansing <u>Usual diet controls (n=16)</u>	**At baseline and regularly until 36 months** - Toxicity - Performance - Pain - Weight - Biomarkers: PSA, Hb, WBC, platelets, serum proteins, and red blood count - Survival: **a**ssessment & comparison early versus late PRD initiation	Observance: no patient stopped the diet - No adverse effects - No significant differences in weight, performance, pain, or blood counts - Significant median cancer-specific survival time of PRD patients was 36 months versus 17 months in controls - PRD diet is safe and well-observed as nutritional therapy	Physical Informational	4 out of 5

Cormie P, Newton RU, Spry N et al. (2013)	To provide initial experimental data on safety and efficacy of resistant exercise in metastatic prostate cancer survivors	Pilot single-blinded, 2-armed prospective randomized controlled trial	Perth, Western Australia Men with metastatic Prostate cancer **N = 20**	Exercise arm (n=10): 12-week, twice/week supervised group resistance exercise sessions Usual care (n=10): offer of exercise program after intervention was finished	**At baseline and 12 weeks** **-** Incidence & severity of adverse events - Pain - Compliance, tolerance and rating of perceived exertion - Muscle strength - Ambulation **-** Exercise capacity - Muscle power - Balance - Falls - Physical activity - Regional & whole-body lean and fat mass - QOL - Distress - Fatigue	- No adverse events - No change in pain medication use - High attendance (70%) - Exercise sessions well tolerated - Trends towards improvement in physical function in exercise arm - No difference in balance - Significant favorable change in whole body and appendicular lean mass in exercise arm - No differences in fat mass - No significant differences in QOL, fatigue or distress	Physical Social	5 out of 5
Galvao DA, Spry N, Denham J, et al. (2014)	Effectiveness of exercise training (resistance and aerobic) in cardio-respiratory fitness, physical functioning, patient-reported outcomes,	Multicenter, 2-armed, prospective randomized controlled trial	Three Health centers Australia and New Zealand Men at stages II, III, IV prostate cancer **N= 100**	EX arm (n=50): progressive resistance and aerobic training with a 6-month supervision PA arm (n=50): PA-modified	**At baseline, 6 and 12 months** - Cardiovascular fitness: 400-m walk - Physical activity - QOL	- EX arm exhibited improvement in fitness, muscle strength and physical function - EX arm showed improved QOL, social functioning at 6 months, role emotional at 12 months, & mental	Physical Social	4 out of 5

biomarkers and body composition			educational booklet + pedometer	- Muscle strength - Biomarkers: testosterone, PSA, insulin, lipids panel, glucose, BP - waist circumference	health index at 6 months - EX arm showed appendicular skeletal muscle gain but no differences on weight and waist circumference - EX arm showed increased HDL at 12 months - No differences in PSA, testosterone or BP		
Huri M, Huri E, Kayihan H, et al. (2015)	To identify the effect of cognitive-behavioral based occupational therapy (OT-CBSM) on occupational participation and QOL To explore which areas of daily life are most affected and in need of support	2- armed randomized controlled trial	Faculty of Health Sciences, Hacettepe University, Ankara, Turkey Men with localized, locally advanced or metastatic Prostate cancer **N = 34**	OT-CBSM arm (n=19): 12-week intervention: individualized daily living training + group recreational activity + CBSM education/in-formation about prostate cancer & relaxation Control arm (n=15): printed home program + instruction on effects of activity training, recreation, stress management and relaxation	**One week before and after the intervention** - Occupational Performance - Self-perception & identify issues in self-care, productivity & leisure - QOL - Prostate-specific QOL (urinary, bowel, sexual & hormonal symptoms)	- 94.7% of participants experienced improvement - Affected areas: self-care (grooming, driving, bathing, dressing), productivity (stairs, typing, storing groceries, home repair, watching grandchildren), leisure (playing, walking pet, going to café, moving after rest, using phone, reading newspaper in bed) - OT-CBSM group reported a significant increase in physical, role & emotional & social functioning compared to controls in	Physical Social Informational Emotional Practical	4 out of 5

						QOL - Urinary, bowel, sexual & hormonal symptoms were decreased in OT group		
Mina DS, Connor MK, Alibhai SMH, et al. (2013)	To examine if 6-months of home-based aerobic and/or resistance exercise training can beneficially increase adiponectin, leptin, and IGF-axis protein levels	2-group, randomized controlled trial	Several urban health centers, Ontario, Canada Men with all stages of Prostate cancer **N = 26**	EAT arm (n=13): Preferred modality of exercise at moderate/vigorous intensity-60 min, 5/week for 6 months; heart monitor provided Resistance arm (n=13): 10 exercises targeting major muscle groups	**At baseline, 3 and 6 months** - BMI - Body fat % - Waist circumference **- VO2 peak** **- Changes in physical activity** **- Biomarkers:** Insulin-growth factor-1, IGF binding protein 3, leptin & adiponectin	- At 6 months, AET group showed significant decrease in IGFBP-3 while RET group showed significant increase - At 3 months, RET group showed significant reduction of IGF-1 - Reductions in weight, BMI & waist circumference associated with reductions in leptin - Increases in VO2 peak associated with reductions in leptin - Home-based exercise intervention (RET) may have beneficial effects on adipokines and IGF axis, maybe due to improvements in body composition because of the exercise.	Physical	4 out of 5
Paterson C, Primeau C, Nabi G. (2018)	To test the hypothesis that the ThriverCare intervention	Pilot randomized controlled trial	Four hospitals in Scotland, U.K.	ThriverCare arm (n=19): 4-component intervention:	**At baseline and 3 months** - Supportive care	- Less prevalence of unmet needs in ThriverCare arm (fatigue, pain, fear,	Physical Informational	4 out of 5

	would improve supportive care needs, psychological outcomes, health related QOL and self-efficacy		Men with metastatic prostate cancer (n=38) Survivor´s caregivers (n=10) **N = 48**	informational self-management booklet + holistic needs assessment + individual self-care plan + group-based seminar <u>Standard care (n=28):</u> usual care by clinicians	needs - Anxiety - Depression - QOL - Confidence in self-management	worries, sexuality, information) - No significant differences in anxiety and depression - No significant differences in QOL - No significant differences in self-efficacy	Emotional	
Primeau C, Paterson C, Nabi G. (2017)	To gain understanding of a multimodal supportive care intervention (ThriverCare) compared to standard care	Qualitative	Two cancer hospitals in Scotland, U.K. Men with localized, locally advanced and metastatic prostate cancer (n=19) Caregivers (n=7) Interprofessional team members (n=7) **N = 33**	**4-component intervention:** holistic care assessment at baseline + individualized self-management care plan + group seminar + educational materials	**At 3 months after the intervention** - Exploratory semi-structured interviews - Field notes	**Themes:** **- Physical needs:** managing the side-effects of treatment, lack of self-management support **- Psychological needs:** uncertainty on cancer progression, lack of compassion from care team **- Practical needs:** lack of motivation, financial burdens **- Sexual needs:** change in sexual function **- Patient-clinician communication:** limited time, lack information **Intervention group:** **- Emotional support:** enough time to share, received info about	Social Informational Emotional	4 out of 5

						their process, additional emotional support **- Informational support:** no unmet needs identified **- Evidenced-based self-management plans & seminar:** perceived benefit - Multimodal supportive care intervention improves care and decreases unmet needs over time		
Serda BC, Vesa J, Del Valle A, et al. (2010)	To share a design and implementation of a progressive rehabilitation program with the purpose of reducing the urinary incontinence symptom and improving QOL	Cohort quasi-experimental	Hospital of Figueres, Girona, Spain Men with localized, locally advanced, and metastatic prostate cancer **N= 33**	24-week progressive strength program: 3 consecutive ordered levels based on the recognition, control, & tonifying the pelvic floor musculature	**At baseline and 24-weeks:** - Type of urinary incontinence - Leakage & frequency - UI Volume - QOL - Fatigue - Hip-waist index, waist perimeter & fat percentage - BP - Treatment toxicity	- 66.66% had UI; 33.33% presented with lower urinary tract symptoms only - Significant decrease in intensity - Significant reduction of constipation, difficulty, frequency, limitation of activities & nocturia - Non-significant decrease in fatigue and pain - Non-significant improvement in QOL after the program - Significant decreases	Physical Social	5 out of 5

				- Exercise habits		in hip-waist index, waist perimeter and fat percentages		
Taaffe DR, Newton RU, Spry N, et al. *(2017)*	To report the efficacy of a 1-year long RCT of varying supervised exercise modalities on fatigue and vitality	3-armed randomized controlled trial	Perth & Brisbane, Australia Men with localized and locally advanced prostate cancer **N = 163**	ILRT arm (n=58): Impact loading & resistance training ART arm (n=54): Aerobic & resistance training DEL arm (n=51): Usual care & delayed exercise	**At baseline, 6, and 12 months** **-** Fatigue - Vitality - Cardiovascular fitness - Muscle strength	- Reduced fatigue in ILRT at 6 & 12 months - Reduced fatigue in ART at 12 months - No change in fatigue or vitality in DEL at 6 months - Increased vitality in all 3 groups at 12 months - Increased muscle strength in ILRT group at 6 & 12 months & in ART after 6 months - All exercise modalities have beneficial effect on fatigue & vitality	Physical Social	4 out of 5
Villumsen BR, Jorgensen MG, Frystyk J, et al. (2019)	To explore the effects of 12-week unsupervised home-based exergaming compared to usual care	Single-blinded, 2-armed randomized controlled trial	Outpatient clinics at Regional Hospital Holstebro and Regional Hospital Viborg, Denmark. Men at all stages of Prostate cancer **N = 46**	Intervention arm (n=23): 90-min instruction on exergaming X-Box 360 Kinect system; 1-hour, 3/week aerobic & strength exercise Usual care (n=23): normal daily activities	**Baseline and 12-weeks** **-** Effects of exergaming-physical function - Leg extension power - Body Composition	- 4.2% improvement favoring the intervention **LEP:** - No significant difference between groups **-** Lean mass increased and fat mass decreased numerically between	Physical Practical	4 out of 5

					- Self-reported QOL - Fatigue	groups-no statistically significant - No difference in QOL between groups-numerical increase in global health status in ntervention arm - No improvements in fatigue in intervention arm - Study shows trends favoring the exergaming intervention		
Winters-Stone KM, Dobek JC, Bennett JA, et al.. (2015)	To report effects of POWIR on muscle strength, physical function, and disability To explore if changes in strength, physical function or fatigue mediated changes in self-reported function or disability	Single-blind, 2-parallel groups, randomized controlled trial	Oregon Health & Science University, Portland, Oregon (USA) Men with localized and locally advanced prostate cancer **N = 51**	POWIR arm (n=29): Supervised program of resistance + impact training FLEX arm (n=22): placebo control program; seated stretching exercise	**At baseline, 6 and 12 months** - Prevalence chronic conditions - Energy in physical activity - Fatigue - Muscle Strength - Physical function performance battery (objective) - Self-reported physical function	- Retention for POWIR arm 90% - Retention for FLEX arm 75% - Attendance while supervised 83% & 67% for POWIR and FLEX respectively - Significant increase of 7% for bench press and 17% for leg press in POWIR group (muscle strength) - No significant changes in objective measures in physical function - POWIR group increased mean self-	Physical Social	5 out of 5

						reported physical function on EORTC QOL and decreased disability on LLFDI subscale - No significant differences in fatigue or 36-item health survey - Overall, men in POWIR reported better levels of hysical function & less disability than men in FLEX		
Yanez B, McGinty HL, Mohr DC, et al. (2015)	To evaluate the participation & retention of a Web-based intervention targeting symptom burden and HRQOL To assess participant satisfaction To report preliminary evidence for the efficacy of a cognitive behavioral stress management (CBSM) on HRQOL and intervention targets	2-armed randomized controlled trial	Robert H. Lurie Com-prehensive Cancer Center of Northwestern University and the Jesse Brown VA Medical Center Chicago, IL (USA) Men with locally advanced (III) or metastatic (IV) prostate cancer **N = 74**	<u>CBSM arm (n=37):</u> Group session targeting stress reduction, coping skills, interpersonal skills, social network <u>HP arm (n=37):</u> Health info and education on sleep, nutrition, & physical fitness	**At baseline, and 6 months** - Feasibility & acceptability: **r**ecruitment, retention & attendance rates - Cancer-related stress - Depressive symptoms - Health-related QOL **-** Intervention targets: **s**elf-efficacy in stress management skills	- Recruitment rate was 31.3% - Retention rate at 6 mo was 85.7% for CBSM and 86.1% for HP - HP group attended more sessions - Acceptability: confidence in material learned was "quite" for CBSM and "somewhat" for HP group - CBSM fewer depressive symptoms than HP - HP reported better social well-being	Social Informational Emotional Practical Psychological	4 out of 5

|								
						- CBSM reported higher scores for relaxation than HP over time Findings support feasibility, acceptability, and preliminary efficacy of a web-based psychosocial intervention		
Yennurajalingam S, Atkinson B, Masterson J, et al. (2012)	To describe the impact of an outpatient palliative care (PC) consultation on symptoms of advanced prostate cancer	Retrospective descriptive study	M.D. Anderson Cancer center, Houston, TX (USA) Charts of patients with metastatic prostate cancer **N = 55**	Outpatient palliative care consultation	**- Age** - Disease state: 10-symptom severity Performance Status - Survival - Biomarkers: hemoglobin, testosterone, PSA **-** Medication changes	- Most relevant symptoms: fatigue, drowsiness & pain **-** Statistically significant improvement in 7 out of 10 symptoms after the PC consultation: pain, depression, drowsiness, fatigue, sleep, sense of well-being & anxiety **-**Longer duration between PC referral and death than in previous studies**:** 175 days versus 141 & 42	Physical Informational Emotional	4 out of 5

Abbreviations: BP, blood pressure; BMI, body mass index, CR, cardiorespiratory; Hb, hemoglobin; HDL, high density lipoproteins HR, heart rate; IGF, insulin growth factor; PC, palliative care; PRD, polyamide reduced diet; PSA, prostate specific antigen; QOL, quality of life; RTC, randomized controlled trial; VO2, oxygen uptake; UI, urinary incontinence; WBC, white blood

Table 2. Interventions, Outcomes, and Main Results per SCNCCF

Domain	Intervention(s)	Outcomes	Results	Studies
PHYSICAL	EXERCISE: . Aerobic exercise . Resistance training . Impact loading . Combination PSYCHOSOCIAL: . Counseling / education	. Fatigue . Body changes . Physical activity . Urinary symptoms . Muscle strength . Vitality . Pain . Overall survival	. Half interventions decreased fatigue . Significant decrease in waist/hip circumference . No significant reduction in weight/BMI . Significant improvement in urinary symptoms . Better muscle strength . More vitality . Only two studies ameliorated level of pain . Longer survival	Badger et al., 2011 Beydun et al., 2014 Bourke et al., 2014 Cipolla et al., 2010 Cormie et al., 2013 Galvao et al., 2014 Huri et al., 2015 Mina et al., 2013 Paterson et al., 2018 Primeau et al., 2017 Serda et al., 2010 Taaffe et al., 2017 Villumsen et al., 2019 Winter-Stone et al., 2015 Yennurajalingam et al., 2012
SOCIAL	. Group mindfulness . Group counseling . Cognitive occupational therapy . Group stress reduction	. Social support . Social well-being . Social belonging	. Significant improvement in all social outcomes across studies addressing social domain	Badger et al., 2011 Beydun et al., 2014 Bourke et al., 2014 Chambers et al., 2012 Chambers et al., 2017 Cormie et al., 2013 Galvao et al., 2014 Huri et al., 2015 Primeau et al., 2017 Serda et al., 2010 Taaffe et al., 2017 Winter-Stone et al., 2015 Yanez et al., 2015
INFORMATIONAL	. Cancer process . Consequences treatment . Daily life: through presenting resources, educating on diet, exercise, self-management, relaxation, or informing about symptom-related problems	. Informational needs . Survival . Fat intake . Coping skills . Sense well-being	. Less prevalence of unmet informational needs . Better sense of well-being . No further physical deterioration . Non-significant reduction in fats intake	Badger et al., 2011 Beydun et al., 2014 Bourke et al., 2014 Cipolla et al., 2010 Huri et al., 2015 Paterson et al., 2018 Primeau et al., 2017 Yanez et al., 2015 Yennurajalingam et al., 2012
EMOTIONAL	PSYCHOSOCIAL: . Mindfulness . Counseling . Occupational therapy . Stress reduction	. Depression . Anxiety . Stress/distress . Fear recurrence . Changes lifestyle	. Two interventions reported as not efficacious . Remaining studies: significant improvement in depression, anxiety, stress, fear, mindfulness ability	Badger et al., 2011 Chambers et al., 2012 Chambers et al., 2017 Huri et al., 2015 Paterson et al., 2018 Primeau et al., 2017 Yanez et al., 2015 Yennurajalingam et al., 2012
PRACTICAL	PSYCHOSOCIAL: technology-assisted: . Counseling . Mindfulness . Stress reduction EXERCISE: . Web Exergaming IDENTIFCATION OF DAILY LIFE ACTIVITIES AFFECTED	. Feasibility . Helpfulness . Physical activity . QOL, body composition	. Reported to be feasible and/or helpful . Non-significant lean mass increase . 4.2% favoring intervention . Ability to identify issues with home help	Badger et al., 2011 Chambers et al., 2017 Huri et al., 2015 Villumsen et al., 2019 Yanez et al., 2015
SPIRITUAL	. No specific component	. Spiritual well-being	. Significant improvement	Badger et al., 2011
PSYCHOLOGICAL	. Stress reduction	. Coping skills	. No available results	Yanez et al., 2015

Abbreviations: BMI, body mass index; QOL, quality of life; SCNCCF, supportive care needs for cancer care framework.

Figure 1. PRISMA flow diagram of the study selection process [24]

57
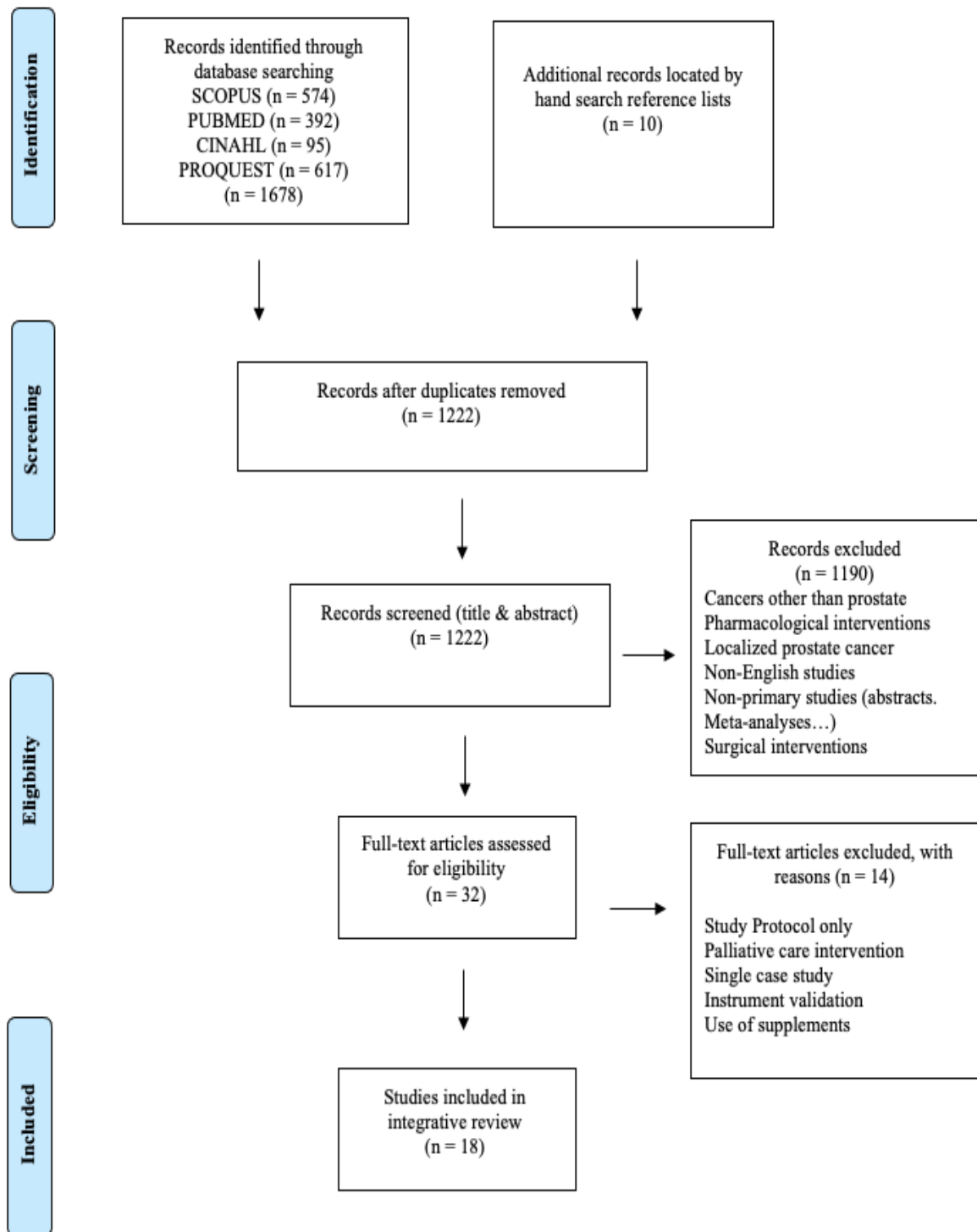
Manuscript 2: Dissertation Study

58

Unmet Supportive Care Needs in Advanced Disease Prostate Cancer Survivors: A Mixed-Methods Exploration of the Prevalence and Association with Quality of Life

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Abstract

Men with advanced prostate cancer can endure a wide range of long-term side effects from cancer and therapies, negatively affecting their quality of life. Few studies have been published about the supportive care needs for this specific population and the correlation of needs with the quality of life. The aim of this study was to conduct a holistic supportive care needs assessment among advanced disease PC survivors guided by the Supportive Care Framework for Cancer Care. Using a convergent mixed-methods approach, 188 American survivors diagnosed with advanced prostate cancer completed a cross-sectional survey (*Supportive Care Needs Survey-Short Form 34*, *PC module*, *Functional Assessment of Chronic Illness Therapy – Spiritual Well-Being*, *European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire*). A subset of 20 survivors agreed to participate in qualitative interviews. Participants identified unmet supportive care needs in every domain of the framework. A negative correlation between needs and quality of life was also established. Results revealed that 95.2% of the survivors had at least one unmet need. The item with the highest prevalence (62.2%) was "fears about the cancer spreading." The findings' integration revealed several areas of convergence (fatigue, sexual dysfunction, practical, and emotional/psychological domains) and divergence (informational and spiritual domains, depression, urinary dysfunction). A priority goal is for advanced prostate cancer survivors to maintain quality of life while reducing their unmet supportive care needs. This study's results can inform the future development of individualized supportive care interventions that meet this population's needs.

Despite massive screening and development of novel treatments, the incidence of prostate cancer (PC) in the United States continues its ascending trend, from 98.8 new cases per 100,000 people in 2014 to 108.0 per 100,000 in 2017.[1] Furthermore, this incidence is estimated to rise 33.6% by 2040, partly due to an increase in men aged 65 years and older.[2] There are more than 3.6 million PC survivors living with this disease in the U.S., a third of whom will experience progression or recurrence (stage III-regionally advanced, stage IV-metastatic, or recurrent / refractory).[3,4,5,6] Treatment with curative intent is no longer an option for survivors with advanced PC. These survivors are typically managed with a combination of therapeutic agents, such as chemotherapy, androgen-deprivation therapy (ADT), and ongoing clinical trials testing individualized immunotherapy, DNA repair inhibition, vaccines, or prostate-directed radiotherapy.[7,8] Although promising, these treatments are often associated with long-term and negative effects that significantly compromise overall quality of life (QOL) and health outcomes.[9,10,11] Unmet physical, emotional, social, psychological, informational, spiritual, and practical supportive care (SC) needs often stem from those effects, costing the U.S. health care system more than $9 billion annually. [4,9-16]

SC needs are defined as survivors' desire for support to maximize QOL and minimize functional and psychosocial deterioration for a problem that arises from the illness or treatments.[17] Evidence from past studies suggests that, despite current cancer survivorship recommendations and guidelines, between 33% and 81% of PC survivors report SC needs that have not been adequately addressed.[14,18] Specifically, the unmet needs include emotional needs (52.9%), physical needs (47.1%), practical and spiritual needs (23.5%), and social needs (11.8%), further impacting QOL.[18] SC is a patient-centered approach that focuses on the prevention and proper management of the side effects of PC and its treatments, improvement of coping and decision-making skills, and reduction of functional impairments

throughout the entire cancer continuum, including survivorship.[16,20,21] The Institute of Medicine, the American Society of Clinical Oncology (ASCO), and the American Cancer Society (ACS) endorse SC as a way to improve QOL and rehabilitation, and lessen the economic hardship of cancer care on healthcare systems.[21] However, the implementation of SC varies significantly across settings, partially due to the SC needs remaining unknown for this subset of survivors.[19,21]

Research to date has investigated PC survivors' lived experiences, predictors of QOL, and the sequelae of PC treatments with curative intent at various stages of the disease. But relatively few published studies have focused solely on advanced disease PC survivors and their specific needs, or have investigated the relationship between unmet SC needs and QOL in this population.[11,15,23,24] Some literature exists on unmet physical and informational SC needs in advanced PC survivors using quantitative or qualitative approaches, but not mixed methods.[11,25] Therefore, a holistic needs assessment was warranted to enhance the understanding of this vulnerable subset of survivors' perception regarding their unmet SC needs. The findings of this study can be translated into development of patient-centered, cost-effective SC interventions aimed at enhancing advanced PC survivors' QOL and reduce burdens to healthcare systems.

The purpose of this convergent parallel mixed-methods study was to conduct an SC needs assessment among advanced disease PC survivors guided by Fitch's Supportive Care Framework for Cancer Care (SCFCC). Specifically, the authors addressed the following research questions: (1) What are the unmet supportive care needs in advanced disease prostate cancer survivors? (2) How do these unmet SC needs relate to QOL?

Methods

Theoretical Framework

61

Outlining a comprehensive taxonomy of seven domains (physical, emotional, social, spiritual, practical, informational, and psychological), the SCFCC served as the guiding theoretical framework for this study (Figure 1). The SCFCC was initially developed as a tool for healthcare providers to understand the global and complex needs of diverse cancer patients throughout the illness continuum.[26] This framework has been used successfully in previous needs assessment studies with various types of cancer survivors.[27,28] The SCFCC guided the identification and selection of a previously validated instrument to measure unmet SC needs due to the similarities between the framework and the Supportive Care Needs Survey (SCNS) domains.[29] It has also helped inform the development of the qualitative interview guide because of its holistic view of SC for cancer.[29,30] Lastly, it has guided the categorization and interpretation of the findings, identifying SC needs across domains that were particularly prevalent and had the potential to impact this population's QOL and overall health outcomes negatively.

Study Design and Setting

This exploratory study used a convergent parallel mixed-methods design. After obtaining IRB approval, cross-sectional quantitative and qualitative data were collected concurrently from advanced disease PC survivors between July and October 2020. We used a multichannel recruitment strategy to identify eligible participants. For the quantitative phase, recruitment settings included a prominent cancer center of an academic medical institution in the southern U.S., Research Match (an online research recruitment tool), various prostate cancer support groups and organizations, and online social media. The study had a waiver of informed consent; however, every eligible participant was provided with a written statement of research with all pertinent study information along with the survey introduction. The survey assessed overall and PC-specific unmet SC needs, spiritual well-being, and cancer

QOL. For the qualitative phase, a subset of survey participants was invited to participate in the interview.
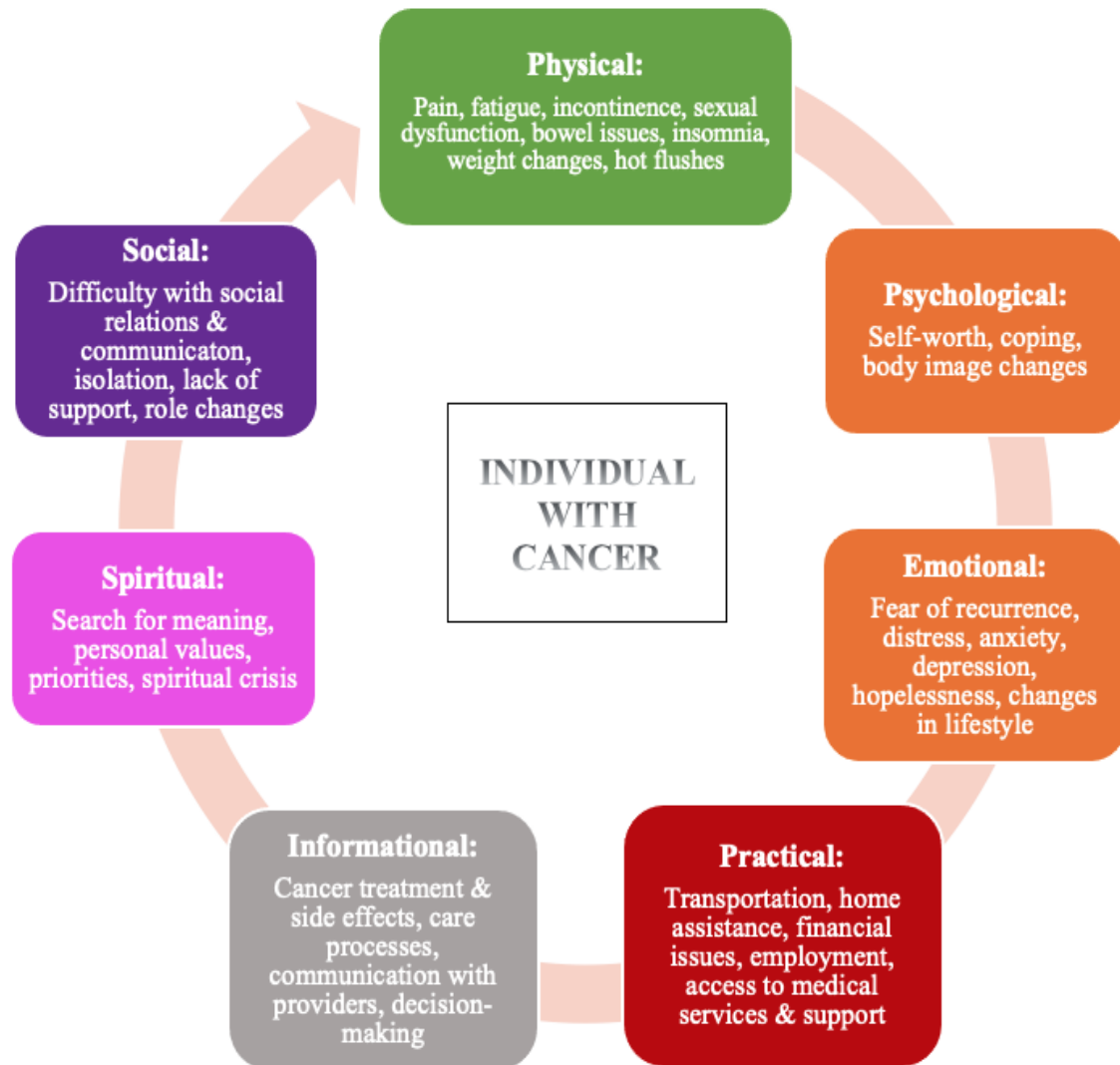
Figure 1: SCFCC Diagram Applied to advanced PC (with permission) [26]

Study Sample

In the quantitative phase, a convenience sample of survivors were enrolled if they reported meeting the following inclusion criteria: (1) had an advanced disease PC diagnosis (stages III, IV, or recurrent); (2) were ≥18 years; (3) were able to read, understand, and speak English; and (4) resided in the United States or its territories. Excluded were those who

endorsed being enrolled in palliative or hospice care or having a physical or mental impairment preventing survey completion.

For the qualitative phase, we purposively enrolled a subsample of participants who completed the survey and indicated willingness to participate in the qualitative interview. Diversity by sociodemographic and clinical factors (e.g., race, ethnicity, age, disease stage, treatments, time since diagnosis, level of education, marital status, and geographical location) was prioritized when possible to ensure maximum variation and to capture the perspective of potentially neglected and underserved populations. Recruitment continued until data saturation was achieved.[31]

Data Collection

Quantitative Data: A cross-sectional online survey was administered nationally using Research Electronic Data Capture (REDCap). Respondents who were eligible and completed the entire survey (n=188) received an electronic gift card as compensation for their time and effort. The survey included the following validated measures:

Socio-demographic and clinical questionnaire. Self-reported data included age, race, ethnicity, marital status, employment, years of education, insurance status, state of residence, age and stage at diagnosis, treatments received, and current disease stage.

Supportive Care Needs Survey-Short Form 34 (SCNS-SF34). The participants' unmet SC needs were assessed with a self-report questionnaire consisting of 34 items mapped onto five domains: physical & daily living (5 items), health care & information (11 items), psychological (5 items), patient care & support (10 items), and sexual (3 items). This instrument has robust similarities with the most relevant domains of the SCFCC.[32,33] However, some domains are not separated within the instrument subscales. For example, the items that measure emotional needs are included in the psychological subscale. The items that measure psychological needs are included in two separate subscales (psychological and

health system and information). Respondents reported the extent to which they needed help with each item over the past month on a 5-point Likert scale (1=not applicable (no need), 2=satisfied (had need but need for help was satisfied, 3=low need, 4=moderate need, 5=high need). All responses were summed within need domain and standardized from 0 to 100, with higher scores representing higher level of needs. The instrument has excellent internal reliability (Cronbach´s α coefficients between .86 and .95), internal consistency, and robust content validity (coefficients between .87- and 96).[34]

Supplementary SCNS PC Module. This module assessed PC-specific unmet needs and it is appropriate for use with patients at varied PC disease stages, treatment modalities, and time since the initial diagnosis. It consists of 8 additional items with the same SCNS-SF34 response set and scoring.[34]

Functional Assessment of Chronic Illness Therapy – Spiritual Well – Being (FACIT-Sp 12). This questionnaire was used to collect data on the participants' spiritual well-being (meaning, faith, and peace). It includes 12 items, derived from a longer questionnaire, with summary scores ranging from 0 to 48. A higher score indicates greater spiritual well-being.[35] This subscale has been validated across multiple cultures and has strong reliability (Cronbach coefficient 0.87).[36] To adapt to the other instruments used in this study, a minor change to the FACIT-Sp questionnaire was made, modifying its time frame from 7 days to one month so that all the unmet needs findings are consistent with the same specific time frame.[37]

European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30. The EORTC QLQ-C30 is an integrated system consisting of 30 items divided in five functional scales, three symptom scales, one global health/QOL scale and 6 individual symptom items. It uses a four-point Likert response set for all the items except for the health status and QOL scales, which are measured on a 7-point scale. Scores were calculated by scale or by item and transformed into a 0 to100 summary score with a

higher score representing higher QOL or higher symptomatology level. It possesses a high degree of consistency with Cronbach' s α coefficients ranging between .70 and .96.[4,38]

Qualitative Data: Qualitative description guided the qualitative arm of the study. Individual, semi-structured interviews were conducted via telephone to explore the influence of SC unmet needs on the QOL of survivors more in-depth. Following the identification of the participants, the principal investigator (PI) contacted them to arrange the interview at a day/time of their convenience. Socio-demographic and clinical information were collected including age, race, ethnicity, education level, marital status, employment status, insurance status, PC stage at diagnosis, current PC stage, age at initial diagnosis, and treatments received. The interview guide was developed based on the SCFCC. Probes were used throughout the interview to elicit additional explanations or to redirect the participant.[31,39] The PI maintained a reflective journal to record impressions about the interview. Every interview lasted between 15-52 minutes, depending on how much the participant wanted to share and was audio-recorded and professionally transcribed using Rev.com.

Data Analysis

Quantitative Data. All statistical analyses were performed using SPSS v25. software.[40] Socio-demographic and clinical data were analyzed using descriptive statistics to provide a summary of the sample characteristics. The SCNS-SF34 and the EORTC-QLQ-C30 instruments were scored according to the manual and the scores converted to a standardized 0-100 scale.[34,38] To identify the unmet SC needs, the mean number of needs, and the prevalence (i.e., frequency, proportion, mean, standard deviation, range) were calculated per domain and individually per item of the SCNS-SF34, the PC-module, and the FACIT-Sp instruments. A total score for the FACIT-Sp and the EORTC-QLQ-C30 was also obtained. The SC needs items with the highest prevalence were also identified and reported. Bivariate correlational analyses with Pearson's *r* computation were performed to determine the strength

and direction of the relationship between each domain of SC needs and QOL. A *p* value of less than 0.05 was used to determine a statistically significant value.[41] Missing data were reported; no imputation was carried out.

Qualitative Data. Descriptive statistics were used to summarize the sample's characteristics. The recordings were transcribed verbatim. The PI cross-checked and read each transcript several times for accuracy, removing any identifying information. Qualitative deductive-inductive content analysis was conducted using NVivo12 to provide a rich account of the data.[16,42,43] The PI performed several coding levels that were further categorized into final themes/subthemes guided by the domains of the SCFCC. An iterative comparative method was followed throughout the qualitative data collection and analysis until data saturation was achieved, using each interview's analysis to inform subsequent interviews [39,44,45] Throughout the analyses, emergent themes were compared across transcripts.

The concepts identified by Lincoln and Guba were followed to ensure rigor.[46] Credibility was established by providing a statement of research to each participant prior to the interview, by writing impressions about the interview, by conducting several levels of data coding, and by having several members of the research team verify the transcripts and themes (S.N and S.Q). Dependability was achieved by keeping an audit trail of all decision-making procedures. Confirmability was established during the interviews through repetitive questioning and probes for clarification, and by including direct quotations as evidence of the data collected. Transferability was ensured by the sampling strategy and documentation of the recruitment and data collection processes.[46] Additional triangulation was performed by contrasting the results with those from the quantitative survey and comparing the final results with prior studies conducted with similar populations.[11,16,39]

Quantitative and qualitative data were analyzed separately. The merging and integration occurred in a subsequent step. Both sets of results were reviewed and synthesized

to compare and contrast emerging themes. This process enabled side-by-side comparison of quantitative and qualitative data to find similarities, differences, and/or inconsistencies.[39]

Results

Demographic and Clinical Characteristics

From a total of 670 survivors who accessed the quantitative survey, 188 were eligible for inclusion in the study. The remaining did not meet the inclusion criteria or started the survey but exited it before completion. Overall, the mean (SD) age of the sample was 69.0 (8.8) years. Most men were White (93.1%), married (82.4%), college degree holders (79.3%), and retired (68.1%). The majority (63.5%) lived in southern states. Almost half of the participants (49.7%) reported having a stage IV cancer. The mean (SD) age at diagnosis was 61.6 (8.1) years. Most participants had completed multiple treatments, such as ADT (74.5%), radiation (63.3%), or surgery (60.1%) (Table 1).

A total of 43 survivors were invited to participate in the qualitative semi-structured interview, but 21 declined or were lost to follow-up. A total of 22 interviews were performed, but two were not included in the analysis because the participants did not meet the inclusion criteria due to a discrepancy on the current disease stage discovered as the interview progressed. The mean (SD) age for the 20 participants was 67.4 (8.4) years (Table 1). Most were White (90%), married (70%), retired (50%), and held a college degree (90%). Current disease stages of III, IV, and recurrent were somewhat evenly represented (25%, 40%, and 35%, respectively). The mean (SD) age at diagnosis was 59.4 (8.8) years. Surgery, radiation, and ADT were also the most commonly received treatments.

Table 1. Sample Demographic and Clinical Characteristics

	Quantitative Survey Participants (N=188)[a]		Qualitative Interview Participants (N=20)[a]	
	n (%)	Mean (SD)	n (%)	Mean (SD)
Age	**143 (73.1)**	**69.0 (8.8)**	**18 (90)**	**67.4 (8.3)**
40-49	3 (1.6)		0 (0)	
50-59	17 (9)		4 (20)	
60-69	53 (28.2)		6 (30)	
70-79	53 (28.2)		7 (35)	
80-89	16 (8.5)		1 (5)	
90+	1 (0.5)		0 (0)	
Race	**187 (99.5)**		**20 (100)**	
White	175 (93.1)		18 (90)	
Black	9 (4.8)		2 (10)	
American Indian/Alaskan	1 (0.5)		0 (0)	
Ethnicity	**186 (98.9)**		**20 (100)**	
Hispanic	2 (1.1)		0 (0)	
Non-Hispanic	184 (98.9)		20 (100)	
Marital Status	**187 (99.5)**		**20 (100)**	
Never Married	7 (3.7)		2 (10)	
Partnership	4 (2.1)		1 (5)	
Married	155 (84.4)		14 (70)	
Divorced	17 (9)		2 (10)	
Widower	4 (2.1)		1 (5)	
Level of Education	**187 (99.5)**		**20 (100)**	
High School or GED	11 (5.9)		1 (5)	
Some College	27 (14.4)		1 (5)	
College Graduate & beyond	149 (79.3)		18 (90)	
Employment Status	**187 (99.5)**		**20 (100)**	
Full Time	43 (22.9)		9 (45)	
Part Time	9 (4.8)		1 (5)	
Unemployed-actively looking	1 (0.5)		0 (0)	
Unemployed	2 (1.1)		0 (0)	
Retired	128 (68.1)		10 (50)	
Disabled	3 (1.6)		0 (0)	
Geographical Location	**181 (96.3)**		**19 (95)**	
Northeast	19 (10.3)		1 (5)	
South	115 (63.5)		8 (40)	
Mid-West	19 (10.3)		2 (10)	
West	15 (8.1)		6 (30)	
Pacific	17 (9.2)		2 (10)	
Age at Diagnosis	**184 (97.9)**	**61.6 (8.1)**	**19 (95)**	**59.4 (8.8)**
30-39	1 (0.5)		0 (0)	
40-49	8 (4.3)		0 (0)	
50-59	63 (33.5)		11 (55)	
60-69	81 (43.1)		6 (30)	
70-79	29 (15.4)		2 (10)	
80+	2 (1.1)		0 (0)	
Cancer Stage at Diagnosis	**187 (99.5)**		**20 (100)**	
Stage I	36 (19.1)		5 (25)	
Stage II	42 (21.8)		7 (35)	
Stage III	59 (31.4)		6 (30)	
Stage IV	49 (26.1)		2 (10)	
Treatments Received	**188 (100)**		**20 (100)**	
Surgery	113 (60.1)		17 (85)	
Radiation	119 (63.3)		14 (70)	
Chemotherapy	42 (22.3)		1 (5)	
ADT	140 (74.5)		11 (55)	
Brachytherapy	18 (9.6)		2 (10)	
Cryotherapy	7 (3.7)		1 (5)	
Other (Vaccine, HIFU…)	27 (14.4)		6 (30)	
Current Cancer Stage	**187 (99.5)**		**20 (100)**	
Stage III	53 (28.2)		5 (25)	
Stage IV	93 (49.7)		8 (40)	
Stage Recurrent	41 (21.8)		7 (35)	

[a] Some of the participants did not provide an answer for some of the sociodemographic and clinical characteristics.
Abbreviations: ADT, Androgen-Deprivation Therapy; HIFU, High-Intensity Focused Ultrasound

Theme 1: Survivors' Perception and Prevalence of Supportive Care Needs

Overall, needs were reported in all seven domains. Up to 95.2% of the PC survivors surveyed reported having at least one unmet SC need. The proportion of survivors reporting PC-specific needs was 83.5%, while 79.8% endorsed emotional/psychological needs, and 74.5% reported sexual needs. Needs were also identified within the physical (64.4%), informational (59.6%), practical (45.7%), and spiritual domains. The mean total number of unmet SC needs was 14.9±10, ranging from zero to 42 for each domain.

Of all the SCNS domains, in those reporting some need (either low, moderate, or high need)[32] the highest level of need was endorsed for the sexuality domain (39.4±29.2), followed by the psychological domain (37.6±22.9) and the physical & daily life (29.9±23.4). In contrast, the lowest levels of need were endorsed for patient care & support *(*27.2±21.0). In three out of the six SCNS domains greater than 50% of respondents reported *some level of need* in the psychological, sexuality, and PC-specific module items. In addition, 38.3% of the participants who completed the spiritual well-being subscale expressed they had "little" or just "somewhat" level of peacefulness. A detailed account of the unmet SC needs' mean scores, frequencies, and percentages is presented in Table 2.

Table 2. Mean (SD), Observed Range, and Frequency (Proportion) of "Some Need" Degree of Supportive Care Needs per Domain (N=188)[a]

Items by Domain			Some Need n (%)			
	Mean (SD)	Range	Low	Moderate	High	OVERALL
Physical & Daily Living	29.9 (23.4)	0 - 80				
Pain			31 (16.5)	13 (6.9)	4 (2.1)	48 (25.5)
Lack energy/tiredness			41 (21.8)	39 (20.7)	13 (6.9)	93 (49.4)
Feeling unwell a lot of time			38 (20.2)	17 (9.0)	4 (2.1)	59 (31.3)
Work around home			27 (14.4)	18 (9.6)	6 (3.2)	51 (27.2)
Not do things I used to do			41 (21.8)	31 (16.5)	15 (8.0)	87 (46.3)
Psychological	37.7 (22.9)	0 - 97.50				
Anxiety			55 (29.3)	26 (13.8)	6 (3.2)	87 (46.3)
Feeling down/depressed			52 (27.7)	20 (10.6)	6 (3.2)	78 41.5)
Feelings of sadness			53 (28.2)	21 (11.2)	6 (3.2)	80 (42.6)
Fears about cancer spreading			63 (33.5)	37 (19.7)	17 (9.0)	107 (62.2)
Worry about results of treatment			46 (24.5)	33 (17.6)	15 (8.0)	94 (50.1)
Uncertainty about future			60 (31.9)	38 (20.2)	11 (5.9)	109 (58)
Learning to feel in control			51 (27.1)	25 (13.3)	4 (2.1)	80 (42.5)
Keeping positive outlook			42 (22.3)	18 (9.6)	10 (5.3)	70 (37.2)
Feelings about death/dying			45 (23.9)	22 (11.7)	10 (5.3)	77 (40.9)
Concerns about worries of those close			42 (22.3)	42 (22.3)	16 (8.5)	100 (53.1)
Health System & Information	27.2 (21.0)	0 - 100				
Be given information about important aspects of your care			27 (14.4)	13 (6.9)	6 (3.2)	46 (24.5)
Be given information (written, diagrams) about aspects of managing illness at home			30 (16)	21 (11.2)	4 (2.1)	55 (29.3)
Be given explanations of tests for which you would like explanations			17 (9.0)	15 (8.0)	10 (5.3)	42 (22.3)
Be adequately informed on benefits & side effects of treatments before you choose			21 (11.2)	22 (11.7)	12 (6.4	55 (29.3)
Be informed about test results as soon as feasible			15 (8.0)	12 (6.4)	10 (5.3)	37 (19.7)
Be informed about cancer under control or diminishing (remission)			26 (13.8)	12 (6.4)	8 (4.3)	46 (24.5)
Be informed about things you can do to help yourself to get well			34 (18.1)	20 (10.6)	10 (5.3)	64 (34.0)
Have access to professional counseling e.g., psychologist, social worker) if your family/friends need it			32 (17.0)	20 (10.6)	10 (5.3)	62 (32.9)
Be treated like a person, not just a case			24 (12.8)	15 (8)	7 (3.7)	46 (24.5)
Be treated in a hospital/clinic as physically pleasant as possible			15 (8.0)	12 (6.4)	6 (3.2)	33 (17.6)
Have member of hospital staff with whom you can talk about all aspects of condition			26 (13.8)	18 (9.6)	14 (7.4)	58 (30.8)
Patient Care & Support	27.2 (21.0)	0 - 100				
More choice about cancer specialist you see			29 (15.4)	21 (11.2)	5 (2.7)	55 (29.3)
More choice about which hospital you attend			26 (13.8)	14 (7.4)	4 (2.1)	44 (23.3)
Reassurance by medical staff that the way you feel is normal			31 (16.5)	15 (8)	5 (2.7)	51 (27.2)
Hospital staff to attend promptly physical needs			26 (13.8)	12 (6.4)	4 (2.1)	42 (22.3)
Hospital staff to acknowledge/show sensitivity to your feelings & emotional needs			27 (14.4)	12 (6.4)	5 (2.4)	44 (23.5)
Sexuality	39.4 (29.2)	0 - 100				
Changes in sexual feelings			46 (24.5)	39 (20.7)	26 (13.8)	111 (59.0)
Changes in sexual relationships			32 (17.0)	30 (16.0)	23 (12.2)	85 (45.2)
To be given information about sexual relationships			30 (16.0)	21 (11.2)	9 (4.8)	60 (32.0)
PC Module	29.6 (19.4)	0 - 78.1				
Urinary incontinence			45 (23.9)	26 (13.8)	12 (6.4)	83 (44.1)
Difficulties passing urine			27 (14.4)	9 (4.8)	7 (3.7)	43 (22.9)
Hot flushes			44 (23.4)	26 (13.8)	11 (5.9)	81 (43.1)
Problems with bowel habits			40 (21.3)	11 (5.9)	4 (2.1)	55 (29.3)
Feeling as you going through a life like women			39 (20.7)	12 (6.4)	8 (4.3)	59 (31.4)
Feeling like you have lost part of manhood			40 (21.3)	34 (18.1)	25 (13.3)	99 (52.7)
Feeling like what you say is not taken seriously by others			25 (13.3)	14 (7.4)	4 (2.1)	43 (22.8)
Feeling like you have lost the ability to be aggressive			24 (12.8)	14 (7.4)	6 (3.2)	44 (23.4)
Spiritual Well-Being - FACIT-Sp Subscale[a]	27.02 (9.2)	0 - 44				

[a] Some of the participants did not provide an answer to some of the SCNS and FACIT questions.
[b] Higher score represents better spiritual well-being.
Abbreviations: FACIT-Sp, Functional Assessment of Chronic Illness Therapy-Spiritual Well-being.

The 12 most prevalent individual unmet SC needs items are presented in Table 3. Almost half (5 out of 12) of the top 12 needs items were associated with the emotional/psychological domains. The remaining belonged to the sexuality (2), PC-specific (3), and physical (2) domains. The three most commonly endorsed items included "fears about the cancer spreading" (62.2%), "having changes in sexual feelings" (59%), and "uncertainty about the future" (58.0%).

Table 3. Top 12 Reported Supportive Care Needs.

Supportive Care Needs	n	Prevalence (%)	Domain
Fears about cancer spreading	107	62.2	Psychological
Changes in sexual feelings	111	59.0	Sexuality
Uncertainty about the future	109	58.0	Psychological
Concerns about worries of those close	100	53.1	Psychological
Feeling like you have lost your manhood	99	52.7	PC-module
Worry about results of treatments	94	50.1	Psychological
Lack of energy / tiredness	93	49.4	Physical & Daily Living
Not do things I used to	87	46.3	Physical & Daily Living
Anxiety	87	46.3	Psychological
Changes in sexual relationships	85	45.2	Sexuality
Urinary incontinence	83	44.1	PC-module
Hot Flushes	81	43.1	PC-module

Quantitative and Qualitative Findings as per SCFCC Domains

1.1. Unmet Physical Needs

Needs that stem from physical symptoms and the inability to carry out activities of daily life belong to the physical domain, reflected in items in the sexuality, physical, and PC-modules of the SCNS domains.[26] A total of 39.5% of the participants reported some degree of needs in the physical domain. The mean scores of the three subscales were 39.4±29.2 (sexuality), 29.9±23.4 (physical), and 29.6±19.4 (PC-module), ranking first, third, and fourth out of the six categories in this instrument respectively. Participants reported several types of cancer and treatment-related unmet SC needs related to this domain. The highest level of need was related to the respondents' sexuality/intimacy (59% "changes in sexual feelings"

and 45.2% "changes in sexual relationships"), followed by fatigue (49.4% "lack energy / tiredness" and 46.3% "not being able to do the things I used to do"), and "urinary incontinence" (44.1%). Additional unmet needs included "hot flushes" (43.1%), gastrointestinal problems (29.3%), and "pain" (25.5%).

The qualitative interviews revealed similar findings. As reflected in the survey data, men also complained of urinary dysfunction, fatigue, and sexual problems in interviews. Urinary dysfunction was reported by 14 out of the 20 men in several forms: urinary frequency, incontinence, and even caring for a urostomy as the result of the treatments. One participant shared: *"Urination, well, my urination, the doctor who removed the prostate left me incontinent and I worked real hard with physical therapy, didn't gain anything. So I wear diapers and I have a penile clamp…"*

Approximately 65% of the interviewees reported fatigue to the point of sometimes interfering with their past hobbies, daily activities, and even socialization. Although some men stated that part of the fatigue was probably the effect of age, some recognized that it became more evident after the diagnosis and treatments, particularly after radiation or ADT. One man said: **"***I am more tired than I ever used to be. And I've noticed that.***"**

Loss of sexual function was a primary concern for many of the participants (n=10). The causes were reported to be either surgery or taking ADT. While one participant seemed content with his sexual function due to a new pumping prosthesis, others qualified sex as "inexistent" and talked about the deep effect that it had on their overall QOL and well-being*:* **"***Well, it has an effect on my sexual interest…And I didn't realize before the surgery, how important that was just to my wellbeing and my mental health***"**

Some of the participants described additional physical needs not captured by the quantitative survey. Although unpleasant, most have accepted these needs as expected consequences of advanced PC and the treatments. Participants talked about hot flushes at

night, pain, weight gain after taking ADT, and sleeplessness, all of which impacted their daily life: *"There's a certain amount of pain that I have to try and manage. So, the pain, in some ways, prohibits me from doing things that I would like to do. So, I'd say it's a great impact."*

1.2. Unmet Emotional Needs

Emotional needs arise from a lack of reassurance and comfort related to living in distress due to the cancer.[26] The mean score of the psychological subscale was 37.6±22.9, reflecting the second highest reported by the total sample, with 44.4% of the respondents endorsing some needs in this domain. The greatest reported emotional needs included "fears about cancer spreading" (62.2%), and "uncertainty about the future" (58%), followed by "worry about results of treatment" (50%), "anxiety" (46.6%), and "depression"/"feelings of sadness" (42.6%).

In the interviews, men spoke of emotional health as one of the most affected areas. Some of the survivors were diagnosed a few years earlier and were still facing unresolved needs related to feelings of anxiety, fear, or depression. Four men even expressed anger and regret about the decisions that they had made after the initial diagnosis. They believed that if they had been better informed, their outcomes, including emotional outcomes, would have been more optimal and they would not feel angry or regretful. One survivor shared: *"And I wish I knew then what I know now, I guess is what I'm trying to say, regarding just the literal day-to-day, how is this going to affect your life."*

Nine men also spoke about the emotional consequences of advanced PC and the treatments, emphasizing that sometimes existential concerns trigger excessive worry and loss of confidence about the future, mainly due to a possible loss of role within their family: *"I spend a fair amount of time thinking about the future and worrying. It all has impacts. I spend a lot of times trying to figure out how to deal with the side effects and that takes time*

74

away from the things I want to do." However, only 25% of the participants revealed strong fear about the disease recurring in the near future. The reason may be that many of those men already had a recurrent or metastatic disease at the time of the interview.

One survivor talked about the emotional toll of becoming an advanced cancer survivor. Anxiety was a problem for half of the interviewees (n=10). Consciously or not, they have suffered from high levels of anxiety at some point during their advanced disease trajectory*: "Sure, definitely as I've mentioned it, I get a kind of a little great worry or anxiety always kind of running in background"* Depression was also a concern reported by 25% of these men, primarily tied to the effects of surgery or as a consequence of prolonged ADT treatment: *"Initially, I had quite a terrible experience my second year of my cancer. And that was due to the Lupron, Leuprolide that I was taking. I was severely depressed…"*

1.3. Unmet Informational Needs

Informational needs stem from a lack of or insufficient information for adequate decision-making.[26] 27.2% of the sample reported some informational needs. The mean score (29.5±21.5) was the second lowest, after patient care & support. The top two needs reported under this domain included "be informed about things you can do to yourself to get well" (34%) and "have member of hospital staff with whom you can talk about all aspects of condition" (30.8%). All the remaining items had a prevalence of less than 30%.

During the interview, all the participants said that they received information on advanced PC and related treatments from various sources. These sources were formal, through their medical team (e.g., pamphlets), or informal, by joining support groups or by personally researching about topics online. However, up to 80% voiced repeated dissatisfaction with the type and/or amount of information they received throughout their journey. For some, the problem arose from the time of diagnosis: **"…***the conventional wisdom, the cliché that you're going to get is, "Oh, prostate cancer's no big deal…"* For

others, the information was insufficient regarding the side effects of the therapies: "*But the hormone therapy, the side effects from it, I had no idea what they were. I was told... I was kind of jokingly told that, "Oh, you're going to have difficulty with a lot of things like sexual ability, et cetera." And it's injecting the female hormone, so I will have a lot of different issues that women have with women's hormones. So that was the end of it. It really didn't go into great detail about it.*" Some complained about the lack of information regarding available sources of support. But no less important was the insufficient guidance regarding latest treatments developments outside their healthcare team that they could benefit from: *"I think one of the challenges is trying to access kind of more emerging information about for example, clinical trials that might be going on. Finding that kind of information seem to be a little bit harder to kind of pinpoint.*"

One survivor expressed regret about not asking questions or communicating effectively with the medical team. However, this was not the only problem. 20% of the participants explained that they had issues understanding the information received, not finding the information they were looking for, or feeling anxious about the information overload: *"Well, reading a lot about prostate cancer in itself is anxiety-provoking."*

1.4. Unmet Practical Needs

Practical needs are related to the cancer journey itself and the demands of the disease on the person and their daily life.[26] In total, 25.1% of the survey participants reported some needs under this domain and patient care & support items had the lowest total prevalence among the various SCNS subscales, with a mean of 27.2 ± 21.0. Only 22.3% responded having needs with "hospital staff to attend promptly physical needs". However, a third of all respondents wished for "more choice about cancer specialist you see". Practical needs stemming from transportation or finances were not specifically measured by any item of the SCNS or the FACIT, despite the topic coming up during the qualitative interviews.

Most interview participants felt that they were sufficiently supported regarding their disease, whether it was by their medical team or the informal internet support community, and none reported transportation challenges. However, some reported having other unmet practical needs. 35% explained that, due to the illness and the side effects of the treatments, they encountered difficulties working around the house. Some even wished they had some assistance with certain home chores: *"I do have difficulty bending over and picking things up. And so housework, a good stove... I get behind on the housework. I could use help there. That's for sure."* In addition, finances were also cited as a reason for worry in some cases. Most participants expressed satisfaction about their medical insurance and monetary situation but 45% of the interviewees said that paying for the insurance premium or for medical expenses related to advanced PC was challenging at times: *"So, from a financial viewpoint, I guess we kind of keeping an eye on our situation because we're somewhat anxious over possible and unanticipated additional medical expenses."*

1.5. Unmet Spiritual Needs

Needs arising from a loss of meaning in life and changed personal values are included under the spiritual domain.[26] The mean FACIT-Sp total score was 27.0±9.2, on a 0-48 scale. Survey respondents expressed a high level of peace/meaning with a mean subscale of 22.9 (range 0-32). Likewise, their level of faith was expressed as slightly above average, with a mean of 8.2 (range 0-16). Regarding individual items, 50% of the participants endorsed "My illness has strengthened my faith/beliefs" and 38.3% endorsed "I find strength in my faith/spiritual beliefs" as none or little.

Interviews highlighted that 65% of the participants considered that spirituality had a prominent role in their lives despite individual differences in spiritual beliefs. Most did not experience any spiritual crises or changes in their relationship with God. For some, their level of faith grew throughout their cancer journey or came back after a brief turndown:

"…gradually, I started going back to church to see how it would go, and it came back. I'm not even sure when and how, but it did. And it's very supportive for me right now."

None of the participants specifically blamed their disease on themselves or their beliefs/religion or searched for a special meaning regarding their diagnosis. Overall, their spirituality and related activities (e.g., church) did not change and they expressed belief that life had become more precious since the time of diagnosis. However, 30% reported that their current PC situation had some degree of impact on their spirituality or personal values: *"Okay. I don't hold on to my own life as fiercely as I once did. I'm more content now to see myself as part of a much larger process…"*

1.6. Unmet Social Needs

Social needs derive from affected social roles and/or lack of social support during the cancer experience.[26] Aside from one isolated item included under the health system & information subscale, "feeling like what you say is not taken seriously by others", the social domain was not evaluated thoroughly in the quantitative data. However, "feeling like what you say is not taken seriously by others" was endorsed as a need in 22.8% of the participants who completed the survey.

The qualitative data also highlighted the limited impact of advanced PC on social well-being. The majority of participants explained that their social life was maintained more or less as usual (e.g., going out to eat, visiting friends or family). Up 50% of the survivors described having some sort of social support, whether it was family members, spouse, friends, church, or the medical or internet communities. However, 25% acknowledged PC having some impact on social life, whether it was in the form of intimacy changes, lack of understanding, or changes in socialization: *"…having cancer is like living in a different world that a lot of people don't understand and will never."*

1.7. Unmet Psychological Needs

According to the SCFCC, psychological needs are associated with inappropriate coping styles or problems with changes in body image.[26] The SCNS and PC modules do not measure any changes in body image but do evaluate coping through three separate items. The item "learning to feel in control" had 42.5% of respondents expressing some degree of need. The other two items, "keeping a positive outlook" and "have access to professional counseling", showed needs in 37.2% and 32.9% of the respondents respectively.

Interview participants explained that they did not have much difficulty coping with the disease. Coping mechanisms were varied and included learning to live with it, considering advanced PC a wake-up call in life, trying to keep a positive attitude, praying, exercising, or showing resignation:*"…it's more it's becoming a resignation, if you will, that either I'm going to live with this and die from something else or I'm going to die from this."* However, 4 participants shared having some problems with their coping. A couple of survivors even admitted needing professional help: *"In terms of coping with the psychological aspect, I realized pretty early on that I was mentally going into a very bad place, dark place. I knew that I needed to reach out to someone…"*

Theme 2: Survivors' Perception of Quality of Life

In terms of survivors' QOL, the mean EORTC-QLQ-C30 total score was 78.6±14.6 (out of possible 100). The global health/QOL subscale had the lowest score (68.5±20.8). A statistically significant negative correlation was found between all the domains of the SCNS and the total QOL score (all $p<.001$), indicating that a higher level of unmet needs was associated with a lower QOL. The correlation magnitude ranged from -.37 (sexuality domain and QOL) to -.76 (physical and QOL).

Most survivors participating in the qualitative interviews had a positive perception of their QOL. However, five men spoke openly about the reasons why they believed their QOL was poor. Often times these reasons were related to the harmful effects of the advanced PC

therapies: "*I feel like I have a good quality of life right now, in part because I'm not in active treatment.*" By contrast, others believed that a lower QOL was associated directly with their impaired emotional health: "*Probably a four, probably sounds terrible but it's more emotional than it is physical. Quality of life physically, I'm probably an eight. But quality of life overall, four or five and that's anxiety related…*"

Integration of Results

After analyzing both strands of data separately, the integration was completed in a separate step. A joint display was created guided by the SCFCC domains (Figure 2). Through triangulation, we were able to note the extent to which both sets of data produce a more comprehensive understanding of the prevalence and type of unmet SC needs among advanced PC survivors and the relationship of those unmet needs with QOL through convergent and divergent points.[39] For instance, while talking to participants about their informational needs (under theme 1), most complained about receiving insufficient information regarding the various aspects of their condition (grey box qualitative codes, figure 2). Notably, this was an area of divergence, as the quantitative findings described a totally different picture (grey bar quantitative mean); only between 17.6% and 34% of the respondents expressed having unmet needs under this domain.

Figure 2. Integration of the Quantitative and Qualitative Results

INTEGRATION OF STUDY FINDINGS

Quantitative Domains Mean	Qualitative Codes	Meta-Inferences
Sexuality	Erectile dysfunction / Lack of sexual life / Decreased libido	**Points of Convergence:**
Emotional/Psycho	Anxiety / Depression / Existential concerns (worry about future) / Fear of recurrence	• EMOTIONAL DOMAIN, similar prevalence in anxiety, and existential concerns
Physical	Fatigue / Gastro-intestinal problems / Pain / Weight changes / Sleep disturbances	• PRACTICAL NEEDS, work around the house
PC-module	Urinary dysfunction / Hot flushes	• PHYSICAL DOMAIN, fatigue, sexual dysfunctions
Informational	Finding the right information / Information deficiencies / Problems with information	**Points of Divergence**
Patient Support	Financial needs / Transportation / Home assistance	• INFORMATIONAL DOMAIN, 19.4%-34% of the quantitative versus 80% in the qualitative interviews on informational deficiencies.
Spiritual WB	Temporary loss of faith / Progressive decline of spirituality	• SPIRITUAL DOMAIN, qualitative data revealed impact on spirituality/personal values in 30% of participants.

The chart shows Quantitative Domains Mean values on a scale of 0, 10, 20, 30, 40, 50.

Additional Meta-Inferences (Points of Divergence continued):
- PHYSICAL DOMAIN: urinary dysfunction was more prevalent on the qualitative findings.
- EMOTIONAL DOMAIN: more fear of cancer spreading and depression found in the quantitative results.

*FACIT-Sp12 instrument
Abbreviations: QOL, quality of life; Spiritual WB, Spiritual Well-Being

Discussion

To the best of our knowledge, the present study is among the first to categorize the prevalence and types of unmet SC needs in American men affected by advanced PC using a mixed-methods design. There were several important findings. First and foremost, this study reported that respondents had unfulfilled needs in every item representing every domain of the SCFCC. This suggests that these survivors experience a wide variety of unmet SC needs. Second, we found that more unmet SC needs were associated with lower QOL among these PC survivors. These findings coincide with multiple past studies conducted in Canada, Australia, and Europe that suggested an association between advanced PC and greater levels of unmet needs and poorer QOL in this population.[4,11,47] Third, more than fifty percent of the items in the three instruments used to collect the quantitative data reflected needs in at least

30% of the participants. This is important for two reasons: (1) most of those needs were also identified during the qualitative interviews, and (2) the prevalence exceeds the threshold suggested by the SCFCC, indicating clinically relevant unmet SC needs that have not been addressed effectively by healthcare systems.[26,30]

There were several areas of convergence between the two sets of data. Consistent with prior research reporting high prevalence of fatigue and sexual dysfunction among advanced PC survivors, both survey and interview respondents identified those as unmet priority physical SC needs. Further, they explained how both fatigue and sexual issues interfered with daily life, leading to a range of negative feelings.[47,48] Regarding fatigue, most of these participants explained that they tried to continue with their life as usual despite its complex and multidimensional effects. Some even described becoming more aware of their health, and making appropriate lifestyle changes regarding nutrition, for example. This finding is not supported by some studies that suggested that the level of fatigue did not improve despite advanced cancer patients' use of several fatigue-reducing strategies.[49,50] Additional research is warranted to explore potential causes for discrepancy.

Sexual dysfunction was found to be the most troubling unmet physical need for almost half of all participants. Although some differences in the study approach and sample can exist, this prevalence is similar to findings in other studies.[16,48] The survivors explained that they would have opted for alternative treatments other than prostatectomy or ADT if they had known the true impact on libido and sexuality. Decision regret has been highlighted as a common experience by many PC survivors. Past studies have associated decision regret with lack of literacy or self-education utilizing the Internet as their primary source for information. [51,52] To ensure that the treatments fulfill the survivor's expectations and preferences regarding expected side effects, clinicians must provide individualized information about the expected

impact of the different treatments on sexual and other body functions consistently and in a proactive manner.[51,53]

Another area of convergence included the emotional and psychological domains. As in other similar studies, many participants felt fortunate having PC over other types of cancer. They acknowledged several coping mechanisms in dealing with the disease, such as acceptance or looking at it in a more positive light.[54] However, some men also revealed anxiety and fear regarding their own mortality, the cancer spreading, the future, and the results of treatments, making them extremely aware about their current situation. These findings coincide with previous research reporting that 54% of advanced PC survivors manifest uncertainty, anxiety, or regret about treatment decisions.[55,56] Further, it has been found that between 66% and 84% of survivors from PC and other cancers (i.e., lung) experience long-term psychological distress and up to 30% clinically relevant levels of anxiety that need professional involvement.[57,58]

On the surface, the findings regarding physical and emotional needs appear to be foreseeable, as the extant literature has associated advanced PC therapies with fatigue, pain, decreased libido, impotence, anxiety, and existential concerns.[4,12,13,21,25] However, the high prevalence of physical and emotional needs is concerning and may be clinically relevant. Despite the profound impact that physical and emotional unmet SC needs have on survivors, despite all the current ACS and ASCO survivorship guidelines, and despite recommendations to connect survivors to appropriate physical and psychosocial screening and interventions, the SC they received beyond routine clinical care appears to be suboptimal at best.[19,20,56,59]

Even though the quantitative and qualitative questions did not match in the practical needs domain, a lower number of practical SC needs were reported in both strands of data. Survivors voiced that areas such as choice of treatment, healthcare team, and transportation were sufficiently met throughout their disease trajectory. However, a few of these men

encountered difficulties dealing with housework and finances. One previous U.S study suggested that the survivorship stage can be the most expensive of all.[25] The few survivors still employed struggled with medical expenses or insurance premiums. This burden will likely continue as they will need further treatments to keep advanced PC under control. More research is necessary to develop and implement strategies that mitigate practical needs and prevent financial toxicity among this subset of survivors.[60]

We found several areas of divergence during the integration process. As reported in Table 2, quantitative reports of unmet informational needs were relatively low. Furthermore, no informational needs were included in the top 12 needs categorized in Table 3. This finding is significant and somewhat unexpected, as during the interviews, 80% of the participants voiced informational deficiencies at some point during the care process. Although a few survivors felt highly confident about the amount and type of information received from their medical team, many highlighted the importance of becoming more knowledgeable through self-education as a way to cope and stay ahead of the illness.

Treatment side effects affecting QOL, or the existence of more novel therapies that could have provided long-term benefit were never explained to some of the participants making them *"feel unprepared for future possibilities."* This finding correlates with past reports of variability in the amount and quality of information that is given to advanced PC survivors during routine care.[61] The discrepancy among the data indicates that more research is warranted to determine the true sources of these informational deficiencies and the timing of informational needs. Causes may include medical factors (i.e., healthcare providers seeing larger amounts of survivors, prioritizing survival to SC), information overload, or patient-related factors (i.e., stoicism, lack of readiness to learn about harmful effects, misunderstanding), as suggested by several studies on prostate and rectal cancers.[54,62,63]

Findings regarding the spiritual domain were also somewhat mixed. Advanced cancer may lead to loss of hope, affecting the individual's body, mind, and soul.[64] Up to 79% of Americans identify with some type of spiritual doctrine despite differences in what spirituality may mean to them.[65] Further, many advanced cancer patients tend to rely on spirituality to cope with the disease, suggesting that higher levels of spirituality are associated with better overall QOL and less prevalence of SC needs.[66] The majority of our cohort described various coping strategies and identified that spirituality played an active role in their life. Despite peace and faith subscales scoring above average, 30% spoke about the conversion of spiritual health into a different process: "*I'm more content now to see myself as part of a much larger process…*" Additional empirical evidence is needed to determine the true impact of advanced PC on spirituality, a domain that continues to be relatively under investigated.[21]

Additional areas of divergence included urinary dysfunction (physical domain) and depression (emotional domain). While only 44% of the survey respondents reported urinary dysfunction, a different picture unfolded as the interviews progressed, with 70% identifying urinary SC needs as a priority. The qualitative findings are congruent with multiple studies suggesting that urinary functional needs are an unavoidable consequence of some common advanced PC therapies.[11] The same applies to depression, usually associated with ADT and the times when test results are revealed. This discrepancy makes it difficult to determine if the depression suffered by these survivors requires professional consideration. More research in this area is needed to quantify depression and make appropriate recommendations.

The findings from this study categorize the unmet SC needs in advanced PC survivors from the United States, highlighting the magnitude of the problem. Understanding these needs is essential as advanced PC survivors will live with these needs for the remainder of their lives. Most of the identified unmet needs stem directly from the harmful effects of the

aggressive treatment approaches usually taken to treat more advanced PC stages. However, some of the SC needs may also be the result of other factors, such as a lack of physical activity, insufficient contact with an oncology nurse, not having a life partner, not knowing about the availability of specific treatments or counseling, or informational deficiencies.[25,47,55] For example, several past studies found that survivors who exercise in a consistent manner or saw cancer specialist nurses throughout the care process reported higher vitality scores, improved sexual functioning, lower anxiety, and higher wellbeing.[67-71] A study by Oliffe et al. found that married or partnered PC survivors were more prone to seek help, lowering their chance to suffer from SC needs. Regardless of the cause, men described an array of ongoing unmet SC needs that warrants further research and addressing by the U.S. healthcare system.[72]

Studies exploring the SC needs in advanced PC and other cancers are not new in the literature. Our results support the assertion that the high prevalence of fatigue, sexual, emotional, psychological, and informational needs coincides with countries such as Canada, Spain, France, or the United Kingdom.[16,47,63] However, some inconsistencies were also evident, particularly within the physical (urinary), spiritual, informational and practical needs compared with past needs assessments conducted in the United Kingdom, Australia, or Malasya.[30,48,73] The similarities and discrepancies may very well be due to cultural context of the people or the healthcare systems, but they could also be the result of gender differences. It has been demonstrated that women with breast cancer for example, are more likely to voice their concerns and needs, and obtain the necessary help.[55] Although it was not always the case of this study, many men still hold fiercely to traditional masculine stoic roles, and it is possible that they are reluctant to discuss sexual, emotional or physical needs with their healthcare team. Further research is needed to clarify the implications that these important

geographical and gender-related factors may have in order to achieve a more patient-centered SC delivery for all advanced PC survivors.

It is important to note the challenges using the SCNS and the SCFCC. Despite being a validated instrument previously used on multiple needs assessments, it was difficult to assess social, practical, psychological, and spiritual needs. This short-coming has already been reported by at least one other mixed-methods study. Fong et al. recommended the inclusion of 11 additional items assessing needs in the spiritual, practical, and social domains to supplement the existing SCNS-SF34, justified by the constructs of Fitch's SCFCC.[74] Using the SCFCC made the categorization of some of the needs difficult, due to an overlap within several of the domains. For example, based on the framework, sexual unmet needs could be classified as either a physical or a psychological need, depending on the investigator's perspective. Also, some themes resulting from the study are not currently contemplated within the SCFCC constructs (i.e., masculine roles, cognitive decline). These minimal but relevant categorization obstacles might have led to different conclusions and omissions depending on the researchers' opinions and interpretations.

Strengths and Limitations

One of the primary strengths of this study includes the use of Fitch´s SCFCC. Despite some minimal aspects not captured by the framework (e.g., cognitive decline), it addresses a broad cluster of SC needs experienced by PC cancer survivors, providing a robust structure to conducting holistic needs assessments in this subset of survivors.[26] Additionally, with a convergent mixed-methods design, the quantitative findings could be further crossmatched with the qualitative data for common trends, places of disconnect, and aspects that were missed by the data. Lastly, we chose previously well-validated instruments with high reliability and validity coefficients used in diverse several cancers past SC needs assessments.

This study had several limitations. The study was cross-sectional, providing only a snapshot at the unmet needs at a particular point in time. The sample size was adequate but was primarily comprised of White, married, retired participants holding a college degree. However, the sample reflected diversity regarding age, advanced PC stage, treatments received, and age at diagnosis. Some caution is advised when interpreting these findings. The needs assessment must be repeated using a larger and more diverse sample of survivors with advanced PC. Convenience and purposive sampling strategies were used in the quantitative and qualitative phases respectively. Self-selection bias is likely, and results may not be generalizable to all advanced PC populations. Although the use of one coder to analyze both strands of data is a limitation, the tables and the codebook were developed in collaboration among all the authors, holding regular meetings to enhance trustworthiness. Also, a female researcher conducted all the data collection. A male researcher may have prompted different responses from some of the participants.

Implications for Research

The findings of this study complement the existing literature but highlight several important gaps. First, most previous studies assessing the unmet SC needs in advanced PC survivors were conducted in countries other than the U.S. More research is warranted to understand the true impact of these unmet SC needs in this specific population. We also emphasized some significant variations in the type and prevalence of SC needs compared to previous work. Most of these men expressed high levels of satisfaction with the overall cancer care they received. However, ongoing unmet SC needs were present in a relatively large proportion of survivors regarding physical, and emotional/psychological domains, and, to a lesser degree, the informational and spiritual domains. Although some survivors felt like they could go on with their life with a positive attitude and self-education, others were evidently seeking help. These results are significant enough to recommend further SC

research. Lastly, quantitative results suggest a preliminary but moderate negative association between unmet SC needs and QOL—the more unmet SC needs the survivors had, the lower their QOL. However, for the purpose of this study, this relationship was not evaluated based on socio-demographic and clinical variables. Additional research is needed to determine if these needs are dependent or vary according to individual demographic and clinical characteristics.

Conclusion

Men with advanced PC suffer from a complex incurable disease. Despite being cross-sectional, our study provides comprehensive information to understand the prevalence and types of SC needs in a population that has received limited attention in the survivorship literature so far. The needs assessment confirms and extends previous work describing the specific unmet SC needs in a sample of diverse American advanced PC survivors.The development and implementation of adequate SC is essential, as the prevalence of SC needs remains high, especially among the physical, emotional/psychological, and informational domains. To improve QOL and outcomes, the SC must be individualized, multidisciplinary, and delivered continuously long after the treatments are finalized, as PC is a cancer with a much longer trajectory than most cancers.

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Barriers and Facilitators to Supportive Care Implementation in Advanced Disease Prostate Cancer Survivors: A Theory-Informed Scoping Review

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Abstract

Background: Individualized supportive care has been recommended to prevent and manage the debilitating effects of advanced prostate cancer and its treatments. Yet, the implementation of supportive care in practice remains limited and inconsistent.

Methods: PubMed, SCOPUS, CINAHL Complete, ProQuest, and PsycINFO were searched for relevant studies published between 2011 and 2020. The sample included studies with original research reporting on a supportive care intervention and including a description of implementation barriers and/or facilitators. The Theoretical Domains Framework was used to characterize implementation barriers and facilitators.

Results: We identified 620 articles, out of which 13 met the inclusion criteria. Primary barriers related to the domains *Environmental Context and Resources* (time constraints, reduced access, limited resources), *Knowledge* (insufficient knowledge on availability and efficacy of supportive care and technology), and *Beliefs About Capabilities* (lack of confidence in materials, difficulty navigating the system, limited competency). The main facilitators fell under *Environmental Context and Resources* (partnerships with local services, uninterrupted availability, supervised group approach), *Reinforcement* (partners inclusion, flexible scheduling, multimodality), and *Skills* (delivery by professionals, specialty nurse).

Conclusions: This review highlighted barriers and facilitators that affect supportive care implementation. Future research that focuses on overcoming barriers and maximizing facilitators is vital to improve, modify, or supplement existing supportive care implementation practices.

Implications for Survivors: As the number of advanced prostate cancer survivors continues to rise, supportive care has the potential to become standard of care. Future interventions must incorporate the following: increased knowledge and funding, alternative delivery models, and consistent use of specialty nurses.

KEYWORDS

According to a recent American Cancer Society report, the most common cancers found in males include prostate cancer, colorectal cancer, and lung cancer [1]. Prostate cancer (PC) survivors make up to 22% of all United States' cancer survivors, currently numbering more than 3.7 million men [2]. Recent incidence data from the Global Cancer Observatory suggest that the number of new PC diagnoses will rise from 1.3 million in 2018 to 2.3 million by 2040 [3]. Most men are diagnosed with PC at a localized stage. However, 30% of men will progress into regionally advanced or metastatic disease or will suffer a recurrence at some point during the illness [4,5].

Effectively managing diverse PC morbidities has become a substantial health and financial challenge. Despite progress in treatments that prolong life, some population-based studies have reported that many advanced disease PC survivors continue experiencing devastating and sometimes life-long side effects requiring ongoing supportive care [5,6]. The American Society of Clinical Oncology and the American Cancer Society have published guidelines advocating for comprehensive supportive care at all stages of PC. The Multinational Association of Supportive Care in Cancer (MASCC), founded in 1990, has defined supportive care as "the prevention and management of the adverse effects of cancer and its treatment" [7], and includes PC surveillance, evaluation and management of all treatments' harmful effects, and psychosocial support [8]. The concept of supportive care has progressively evolved from the 1960s modern hospice movement, gaining momentum in the past few years among worldwide health providers and researchers [9]. Furthermore, supportive care entails the provision of all necessary individualized interventions to meet the advanced PC survivors' physical, emotional, social, informational, practical, spiritual, and psychological needs through the entire cancer care continuum, as advanced PC has a tremendous impact on the person's life beyond the physical body [10].

Despite enhancing PC survivors' experience of care, rehabilitation, and quality of life (QOL), the prevalence of supportive care delivery continues to remain consistently low [11,12,13]. A recent study determined that up to 81% of cancer survivors had unmet supportive care needs and reported dissatisfaction with current supportive care services [14]. Advanced PC survivors report an array of overlapping supportive care needs encompassing the emotional, social, psychological, informational, physical, practical, and spiritual domains [4,5,13,14]. Left untreated, these unmet needs may lead to additional morbidity and distress. In order to be most effective, supportive care interventions must follow a multidimensional approach and be provided by a multidisciplinary team in a timely manner [15,16]. Since every PC survivor is unique, the interventions need to be tailored to the patient's specific needs, objectives, and coping style [13].

Given the increasing number of advanced PC survivors and the multidomain needs they experience, several organizations and agencies have recommended integrating supportive care services into standard cancer care [16]. However, the implementation remains complex. The extant literature primarily focuses on the functional outcomes of PC therapies, survivors' needs assessments, and barriers and facilitators of PC survivors' individual behavior [6,12]. A closer exploration of the barriers and facilitators affecting the implementation of supportive care in PC using a theoretical framework is critical to advancing knowledge on the factors that contribute to more sustained and cost-effective delivery [12]. Thus, the aims of this scoping review are to (1) identify supportive care interventions for advanced PC survivors using the Supportive Care Framework for Cancer Care (SCFCC), and (2) synthesize the barriers and facilitators to implementing supportive care interventions through the lens of the Theoretical Domains Framework (TDF) as reported by advanced PC survivors and healthcare professionals (HCPs).

Methods

99

Theoretical Frameworks

Scoping reviews are helpful in exploring the extent of the literature for topics that are under-researched [17]. This scoping review was performed with the guidance of two theoretical frameworks. First, supportive care was defined and the supportive care interventions in the selected studies were identified using the SCFCC for advance PC. The SCFCC framework was initially developed to assist clinicians in meeting the unique and complex needs of cancer patients. It outlines a comprehensive taxonomy of seven domains of needs, including physical, emotional, informational, social, practical, psychological, and spiritual [13]. The SCFCC has been used in multiple prior needs assessment studies as well as in guiding supportive care interventions development worldwide [13,18,19].

Once the interventions were identified using the SCFCC, the TDF provided structure for classifying and synthesizing the barriers and facilitators in implementing those supportive care interventions. TDF was initially developed to guide implementation research and has proved useful in identifying factors affecting the implementation of many types of care interventions [20]. The TDF can be applied to qualitative and quantitative studies to understand patients and HCPs behaviors [20]. It is an integrated theoretical framework consisting of 14 domains: *Knowledge; Skills; Memory, Attention, and Decision Processes; Behavioral Regulation; Social/Professional Role and Identity; Beliefs About Capabilities; Optimism; Beliefs About Consequences; Intentions; Goals; Reinforcement; Emotions; Environmental Context and Resources; and Social Influences* [20,21].

The TDF uses an evidence-based schema derived from theory that has been successfully used in many past literature reviews [22]. In a 2020 scoping review, Moncion et al. used the TDF to describe factors influencing aerobic exercise implementation in stroke rehabilitation [23]. In addition, TDF was also used by Adrian et al. to identify the barriers and facilitators influencing HCPs' behavior in the care of infants with neonatal abstinence

100

syndrome [24]. Accordingly, the TDF provides a useful framework to identify and synthesize behavioral factors that may affect the implementation of supportive care interventions in PC survivors suffering from advanced disease.

Design and Search Strategy

This scoping review followed Arksey and O'Malley s' methodology, which includes five well-distinguished stages: (1) research problem identification; (2) literature search; (3) selection of appropriate studies; (4) extraction of the data into a matrix; and (5) summary and report of the results [25]. The search strategy started by consulting an expert reference librarian who suggested the use of Boolean operators and MeSH terms to find the most relevant studies. The following electronic databases were searched: PubMed, SCOPUS, CINAHL Complete, ProQuest, and PsycINFO. The following key search terms were searched in each database: (*prostate cancer* OR *prostate neoplasm)* AND (*interventions* OR *intervention OR programs OR program)* AND *(supportive care).* We decided not to include the term *implementation* in the search strategy, as this may have significantly limited the number of studies involving supportive care interventions relevant to the review. Hand searching of the resulting studies' reference lists identified additional pertinent articles for evaluation.

Inclusion and Exclusion Criteria

Studies were eligible for inclusion in this review if they reported quantitative, qualitative, or mixed methods original research. Studies had to (1) include a supportive care intervention or program directed at advanced disease PC survivors and (2) have a direct or implicit description of the barriers and/or facilitators to implementing the intervention. For the purpose of this review, a barrier was defined as any "circumstance or obstacle that keeps people or things apart and /or prevents communication or progress," whereas a facilitator was described as "a person or thing that makes something possible" [22]. Exclusion criteria

consisted of other types of cancers, studies focusing on solely localized PC, reviews, and unrelated subjects such as pharmacological or surgical interventions. The search was limited to studies published in English from 2011 to 2020 to ensure that the most recent studies were included. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guided the articles selection to ensure methodological rigor (Figure 1) [26].

Data Extraction and Analysis

The database search identified 620 potentially relevant articles. Two additional articles were added from the reference lists hand searches due to relevance to the topic. After duplicates were removed, the first author independently screened 478 titles and abstracts for eligibility. A final count of 35 articles underwent a full-text evaluation by the first author with 22 articles excluded for being non-original research (n=9), describing other than supportive care intervention implementation (n=12), or investigating localized PC only (n=1). Twenty percent of the title, abstracts, and full text were reviewed by a second reviewer (SQ) for validity and trustworthiness of the studies selected. Ultimately, all authors agreed to include a total of 13 articles meeting the inclusion and exclusion criteria.

The primary goal of data extraction includes drawing a rigorous conclusion about the research problem by ordering, coding, categorizing, and synthesizing the data from the selected studies [25]. The data extraction process was based on prior literature and guidance to perform systematic scoping reviews. The following data were ordered, extracted, and exported into a comprehensive evidence table: author(s), year, purpose, design, setting, sample, intervention, key results, TDF domain, and level of evidence (Table 1). Any facilitators or barriers identified in the selected studies were critically appraised and classified according to the 14 domains of the TDF to facilitate the analysis of issues and variable characteristics (Table 2 & 3). Despite not being required for scoping reviews, the sample's

level of evidence was also evaluated using the John Hopkins evidence level and quality guide
[27].
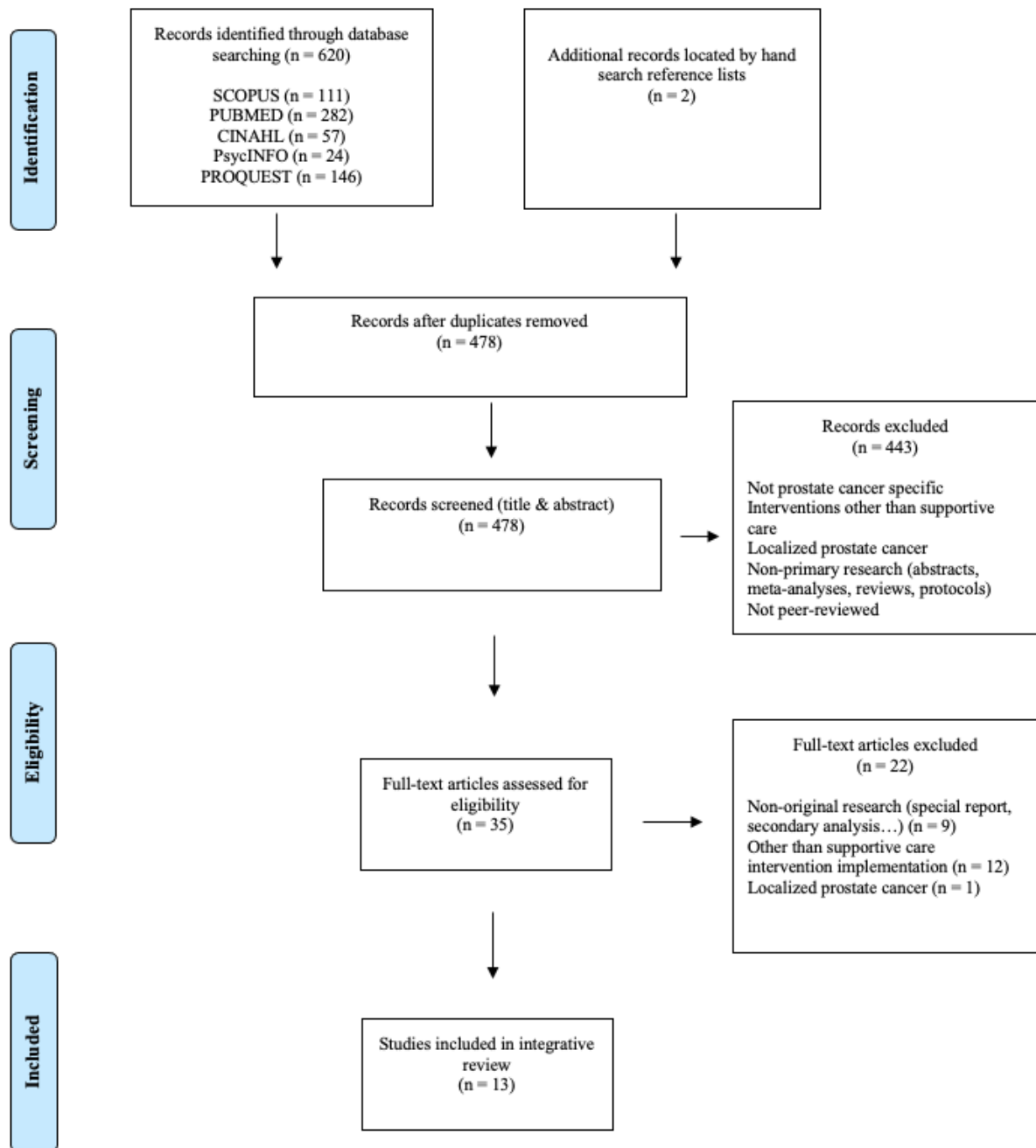
Figure 1. PRISMA flow diagram of the study selection process.

Results

Study Characteristics

Table 1 displays an overview of the selected studies' characteristics. The sample of studies included original intervention research, and all were published between 2011 and 2020. Six of the studies used a quantitative methodology, of which three were randomized controlled trials [29-31], one was a retrospective cohort study [6], and two were cross-sectional descriptive studies [32,33]. The remaining seven studies utilized either a qualitative design (n=4) [22,34-36], a mixed-methods methodology (n=2) [37,38], or a quality improvement design (n=1) [28]. The chosen studies also represent wide geographic settings, as they were undertaken in Canada [7,28,33,37], Australia [22,29,34,36,38], or the United Kingdom [30-32,35]. All 13 studies included a sample of advanced stage PC survivors (stages III, IV), either exclusively or in combination with other stages. Five studies included the partners or caregivers in the program [28,30,33,35,37]. Only one study applied the TDF or any other conceptual theory to guide the design and the categorization of the results [22]. Regarding the studies' levels of evidence, three provided a level I, two studies a level II, and eight studies a level III. Every study was included in the review due to the relevance to the topic and the valuable information it provided regarding barriers and facilitators to supportive care implementation.

Supportive Care Interventions

Numerous resources, including past literature and several published clinical guidelines, assist HCPs in developing and implementing appropriate interventions according to the survivor's domains of need (physical, emotional, social, spiritual, informational, practical, and psychological) [13,39,40]. Figure 2 displays the supportive care interventions implemented in the sample of selected studies, categorized according to the SCFCC domains of needs. Many interventions in the selected sample of studies addressed the SCFCC informational domain (n=6). PC survivors were informed or educated about various topics such as nutrition, side effects of the treatments, psychological management, or available

resources for PC [28,30-32,35,37]. Five interventions addressed the physical domain, whether it was by implementing an exercise program, a pelvic muscle rehabilitation intervention, yoga training, or by applying principles of a healthy diet [7,28,29,33,34]. Mindfulness, psychosexual therapy, and yoga covered the emotional domain in three of the studies [32,33,38]. Most interventions (n=9) addressed the social domain by implementing them in a group format, motivating relationships, collaborative activities, and camaraderie [22,29,30,32-37]. Interventions delivered by teleconference, conducted online, or emphasizing individual needs assessment addressed the practical domain by decreasing the demands on the individual's life at home [22,30,35,36,37].
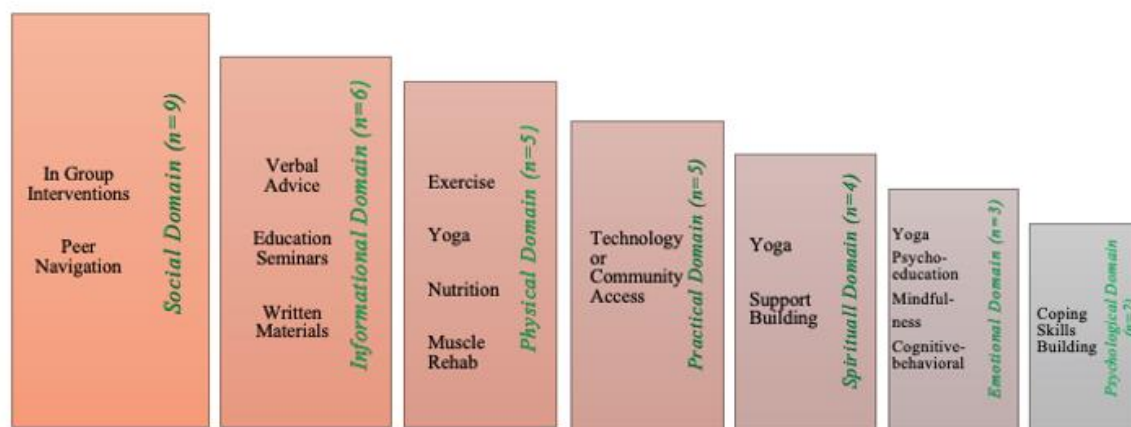
Figure 2. Supportive Care Interventions per Seven SCFCC Domain.

Some programs aimed at alleviating several domains of needs, such as psychosexual counselling or coping skills development, which addressed not only the emotional domain but also the psychological domain [7,31]. By contrast, the spiritual domain was the only domain not addressed directly by any intervention; however, programs focusing on support-building or yoga may have an effect in strengthen PC survivors' personal sense of meaning in life and spirituality [13,22,33,36]. Some interventions involved the survivor alone, and some involved the survivor and their partner/caregiver [30,33,35]. The instruction methodology

differed from accredited HCPs being in charge of the implementation [22,29,31,32-34,36] to nurses or implementation [22,29,31,32-34,technicians facilitating the sessions [7,28,30,35,37, 38].

Barriers and Facilitators to Supportive Care Interventions Implementation

All 13 studies in this sample included facilitators and/or barriers to implementing supportive care interventions for advanced PC survivors, whether they were directly mentioned or indirectly discussed [7,22,28-38]. For each study, the number of barriers ranged from zero to 15, and the number of facilitators ranged from zero to 10. A total of 137 factors were identified in the selected articles, with 58 coded as barriers and 79 as facilitators, according to the TDF constructs. In nine studies, patient-related and healthcare providers-related (HCPs) barriers and facilitators were identified [7,22,28,30,31,33-35,37,38], while the remaining four studies involved HCP perspectives exclusively [29,30,32,36]. Twelve studies addressed both barriers and facilitators, with one study addressing only facilitators [29].

All 14 TDF domains were represented across the sample, and barriers and facilitators were coded across the 13 out of 14 TDF domains. No barriers were mapped under *Emotion* and no facilitators were found coded under *Behavioral Regulation*. The TDF domains most frequently identified for barriers included *Environmental Context and Resources* [7,22,28,29,31-38], *Knowledge* [22,28,30,32-34,36,37], and *Beliefs about Capabilities* [21,27,30,34,36]. Facilitators fell most frequently under *Reinforcement* [7,22,28,30,32-35,37,38], *Skills* [28,30-33,35,37], and again *Environmental Context and Resources*. Two factors —"partners/caregivers' involvement" and "accessibility to the program" (one centralized location)—were identified as both barriers and facilitators, depending on the stakeholders' perspective. Three other factors were given codes from two different TDF domains. For example, "discomfort posting on forums" and "muted preferences on supportive care due to stoicism" were coded under *Social/Professional Role and Identities*

106

and *Social Influences*. The facilitating factor of "materials/software easy to understand" was mapped to the TDF domains of *Skills* and *Beliefs about Capabilities*. The results were arranged giving a special emphasis to the three most influential TDF domains under which the numerous barriers and facilitators were found. Then, factors under the remaining TDF domains were subsequently described. To summarize the data, Table 2 lists the frequencies and percentages of every barrier and facilitator found per TDF domain. Table 3 summarizes all the identified factors and the corresponding TDF domains per each study included in this review .

1. *Barriers*

1.1.*Environmental Context and Resources Domain*

The most predominantly identified barriers to supportive care implementation appear to be in the *Environmental Context and Resources (ECR)* domain, which includes constructs such as resources/materials used during the intervention, organizational climate or culture of the facility, interactions between the persons (HCPs/patients) and the interventional environment, or environmental stressors (e.g., location, time of the day) [21]. All studies except for one identified barriers under the *ECR* domain. Major barriers to supportive care implementation included time constraints, lack of sufficient resources, and reduced accessibility to the programs. For example, additional survivors could have benefited from a yoga program if accessibility had been boosted by a clearer physician referral pathway [33]. Despite the benefits reported from a group mindfulness intervention, only 38.5% of the participating survivors agreed with the excessive time commitment to carry out all the program activities and requirements [38]. HCPs specifically reported challenges with their conflicting schedules as well as time constraints to promote or deliver supportive care due to an increase in patient overload during office hours [33,36]. Scarce resources (e.g., technology) and lack of funding to offer the interventions to larger groups of survivors were

two of the largest barriers to appropriate implementation, reported in four of the studies [22,28,31,32]. Further, limited funds leading to long waiting lists for survivors to be called has been suggested to impact optimal program implementation [32].

1.2 Knowledge Domain

The second most predominant domain was *Knowledge,* which includes knowledge about how to proceed with a supportive care intervention as a patient or as a provider, knowledge about the condition/scientific rationale (e.g., benefits) regarding the intervention implementation, and knowledge of task environment [21]. In five separate studies, both survivors and HCPs described lack of knowledge regarding supportive care programs availability and effectiveness, variations in HCPs' expertise on supportive care, challenges maintaining knowledge currency, and deficient technology proficiency, as barriers to implementing supportive care programs appropriately (Table 3) [22,28,30,36,37]. For example, two studies reported HCPs' notable unawareness of the importance and benefits that physical activity may provide to these survivors [33,34]. Ralph et al. conducted two consecutive studies in 2019 and 2020. The first one aimed at understanding the implementation context of a telephone-based nurse-led supportive care intervention, and the second one at identifying barriers and potential solutions for an optimal implementation [22,36]. The data collected during those two studies suggested that the frantic speed at which treatment options for advanced disease PC are progressing and the uncertainty about which treatment provides survivors the most benefit (based on their clinical characteristics) create challenges for clinicians to keep up with the latest developments on supportive care in terms of effectiveness. Since advanced PC is a progressive disease with a long trajectory, being aware of the newest advances is essential, as information may lose relevance over time [22]. Additionally, wide variations in HCPs' knowledge and expertise regarding supportive care

within the same health system or region create difficulties for developing more standardized supportive care plans that meet the recommended survivorship guidelines [30].

1.3 Beliefs About Capabilities Domain

The third most common TDF domain, *Beliefs About Capabilities,* addresses HCPs' self-confidence in implementing a supportive care intervention or in carrying out the activities of the intervention, perceived professional competence, self-efficacy, perceived behavioral control, beliefs in being capable of delivering or receiving the intervention, self-esteem, and empowerment [21]. Five separate barriers were identified in three studies concerning this domain. The barriers were associated primarily with the program materials/resources or the delivery methodology. For example, many survivors expressed their discomfort with posting personal or clinical information on the online program forum, because they believed that they lacked the necessary proficiency to avoid unforeseen loss of confidentiality [37]. In the same study, HCPs believed that a purely online format was not always an acceptable format for intervention delivery, advocating for more hybrid formats that facilitate every survivor's capability and learning style [37]. A separate qualitative study exploring the experiences of survivors, partners, and the interprofessional team with a multimodal supportive care intervention found that patients were not always capable of navigating the health system in search for adequate supportive care [35]. Additionally, HCPs experienced a moderate degree of frustration addressing certain topics with their patients, such as sexual dysfunction, therefore not meeting the survivors' needs and expectations effectively [31]. This frustration could stem from a lack of competency in those fields or conflicting professional capabilities [35,41].

1.4. Additional Identified Barriers

Several other barriers were identified in the sample of studies (Table 3). Three studies found that limited training of HCPs in oncological supportive care (*Skills*) was a major

barrier to the implementation of the intervention [22,28,31]. Interprofessional disagreement

regarding the intervention focus (e.g., weight management versus disease progression),

coordination challenges, and persistence of survivors' traditional masculine roles

(*Social/Professional Role and Identity)* decreased the uptake of supportive care despite the

high demand [22,28]. Survivors also described feelings of discomfort and anxiety posting

personal information in interventional online forums or voicing personal preferences

regarding certain supportive care modalities (i.e., sexual rehabilitation, mental health) due to

fear to opinions and reactions from the surrounding environment (*Beliefs about*

Consequences) [22,37].

Three barriers were identified under *Goals,* which were associated with not meeting

the survivors' needs, the partners' expectations, or not easing coordination of the program

[22,28,32]. For example, data from a nutritional education intervention suggested that

additional objectives, such as describing the role of certain nutritional components,

addressing individual nutritional concerns, and practical meal planning tips, should have been

included as part of the intervention description [28]. One other study reported that survivors

tend to prioritize treatments that extend life over supportive care, complicating HCPs'

referrals to appropriate programs (*Intentions)* [22].

Because of the existing social norms and stigma around PC, survivors identified

social pressure as a barrier to seek supportive care when needed (*Social Influences)* [22,36].

However, they also found motivators to participating in certain programs involving

mindfulness or peer navigation, for example. Studies that prevented caregivers from

participating in the intervention activities or that lacked a complete in-person interaction were

found to incentivize participation and continuity the least (*Reinforcement)* [37,38]. In some

cases, successful implementation meant empowering survivors enough for them to break old

habits (e.g., sedentarism or poor diet) or make them believe in the benefits that the supportive care intervention can bring into their daily life (*Behavioral Regulation*) [22,31].

Some pessimism was identified among survivors whose PC was managed exclusively by urologists (*Optimism*) [22]. One study specifically reported that supportive care is a field that may fall outside the scope of practice of this type of HCPs. Thus, survivors are forced to live for long periods of time with the side effects of the treatments believing that they cannot obtain an appropriate referral from these medical specialists leading to gloomy feelings. Furthermore, many of these specialists did not revisit important information regarding PC and supportive care processes (*Memory, Attention, and Decision* Processes).

Facilitators

2.1 Environmental Context and Resources Domain

The most predominantly identified facilitators also fell under the *ECR* domain and included recognition of the extra resources (e.g., locations, educational materials) and capacity (e.g., staff) needed to deliver the intervention (Table 2) [32]. Partnerships with local PC support groups and supportive services enabled to approach and care for larger groups of survivors with different needs at once [32,37]. Uninterrupted availability of supportive care programs during longer periods, such as in exercise programs, as well as increased accessibility to the program professionals via in person or technology were essential to maintain the beneficial effects of the intervention over time [28,29,31,35]. Cultural competency, such as using translators and linguists, brought a robust sense of self-efficacy to the providers in charge in the ability to implement a supportive care program more effectively [36]. Structured, supervised group approaches were also reported in two separate studies, not only as implementation facilitators, but also as a way to deliver more cost-effective programs reaching a greater number of survivors simultaneously [34,38].

2.2. Reinforcement Domain

The second most predominant domain for facilitators was *Reinforcement*, which

relates to rewards (e.g., benefits) from completing an intervention or program, incentives for

participation (e.g., financial compensation, further referrals), consequences from not meeting

the patients' needs or not completing all the prescribed activities, reinforcement,

contingencies, and sanctions due to procedural errors, for example [21]. Fifteen facilitators

were identified in ten separate studies under *Reinforcement.* These facilitators were primarily

associated with the inclusion of the partners/caregivers during the intervention, flexibility in

scheduling interventional sessions, and the multicomponent approach taken with the

intervention. Four of the studies found that involving direct caregivers in the intervention

activities led to higher patient engagement, increased social and emotional support, and

enhanced information retention due to the additional reinforcement provided by the

partners/caregivers [33-35,37]. HCPs reported that flexibility in scheduling the intervention

sessions helped meet the survivors' needs in terms of time and location, encouraging

accessibility and reach [32,38]. Multimodality in intervention delivery (i.e., combining

several different modules or activities) was also essential to incentivize participation among

advanced PC survivors [22]. Furthermore, five separate studies determined specifically that

the multicomponent delivery option offered a more comprehensive view of the disease and

the treatment side effects, promoting a more holistic care to meet the survivors' supportive

care needs and expectations [7,28,32,35,38].

2.3. Skills Domain

The *Skills* domain was the third most prevalent domain, and it is associated with the

necessary skills to deliver supportive care, skills development (e.g., HCPs' continuing

education on the latest developments; patients' increasing abilities in terms of the

intervention activities), competence to implement this type of programs, ability, skill

assessment, interpersonal skills to encourage participation, and practice/professional

experience with this line of work [21]. Interventions that were supervised and moderated by accredited, trained professionals, such as nutritionists or exercise physiologists, reported positive results on the outcomes and a higher level of satisfaction among participants [29,31,32,34,36,38]. For example, in a mixed-methods study to investigate the acceptability and effectiveness of a supervised mindfulness-based cognitive therapy delivered by psychologists, the authors reported statistically significant improvements in the survivors' level of anxiety ($p=.027$), avoidance ($p=.032$), and mindfulness skills after three months of implementation ($p=.019$) [38]. Through qualitative interviews, exercise physiologists were identified as pivotal in helping participants understand the physiological and psychosocial benefits of exercise [34]. Two additional studies endorsed the use of trained nurse specialists in the delivery of supportive care, as it was found that this approach enhanced survivors' well-being [31,36]. This delivery strategy is well supported in the existing literature and has demonstrated feasibility and cost-effectiveness. Additionally, the ability to develop alternative gentle physical activity options for advanced disease PC survivors such as yoga, was found to be a facilitating factor. Not only was the program successfully implemented, but it also reported high adherence (87%) and statistically significant results in improving mood ($p=.000$), fatigue ($p=.000$), and stress ($p=.004$)[33].

2.4. Additional Identified Facilitators

When HCPs had clear referral pathways and evidence-based information at hand on how to provide patient-centered supportive care (*Knowledge*), it facilitated survivors in obtaining appropriate interventions in a more timely manner [32,36]. Further, when supportive care interventions and health awareness campaigns were individualized with tailored shared objectives (*Goals),* it helped address supportive care needs in a more holistic manner, whether it was by increasing participation or reducing social stigma about advanced PC [22,30,31,35,36]. Interventions that intentionally approach supportive care holistically

have been found to be more cost-effective in addressing more supportive care needs at once (*Intentions*) [35].

Certain intervention materials and resources provided confidence to support goals or intentions in facilitating a supportive care intervention (*Beliefs about Capabilities*). For example, a Peer Navigation Training Program was found to be feasible, acceptable, and effective in promoting eHealth literacy and satisfaction because participants felt capable of using the intervention materials [37]. User-friendly sessions enhanced empowerment and benefits in a separate nutrition educational program [28]. However, an optimistic team climate has also been found to be helpful (*Optimism)* as the demand for specific supportive care interventions can sometimes be high when the availability is low [36].

Appropriate program length, inclusion of a multidisciplinary team, and adapting the intervention to the most common masculine ideals were reported as facilitators in four separate studies (*Social/Professional Role and Identity*). These factors led to a network of services that was more comprehensive, had better control of advanced PC side effects, and higher completion rates (88%) [28,31,32,34]. Likewise, small group and social learning formats indicated better intervention adherence (87%), social identification, information retention, and a strong bond of camaraderie among participating survivors [29,33,34,37,38]. Equally important for implementation success were
continuous program evaluations and diary keeping (*Memory, Attention, and Decision Processes*) or program safety (*Beliefs About Consequences*) as they helped facilitating session planning, benefits, sustainability, and currency over time [29,31-33].

In addition to all added benefits, supportive care interventions have also been found to be the optimal setting to share experiences. These opportunities often led to higher emotional cohesion among the participating survivors, which subsequently, increased attendance (*Emotion*) [33]. The same benefits were seen in the case of authentic in-person interaction

and role-playing formats, which were highly valued and contributed to enhancing self-efficacy and e-Health literacy [37].

Discussion

This scoping review examined the barriers and facilitators to supportive care implementation in advanced PC, focusing primarily on the most prevalent domains of the TDF. Advanced PC survivors report a wide range of supportive care needs due to the effects of cancer and its various therapies. Effective supportive care interventions can assist with preventing and managing the harmful effects at the physical, emotional, social, psychological, informational, practical, and spiritual levels to improve outcomes [13]. All the studies in this review focused on supportive care and identified barriers and facilitators to its implementation. However, there was considerable variation among the supportive care interventions regarding focus (e.g., physical activity and mindfulness), content (e.g., nutrition education and aerobic exercise routines), method of delivery (e.g., in-person, online and group sessions), and expected outcomes (e.g., domain of needs) (Table1). The studies revealed a wide range of barriers and facilitators related to all TDF domains, further sustaining the multifaceted nature of supportive care implementation in advanced PC. Stakeholders consistently reported that the absence of the barriers or the enhancement of facilitators would significantly benefit the implementation of more patient-centered supportive care programs [7,12,22,28-36,38,42]. Therefore, future research and action must be directed towards these goals. It is important to note that the study sample explored patient and HCP perspectives regarding barriers and facilitators, with slightly more studies focusing on HCPs alone [7,21,29,31-33,35-38]. For both barriers and facilitators, individual factors (e.g., time constraints, in-person interaction) and contextual factors related to all organization levels (e.g., scarce resources, multiapproach programs) were identified.

Barriers Affecting Supportive Care Implementation

115

The majority of the studies' participants viewed supportive care implementation positively, highlighting more facilitating factors than barriers (Tables 2 and 3). More barriers were referenced under *ECR*, *Knowledge,* and *Beliefs about Capabilities* domains. Commonly perceived barriers under *Knowledge* included unawareness of supportive care interventions availability and/or effectiveness, variations in providers' knowledge and expertise, lack of technical proficiency, and challenges keeping up with the latest developments in PC supportive care [22,28,30,33,36,38]. This mirrors the results of published studies conducted with PC and other cancer survivors which found that many supportive care programs are not accessed either because the survivors are unaware of the programs or because the HCPs lack adequate prostate-specific expertise [10,43]. Further, some of those studies reported that HCPs often focus on seeking information regarding disease progression, prognosis, or the physical aspects of the disease, encouraging patients to seek support through peer groups [10]. In order to provide PC survivors with optimal supportive care that meets all their complex needs, it is vital for HCPs to possess the requisite knowledge regarding supportive care during survivorship and act proactively in prescribing the appropriate interventions [16,43]. HCPs have expressed willingness to further their PC supportive care-specific knowledge so that needs identification and care coordination can be carried on more effectively [43].

Survivors and HCPs have expressed that a lack of adequate resources and accessibility to interventions, as well as time commitments, are major barriers under the *ECR* domain [7,22,28,31-33,36,38]. Previous studies have reported that the urologist is the provider who predominantly delivers information and prescribes services to advanced PC survivors [12]. Furthermore, some researchers have found that HCPs are sometimes responsible for caring for a growing number of survivors in already overly stressed healthcare systems, inhibiting them from allocating sufficient time and attention to their patients'

supportive care needs [10,43]. For example, in line with our findings, a study conducted with metastatic PC survivors and their partners showed that up to 36% of the HCPs shared an apparent desire to improve supportive care by allocating further resources, such as increased access to specialty nurses, in-home nursing care and education, more time and locations, or access to support groups [10,14,23].

Additional barriers worth mentioning included "discomfort to post in online forums" (*Beliefs About Capabilities, Beliefs About Consequences*), "male stoicism or stigma" (*Social/Professional Role, Social Influences)*, "a purely online as an always acceptable format" (*Beliefs About Capabilities)*, and "lack of program comprehensiveness" (*Goals*) (Table 3). Many studies have highlighted the fact that men are often reluctant to seek support as it reflects traditional male norms of being stoic, strong, and capable [5,44]. "Masculinized" supportive care interventions (e.g., exercise and education) that connect survivors could promote male camaraderie, positive masculinities, and commitment to solving shared advanced PC issues, particularly pertaining to emotional support [45,46]. Despite the Internet offering a convenient and cost-effective way to provide supportive care to advanced PC survivors by narrowing social disparities, many providers have expressed that an exclusively online format is not always an acceptable format [37,47]. Survivors favored care modalities with additional in-person interaction, which has also demonstrated a better acceptance in a study conducted with breast cancer survivors [48].

Facilitators Affecting Supportive Care Implementation

Most perceived facilitators were derived from the *ECR*, *Reinforcement*, and *Skills* domains. Stakeholders particularly appreciated interventions that were conducted in small groups [29,33-35,38], involving additional local PC support services [32,37], and providing greater access to a specialty nurses or accredited therapists [29,31,32,34,36-38]. Supportive care interventions delivered in a group format, whether in person or via technology, were

found to significantly improve outcomes such as social support or social well-being in past studies [35,49,50]. In addition, supportive care interventions based on established partnerships with available PC support groups and community services increase accessibility, reduce centralization, and address individual survivors' needs more effectively [32,37]. This finding is supported by a study conducted in Michigan that tested a partnership between several academic health providers, PC support groups, and PC survivors and their partners in facilitating broader dissemination of supporting information materials directed at PC survivors [51].

A notable finding of this review is that a nurse specialist in the role of primary intervention deliverer was regarded positively in more than 50% of studies [29,31,32,34,36-38]. Despite supportive care interventions being implemented by providers from diverse health disciplines, a significant imbalance of nurse specialists in caring for PC survivors was found in several studies [10,52]. For example, a qualitative study conducted in Australia with PC survivors found that the inclusion of nurses with oncology expertise in the multidisciplinary team increased care coordination and overall well-being in this population [46]. Additional separate studies determined that supportive care delivered by PC specialist nurses improved satisfaction, coordination, and continuity of care at the different points of the cancer journey making the role of nurses an increasingly integral part of multidisciplinary supportive cancer care [10,52,53]. Limited nursing-led supportive care may be due to insufficient training in provision of supportive care, limited resources for coordination, or the actual structure of the specialty cancer services [54,55]. However, it appears evident that despite the existing variations, nurse-led programs demonstrated higher retention and satisfaction rates and have the potential to overcome some of the implementation barriers previously mentioned (e.g., time constraints, better use of limited resources, disjointed care).

Other facilitators to supportive care implementation included "multimodal intervention" (*Reinforcement*), "inclusion of partners/caregivers" (*Reinforcement*), "appropriate intervention length" (*Social/Professional Role and Identities*), and "materials/software easy to use and understand" (*Skills* and *Beliefs About Capabilities*) [7,22,28,32,35,37,38]. Despite the benefit of connecting with other men facing similar needs, involving caregivers in the programs appears to have a reinforcing role and to improve the wide range of unmet needs of the dyad as a whole [35,56].

There were three additional findings from this review. First, some factors, such as "discomfort posting on forums," "muted preferences on supportive care due to stoicism," or "materials/software easy to understand" were coded under several TDF domains. Additional work needs to focus on developing clearer operational definitions of each domain and the associated constructs so as to avoid "overlap" between domains [57]. Second, there were no facilitating factors found under the *Behavioral Regulation* domain. This can be an area of potential future research as behavioral regulation is key to sustain new healthier habits over time. Third, there was a notable lack of information available regarding barriers and facilitators of supportive care implementation from the United States, as all 13 studies were conducted in Australia, Canada, or the United Kingdom. This review has synthesized some of the factors but the extent of their role as well as the actors involved remain unknown.

Strengths and Limitations

There are several strengths to this scoping review. An expert reference librarian assisted with the search keywords, databases, and overall strategies. There was a variety of settings, supportive care programs, and study designs within the selected sample of studies. Additionally, Arksey and O'Malleys' rigorous methodological framework, along with the SCFCC and TDF, helped guide the synthesis of the evidence and the organization and interpretation of the findings, respectively. The use of theory has proven to enhance the

understanding of how and why the interventions are developed and implemented successfully [58].

However, several limitations must also be acknowledged. Although most studies included both survivor and HCP perspectives on supportive care implementation, more studies focused on the HCPs' opinions exclusively, which could have altered the interpretation of the results [7,22,28,30-33,35 -38]. In addition, despite their high methodological quality, only three out of the 13 studies provided level I evidence. Studies were limited to the English language and the last 10 years, resulting in the possible omission of relevant information. Finally, the review was primarily conducted by one reviewer, increasing the risk of bias.

Implications for Survivors

As therapies for advanced PC continue to improve, there will be a growing number of advanced PC survivors, particularly in developed countries [48]. This scoping review expands understanding of the factors that may influence supportive care implementation for this population. Overcoming existing barriers and enhancing facilitators has the potential to better inform future research regarding how to develop and implement more cost-effective, patient-centered supportive care interventions that meet all PC survivors' needs. Based on the results of this scoping review, future supportive care initiatives must focus on the following critical elements to close the existing knowledge gap: (1) improving accessibility and knowledge, increasing resources, considering several formats of supportive care, and overcoming masculine help-seeking behaviors; (2) giving special attention to factors that are coded under the *ECR* domain, whether as a barrier or a facilitator, as they are significantly more prevalent, and (3) developing and implementing nurse-led programs, as they have demonstrated efficacy and high levels of satisfaction among PC survivors.

Conclusion

Our scoping review has highlighted the multifactor barriers and facilitators affecting the implementation of supportive care in advanced PC survivors. The findings from this review are unique because, for the first time, these factors were categorized and classified according to the TDF domains. The resulting knowledge provides details about the barriers that need to be addressed and the facilitators that can be maximized to develop and deliver supportive care to advanced PC survivors. Future research must focus on improving, modifying, or supplementing current supportive care implementation practices. This scoping review contributes to the existing literature with novel findings that will help bridge the existing knowledge-practice gap.

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Table 1. Evidence Table of Selected Studies

Authors (Year)	Study Purpose	Design	Setting; Sample (N)	Intervention Type	Primary Results	Factors	TDF Domains	Level Evidence
Bender JL, Flora PK, Milosevic E, et al. (2020)	To evaluate the feasibility, acceptability, and effectiveness of the Peer Navigation Training Program among prostate cancer survivors	Explanatory sequential mixed methods	Toronto (Canada) Survivors & Caregivers (N=28)	Educational Online Peer Navigation (12 weeks)	Online training program feasible and acceptable Satisfaction score 9.4/10 Perceived usability 84.5/100 Statistically significant differences in learning (p<0.0001) Self-efficacy increase (p<0.0001) Increase in eHealth literacy (p<0.0001)	Facilitators; Barriers	Knowledge Beliefs about capabilities Beliefs about consequences Reinforcement Intentions Environmental context/resources Social influences Emotion	III
Chambers SK, Foley E, Galt E, et al. (2012)	To investigate the acceptability and effectiveness of mindfulness-based cognitive therapy for men with advanced prostate cancer	Pilot exploratory mixed methods	Queensland (Australia) Advanced prostate cancer survivors (N= 9)	Group mindfulness sessions + written manual (8 weeks)	Improvements in anxiety (p<0.027), avoidance (p<0.032), and fear of recurrence (p<0.062) No QOL differences Increased mindfulness, non-significant Urban group quotas ideal; low quotas in regional groups Qualitative themes: (1) group identification; (2) acceptance of diversity;	Facilitators; Barriers	Skills Reinforcement Environmental context/resources Social influences	III

127

					(3) peer learning; (4) acceptance of disease progression		
Cormie P, Turner B, Kaczmarek E, et al. (2015)	To provide an in-depth description of the experience of exercise programs among men with prostate cancer and to identify elements critical to optimizing patient engagement and participation	Qualitative	Perth, Australia Prostate cancer survivors (N=12)	Group aerobic and resistance exercise sessions (12 weeks)	**Themes:** (1) Health-related benefits: physical and mental well-being (2) Support from exercise physiologists as educational resource (3) Peer support: social connections and camaraderie	Facilitators; Barriers	Knowledge Skills Social/professional role identity Optimism Reinforcement Environmental context/resources Social influences	III
Cormie P, Taaffe DR, Spry N, et al. (2013)	To report the effect of a 12-week exercise program on sexual activity in prostate cancer patients	Randomized-Controlled Trial (2-armed)	Western Australia Prostate cancer patients (n=29) Usual care (n=27) (N=56)	Moderate to high intensity group resistance and aerobic exercise (12 weeks)	**Intervention group:** Level of sexual activity maintained Statistically significant changes in general health, vitality, physical health Statistically significant higher percentage in interest in sex No difference in sexual function scale between groups	Facilitators	Skills Beliefs about consequences Environmental context/resources Social influences	I
Ferguson J & Aning J. (2015)	To describe the early experience and impact of implementing a nurse-led service model	Descriptive	Newcastle, U.K Men with prostate cancer (N=76)	Face-to-face appointments with nurse specialist (tailored care) and Living With & Beyond	90% participants reported engaged in at least one component of the program High user satisfaction	Facilitators; Barriers	Knowledge Skills Social/Professional role and identity Reinforcement Goals Memory	III

				educational course (6 weeks)	Reported improvement in QOL		Environmental context/resources	
Hedden L, Pollock P, Stirling B, et al. (2019)	To examine registration rates, timing/intensity of follow-up with prostate cancer supportive care. To explore clinical and socio-demographic factors associated with participation and non-participation	Retrospective cohort	Vancouver, Canada Patients with prostate cancer: participated in the program (n=526) Did not participate (n=92) (N=618)	Prostate cancer supportive care (PCSC) program with individual clinical appointments and group educational sessions	Men on ADT had significantly lower odds of registering Men with larger travel distances and lower income had lower odds of registration Radical prostatectomy was a predictor in participation (4 times more) Kaplan-Meier curves varied significantly by treatment modality and Gleason score 85.58% of registrants completed the program No difference in participation by age, distance to clinic, socioeconomic quintile, or other variables	Facilitators; Barriers	Reinforcement Intentions Environmental context/resources	II
McLaughlin K, Hedden L, Pollock P, et al. (2019)	To advance understanding of (1) the nutritional needs of men with prostate cancer; (2) health providers´ assessment of nutritional services; (3) existing nutritional services	Quality Improvement	Vancouver, Canada Patients with prostate cancer (n=135) Patients' partners (n=72)	Prostate cancer supportive care (PCSC) program nutrition education session	**Patients and partners:** 88% agreed session was right length 94% found it useful 63% participants found it beneficial **Thematic analysis:**	Facilitators; Barriers	Knowledge Skills Social/Professional role and identity Beliefs about capabilities Beliefs about consequences Reinforcement Goals Environmental context/resources	III

	for men with prostate cancer		Healthcare providers (n=38) (N=245)		(1) high level satisfaction (2) inclusion of partners useful for processing information and supporting changes at home (3) 27% reported gaps in information – dietary components, individual concerns, and practical meal planning **HCPs:** 85% reported that patients expressed nutritional concerns 60% agreed that patients need more nutritional support No significant differences in responses between physicians and dietitians except for focus on nutritional support 67% believed that nutritional support should be continuous			
Paterson C, Primeau C, Nabi G. (2018)	To determine the effectiveness of a multimodality supportive care intervention on prevalence of unmet needs in men with advanced prostate cancer and their	Pilot parallel randomized controlled trial (2-armed)	Scotland, UK Patients with advanced prostate cancer and partners (n=19) Usual care (n=29)	ThriverCare with 4 components; informational materials, holistic needs assessment, individualized self-management care plans, group-based	No significant difference in prevalence of unmet needs at baseline Statistically significant difference after 3 months post-intervention in prevalence of unmet needs (p<0.002)	Facilitators; Barriers	Knowledge Reinforcement Goals	I

partners (ThriverCare)		(N=48)	educational seminar	Greatest improvements in physical symptoms, fear recurrence, fear of death, changes in sexual feelings, concerns of those closest to you No statistically significant differences in self-efficacy, anxiety, depression, QOL				
Primeau C, Paterson C, Nabi G. (2017)	To explore the experiences of patients with metastatic prostate cancer and their partners as well as an interprofessional team with a multimodal supportive care intervention	Qualitative	Scotland, UK Patients (n=19) Partners (n=7) Interprofessional team members (n=7) (N=26)	Intervention with 4 components; informational materials, holistic needs assessment, individualized self-management care plans, group-based educational seminar	**Patients and partners themes:** (1) emotional support: given time for expression and provided additional support (2) Informational support: nurse seen as a hub of supportive care (3) Evidence-based self-management plans: facilitated referrals to exercise programs or tailored self-management plans. (4) Evidence-based educational group seminar: perceived benefit in looking after themselves at home **Interprofessional team:** (1) Reported benefits in the holistic approach to patients care	Facilitators; Barriers	Beliefs about capabilities Reinforcement Intentions Goals Environmental context/resources	III

					(2) Greater access to specialist nurses and ability to target unmet supportive care needs			
Ralph N, Chambers S, Laurie K. et al. (2020)	To identify barriers to implementing supportive care for men with prostate cancer To inform the creation of a preimplementation plan for a nurse-led supportive care intervention (ProsCare)	Qualitative	Queensland, Australia Healthcare providers (N=21)	Individualized supportive care program (ProsCare) pre-implementation	Low awareness about supportive care effectiveness Difficulty keeping knowledge currency Gap in care coordination Traditional male roles influence uptake of care Patients don´t know how to navigate the healthcare system Participants expressed pessimism about the perceived effectiveness of supportive care Participants believed being stoic does not allow men to express their preferences for supportive care Several modalities of care necessary Participants believed that patients prioritize living longer than QOL Participants called for a decentralized access to care and increase awareness	Facilitators; Barriers	Knowledge Skills Social/professional role and identity Beliefs about capabilities Optimism Beliefs about consequences Reinforcement Intentions Goals Memory, attention, decision processes Environmental context and resources Social influences Emotion Behavioral regulation	III

| | | | | | Concerns about decisions not being revisited

Challenges to supportive care include cost, time, access difficulty

Stigma seen a social challenge
Participants called for improvement in psychosocial care

Participants emphasized patients´ preference to discuss supportive care with nurses | | | |
| Ralph N, Chambers S, Pomery A, et al. (2019) | To explore the insights of clinical nurse specialists regarding the context and delivery of the delivery of supportive care program (ProsCare) for men with advanced prostate cancer | Qualitative | Queensland, Australia

Specialist nurses (N=30) | Individualized, telephone-based supportive care intervention to facilitate decision support, training for symptoms self-management, screening for psychological distress, communication with HCPs | Participants reported that ProsCare is innovative, with high level of adaptability and trialability

Intervention easy to implement

Intervention met the needs of patients and HCPs

Intervention allows continuity of supportive care

Intervention will be successful if health services network with major prostate cancer services | Facilitators; Barriers | Knowledge
Skills
Social/Professional role and identity
Optimism
Goals
Environmental context/resources
Social influences | III |

					Teleintervention well supported by participants			
					Participants advocated for an inclusive learning climate for nurses Importance of a culturally competent delivery of Proscare.			
Ross Zahavich AN, Robinson JA, Paskevich D, et al. (2012)	To examine the feasibility and benefit of a therapeutic yoga program offered to prostate cancer survivors and their partners	Cross-sectional	Alberta, Canada Prostate cancer survivors (n=15) Partners (n=10) (N=25)	Supervised yoga classes (7 weeks)	High attendance (6.1/7) Statistically significant improvements in survivors and partners' mood, and decrease in fatigue and stress Non-statistically significant differences changes in physical activity Non-statistically significant changes in QOL Ratings of perceived social support higher for those bringing a partner Improvement in flexibility (p< 0.048) No improvements in other anthropometric measures	Facilitators; Barriers	Knowledge Skills Beliefs about consequences Reinforcement Environmental context/resources Social influences Emotion	II
Watson EK, Shinkins B, Matheson L, et al. (2018)	To test the feasibility and acceptability of a nurse-led psycho-educational	Pilot Randomized Controlled Trial	Oxford, Cambridge, UK Patients with prostate cancer:	Nurse-led psycho-educational intervention with	No between group differences in urinary, bowel, sexual, or hormone-related symptoms	Facilitators; Barriers	Skills Social/Professional role and identity Beliefs about capabilities Goals	I

| | | Intervention group (n=42)

Control group (n=41)

(N=83) | initial face-to-face appointment tailored face-to-face nurse contacts, and final follow-up telephone contact.
(6 months) | Non-statistically significant reduction in 4 domains of unmet needs in interventional group

No differences in psychological well-being

Intervention group reported improved self-efficacy across majority of items – non-statistically significant

Qualitative evaluation:
Completion rates high - 95% interventional group

All participants found intervention duration and schedule appropriate

Intervention benefited sense of well-being and emotions

Few participants reported no changes in physical symptoms

Program useful for men avoiding help seeking

Nurses praised the tailored follow-up design but were disappointed to find some men failing to act on their advice | | Memory
Environmental context/resources
Behavioral regulation | |
| intervention versus usual care (PROSPECTIV) | | | | | | | |

Abbreviations: QOL, quality of life; ADT, Androgen-deprivation therapy; HCPs, healthcare providers

Table 2. TDF Coding Percentages

TDF Barriers (N=58)			TDF Facilitators (N=79)		
Domain	(n)	(%)	Domain	(n)	(%)
ECR	17	29.3	ECR	18	22.7
Knowledge	11	18.9	Reinforcement	15	18.9
Beliefs about Capabilities	5	8.6	Skills	8	10.1
Goals	5	8.6	Goals	8	10.1
Skills	3	5.1	Social Influences	7	8.8
SPRI	3	5.1	B. about Capabilities	5	6.3
Reinforcement	3	5.1	SPRI	4	5.0
Social Influences	3	5.1	Knowledge	4	5.0
Beliefs about Consequences	2	3.4	B. Consequences	2	2.5
Intentions	2	3.4	Optimism	2	2.5
Behavioral Regulation	2	3.4	Intentions	2	2.5
Optimism	1	1.7	MADP	2	2.5
MADP	1	1.7	Emotions	2	2.5
Emotions	0	0.0	Behavioral Regulation	0	0.0

Abbreviations: TDF, Theoretical Domains Framework; ECR, Environmental Context and Resources; MADP, Memory, Attention and Decision Processes; SPRI, Social/Professional Role and Identity

Table 3. Identified Barriers and Facilitators using the Theoretical Domains Framework

STUDY	STAKEHOLDERS	BARRIERS	FACILITATORS	TDF DOMAIN(S)
BENDER JL, FLORA PK, MILOSEVIC E, ET AL. (2020)	**Patients**	- Discomfort posting in An online forum - Need for more in- person interaction (not all online) - Lack of technology proficiency	- Motivation to guide other survivors - Intensive but manageable workload - Flexible online environment - E-learning software easy to use - Authentic in-person role-playing and interaction	Knowledge Beliefs about capabilities Beliefs about consequences Reinforcement Intentions Environmental context/resources Emotion
	HCPs	- Lack of prior knowledge on qualities needed to recruit effective peer navigators - Purely self-study online not always acceptable format	- Partnerships with local PC support groups - Use of social learning (forum) - Inclusion of caregivers	Knowledge Beliefs about capabilities Reinforcement Environmental context/resources Social influences
CHAMBERS SK, FOLEY E, GALT E, ET AL. (2012)	**Patients**	- Lack caregivers' involvement -Excessive time commitment	- Group approach promotes identification	Reinforcement Environmental context/resources Social Influences
	HCPs	- Lower attendance from regional areas vs. urban	- Supervised sessions facilitated by trained psychologists - Intervention implemented in multiple locations - Cost-effectiveness group approach - Multicomponent	Skills Reinforcement Environmental context/resources
CORMIE P, TURNER B, KACZMAREK E, ET AL. (2015)	**Patients**	- Acknowledgment importance of exercise	- Pivotal role of exercise physiologists on compliance - Value of group format (support) - Humor as contributing element to foster supportive group dynamic - Exercise fits masculine ideals - Positive feedback from family/friends motivated engagement	Knowledge Skills Social/professional role identity Optimism Reinforcement Social influences
	HCPs	- None identified	- Structured, supervised program - Small group approach	Skills Environmental context/resources

			- Run by accredited exercise physiologists - Program free of charge	Social influences
CORMIE P, TAAFFE DR, SPRY N, ET AL. (2013)	**Patients**	- None identified	- None identified	
	HCPs	- None identified	- Small group approach - Supervised by expert exercise physiologists - Exercise is non-invasive - Intervention highly accessible	Skills Beliefs about consequences Environmental context/resources Social influences
FERGUSON J & ANING J. (2015)	**Patients**	- None identified	- None identified	
	HCPs	- Waiting lists due to limited resources and funding - Program did not address partners' needs	- Recognition of extra capacity needed to deliver program - Innovative patient-centered program delivered by nurse specialist - Inclusion of multidisciplinary team in program planning/ development - Involvement of several local services accessible to patients - Clear referral pathway - Flexibility in scheduling sessions - Multiapproach: counseling and education - Homely environment - Continuous program evaluation - Partner involvement	Knowledge Skills Social/Professional role and identity Reinforcement Goals Memory Environmental context/resources
HEDDEN L, POLLOCK P, STIRLING B, ET AL. (2019)	**Patients**	- Lack of continuity due to treatments - Long travel distance	- None identified	Intentions Environmental context/resources
	HCPs	- Low income - One centralized location - Program for patients/partners	- Multimodal: group educational and individual clinical sessions - Materials free of charge	Reinforcement Environmental context/resources
MCLAUGHLIN K, HEDDEN L,	**Patients**	- Not comprehensive (missing topics)	- Materials easy to understand - Appropriate length	Skills Social/Professional role and identity

POLLOCK P, ET AL. (2019)			- Inclusion of partners	Beliefs about capabilities Beliefs about consequences Reinforcement
	HCPs	- Unaware of current nutritional programs for PC - Belief of nutrition not being critical for PC - Interprofessional disagreement focus of nutritional program - Lack of funding - Limited dieticians with oncology experience	- Individual benefit from various formats - Ongoing availability through cancer continuum	Knowledge Skills Social/Professional role and identity Reinforcement Goals Environmental context/resources
PATERSON C, PRIMEAU C, NABI G. (2018)	Patients	- None identified	- None identified	
	HCPs	- Variation in providers' knowledge/expertise	- Personalized program - Precise standardization of EB self-management interventions - Discussion of SC needs with clinician	Knowledge Reinforcement Goals
PRIMEAU C, PATERSON C, NABI G. (2017)	Patients	- Difficult phone access to nurse after appointment	- Individualized information - Ample time with nurse - Non-technical language - Focus on self-management - Inclusion of partners	Beliefs about capabilities Reinforcement Goals Environmental context/resources
	HCPs	- None identified	- Holistic approach - Greater access to specialty nurse - Multimodal intervention	Reinforcement Intentions Environmental context/resources
RALPH N, CHAMBERS S, LAURIE K. ET AL. (2020)	Patients	- Inability to navigate health system - Muted preferences on additional SC due to stoicism - Prioritizing extension of life vs. quality life - Stigma - Fear, stress and unawareness of symptoms on psychosocial well-being	- None identified	Beliefs about capabilities Beliefs about consequences Intentions Social influences Emotion

	HCPs	- Low awareness of SC programs - Challenging to maintain knowledge currency - Uncertainty on SC effectiveness - Lack of skills on SC and care coordination - Patient stoicism - Pessimism about specialists engaging on SC - Centralized access of SC - Lack of revisitation - Scarce resources - Lack of specialty nurses - Challenges breaking habits	- Various formats of SC - Campaigns to reduce stigma	Knowledge Skills Social/professional role identity Optimism Reinforcement Goals Memory Environmental context/resources Behavioral regulation
RALPH N, CHAMBERS S, POMERY A, ET AL. (2019)	**Patients**	- None identified	- None identified	
	HCPs	- Knowledge base on nurses' teleconference delivery - Concerns on adding program to nurses' workload - Coordination challenges - Time constraints - Peer pressure	- Easy delivery via teleconference - Individualized program - Intervention delivered by specialty nurses - EBP intervention - High level of adaptability - Care continuity - Cosmopolitanism - Ideal team climate-optimism - Cultural competency	Knowledge Skills Social/Professional role and identity Optimism Goals Environmental context/resources Social influences
ROSS ZAHAVICH AN, ROBINSON JA, PASKEVICH D, ET AL. (2012)	**Patients**	- Time constraint - Accessibility	- High acceptance - Safe intervention	Beliefs about consequences Environmental context/resources Emotion
	HCPs	- Lack of knowledge optimal physical activity for PC - Lack of referrals	- Feasible activity - Group format enhances support - Inclusion of caregivers/partners	Knowledge Skills Reinforcement Social influences
WATSON EK, SHINKINS B,	**Patients**	- None identified	- Appropriate length - Welcoming and safe environment	Social/Professional role and identity Environmental context/resources

MATHESON L, ET AL. (2017)				
	HCPs	- Strain meeting patients' needs - Lack of right timing for all patients - Frustration dealing with some topics - Hard to motivate some patients - More training needed - Need for more resources/funds	- Nurse delivered intervention - Program based on self-management - Tailored individual follow-up - Open availability - Ability to work ahead	Skills Beliefs about capabilities Goals Memory Environmental context/resources Behavioral regulation

Abbreviations: PC, prostate cancer; SC, supportive care; EBP, evidence-based practice

Summary

Overview

      This dissertation compendium includes three manuscripts investigating interrelated and essential aspects of supportive care among advanced disease prostate cancer (PC) survivors. The first manuscript describes an integrative review that critically appraised the availability of supportive care interventions for this population and its effects on quality of life using the Supportive Care Framework for Cancer Care (SCFCC). In the second manuscript, results are reported from a holistic needs assessment conducted using a mixed-methods approach, also guided by the SCFCC. The third and final manuscript delineates a scoping review identifying common supportive care interventions and exploring barriers and facilitators to their implementation using the Theoretical Domains Framework (TDF).

      Prior research has reported that advanced PC survivors suffer from greater unmet needs that affect all individual dimensions, lowering their quality of life (QOL).[1] Ongoing and consistent supportive care has demonstrated to be an effective way to prevent and manage these overlapping unmet needs, maximizing QOL and rehabilitation.[2-4] However, despite all the recommendations from the Institute of Medicine, the American Society of Clinical Oncology, and the American Cancer Society, implementation of supportive care among this subset of survivors is limited and irregular.[5] The contributing results from the integrative review confirmed that, in fact, supportive care interventions for advanced PC survivors are not as widely available as they should be, despite some positive results on the outcomes. Supportive care efforts focus mainly on exercise, cognitive-behavioral, and educational interventions, leaving domains such as the spiritual, practical, and psychological lacking appropriate addressing in need for development of additional interventions. This deficiency doesn't but amplify even more supportive care needs in this population. Therefore,

a mixed-methods study that explored these needs in a comprehensive manner was necessary to strategize additional supportive care interventions.

The results from the mixed-methods convergent study indicated that advanced PC survivors have unfulfilled needs in every domain and that in fact, more needs were associated with lower quality of life. Up to 30% of the survivors reported having needs in at least half of the items, which is highly concerning. Areas of data convergence included sexual dysfunction and fatigue (physical domain), anxiety and existential concerns (emotional domain), and help around the house (practical domain). Numerous other needs identified in the mixed-methods study did not triangulate, leading to divergence among the data. Needs related to information were found to be most prevalent and important during the qualitative interviews but barely identified in the quantitative survey. The same was true for spiritual needs and urinary dysfunction, but not for depression, which had a higher prevalence in the quantitative data. In order to develop and implement successfully supportive care interventions that address the multidomain needs identified during the mixed-methods study, it was necessary to have a better understanding of the barriers and facilitators that have an effect on supportive care delivery.

The 13 studies included in the scoping review revealed a myriad of factors influencing supportive care implementation. Despite vast differences in supportive care interventions regarding focus, content, methodology, and outcomes, most of those barriers and facilitators fell primarily under three TDF domains. Barriers were identified under *Environmental Context and Resources* (*ECR*), *Knowledge*, and *Beliefs About Capabilities*, while most facilitators were categorized within the *ECR*, *Reinforcement*, and *Skills* domains. Primary barriers included lack of knowledge on supportive care interventions availability and/or effectiveness from both perspectives, patients and healthcare providers, variations in providers' expertise, insufficient technical proficiency, limited resources and access, time

constraints, lack of self-confidence in the intervention materials, hardships navigating the health system, and little competency. Main facilitators included making partnerships with local services, continuous availability, supervised group formats, partners inclusion, flexible scheduling, multimodality, delivery by professionals, and specialty nurse involvement. Additional barriers and facilitators from other TDF domains were also identified and included in the findings to better understand all potentially influencing factors to supportive care implementation.

Implications for Nursing and Cancer Care

Extensive past research has focused primarily on PC survivors' unmet needs at the early stages of the disease or undergoing specific treatments, such as androgen deprivation therapy.[6,7] More nursing research efforts in this area of cancer care are needed to decrease the morbidity associated with advanced PC and reduce disparities in supportive care implementation. For example, five out of the 12 most prevalent supportive care needs identified in the mixed methods study belong to the psychological/emotional domain. The integrative review findings support these results as they indicated insufficient interventions addressing this specific domain, potentially contributing to the higher prevalence of unmet needs. That limitation in interventions may be due to some of the barriers identified on the scoping review with the TDF guidance (knowledge, resources). Healthcare providers must concentrate their efforts on researching novel ways to provide patient-centered, cost-effective, multimodal supportive care that improves QOL and maximize health outcomes. In particular, as direct providers of care, specialty nurses are in an optimal position to assess the evolving needs of advanced disease prostate cancer survivors and become primary deliverers of supportive care.[8-10] Although the implementation of these interventions by accredited multidisciplinary professionals is vital, results from the three manuscripts emphasize the role

of specialty nurses. Although limited, interventions that were nurse-led reported higher levels of satisfaction and well-being among participating survivors.[10]

Future Directions

There are several diverse areas for future research based on this dissertation work. This was the first study exploring the unmet supportive care needs of advanced PC survivors living in the United States at a national level. Additional needs assessment in this population guided by multidomain frameworks is needed to confirm the study results and their generalizability, mainly longitudinally. Further, there is a need to investigate if the unmet needs in this subset of survivors vary according to socio-demographic and clinical characteristics and if needs predict QOL. The results also provide a future opportunity to conduct a review on all available instruments used to collect information regarding unmet supportive care needs and quality of life to determine their efficacy in providing comprehensive and accurate information. Additionally, the next steps necessarily include expanding and testing new patient-centered, cost-effective interventional research in order to narrow down the existing gaps in supportive care implementation. Interventions must focus on the needs with the highest prevalence, such as information regarding advanced PC treatments and self-care, physical and sexual functionality, and emotional/psychological support. However, it must also promote spiritual and practical well-being, as these domains can significantly improve QOL and sense of overall meaning among these survivors. Lastly, special attention must be given to the areas of data divergence (urinary dysfunction, depression, information and spiritual well-being). Further exploration is necessary to confirm these points of disconnect and the possible causes behind the differences.

Lessons Learned

Despite reaching the sample size for both the quantitative and the qualitative arms, participants were primarily non-Hispanic White, married, retired, and with higher education,

limiting the generalizability of the findings. It is possible that the recruitment efforts and settings led to this lack of diversity of survivors. The same was true for the sample of studies selected for the integrative review. Future work must ensure sociodemographic diversity and larger samples to increase generalizability. Further, investigators need to start incorporating diversity based on sexual orientation as well, since the supportive care needs can differ between heterosexual and homosexual advanced PC survivors.

The use of the SCFCC and TDF frameworks provided a solid structure for this dissertation work. This is unique, as the extant literature on supportive care for advanced PC survivors typically lacks guidance from theoretical or conceptual models. Selecting appropriate theoretical frameworks eases the understanding of how and why supportive care interventions are successfully or unsuccessfully implemented and if they address supportive care needs effectively, for example.[11] The SCFCC was a key element in categorizing not only the available supportive care interventions but also the unmet supportive care needs, all based on its holistic view of cancer.[12] However, some challenges were faced with the use of the TDF in synthesizing barriers and facilitators to supportive care implementation, mainly due to its numerous domains. Additional exploration of these factors is warranted using other suitable frameworks, such as the social-ecological model.

Conclusion

The three manuscripts of this dissertation explore several aspects of supportive care in advanced PC survivors. This research has indicated that this subset of survivors has a wide variety and prevalence of supportive care needs that do not appear to be appropriately addressed by existing cancer care services. This may be due to supportive care interventions being limited and inconsistent because of the existing barriers to their implementation. In the coming years, as the number of advanced PC survivors continues its ascending trend, more holistic, cost-effective supportive care will be vital to meet those multidomain needs and

optimize the QOL and overall health outcomes. The findings of this dissertation can be

applied to the development of new interventional programs that focus on areas of most need,

maximizing community partnerships, availability, multimodality, and specialty nurse

involvement.

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Institutional Review Board for Human Research (IRB)
Office of Research Integrity (ORI)
Medical University of South Carolina

Palmetto Place Office Park
1 South Park Circle, Bldg. 1, Suite 401
Charleston, SC. 29407
Federal Wide Assurance # 1888

APPROVAL:
This is to certify that the research proposal **Pro00100551** entitled:
A Mixed-Methods Study to Investigate the Unmet Supportive Care Needs in Advanced Disease Prostate Cancer Survivors.

submitted by: **Alejandra Schimmel**
Department: **Medical University of South Carolina**

for consideration has been reviewed by **IRB-I - Medical University of South Carolina** and approved. In accordance with 45 CFR 46.101(b), the referenced study is exempt from Human Research Subject Regulations. No further action or Institutional Review Board (IRB) oversight is required, as long as the project remains the same. However, you must inform this office of any changes in procedures involving human subjects. Changes to the current research protocol could result in a reclassification of the study and further review by the IRB.

Because this project was determined to be exempt from further IRB oversight, consent document(s), if applicable, are not stamped with an expiration date.

Approval Date: **6/19/2020**

Type: **Exempt**

Administrator, **IRB-I - Medical University of South Carolina**
Kristin Zaks∗

∗Electronic Signature: *This document has been electronically signed by the IRB Chairman through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.*

Important Note: Approval by the Institutional Review Board does not, in and of itself, constitute approval for the implementation of this research. Other MUSC clearances and approvals or other external agency or collaborating institutional approvals may be required before study activities are initiated. Research undertaken in conjunction with outside entities, such as drug or device companies, are typically contractual in nature and require an agreement between the University and the entity.

APPENDIX B. Hollings Cancer Center Protocol Review Committee Approval

Protocol Review & Monitoring System
86 Jonathan Lucas St.
Suite 373, MSC955
Charleston, SC 29425
Phone: (843) 792-9409
Fax: (843) 876-1962
E-mail: hccprms@musc.edu

May 29, 2020

Alejandra Schimmel, MSN, MBA, BSN, RN
Doctoral Student
Department of Nursing
Medical University of South Carolina
Charleston, SC 29425

Dear Dr. Schimmel:

At the May 29, 2020 meeting of the Protocol Review Committee (PRC), your research protocol entitled "A Mixed-Methods Study to Investigate the Unmet Supportive Care Needs in Advanced Disease Prostate Cancer Survivors" (CTO #: 103280/Sponsor: MUSC; protocol version May 27, 2020) was **approved** as written for use at Hollings Cancer Center.

As required by the NCI for all Designated Cancer Centers awarded a Cancer Center Support Grant (CCSG), MUSC-HCC must report all oncology clinical trial activity occurring at MUSC. Because the abovementioned study has qualified for PRC review and approval, this study is subject to ongoing reporting requirements to the PRC to ensure compliance to CCSG standards. Furthermore, since this trial is an investigator-initiated trial sponsored by MUSC faculty, additional reporting requirement to the NCI Clinical Trials Reporting Program (CTRP) is required.

As Principal Investigator, it is your responsibility to ensure the following information is submitted to the HCC PRC at hccprms@musc.edu. Please make sure that CTO#103280 is listed in any email correspondence.

 1) MUSC IRB Initial Approval Letter and Date of Study Activation
Please note that consideration for approval of this study by the MUSC IRB is pending. The MUSC IRB will require the provision of a PRC approval letter within your IRB application. Once a study is IRB approved, please submit the IRB approval letter to the PRC. If the study does not receive IRB approval and the study is withdrawn, please contact the PRC of this status. Study Activation is defined as the time when the study is eligible to begin enrollment to the trial. When the study is activated, please provide the PRC this activation date.

2) <u>All Significant Protocol Amendments require PRC approval</u>
Significant Protocol changes are defined as changes in any of the following: a) Study objectives, b) Research plan or study design, c) Eligibility, d) Statistical Consideration, e) Patient population and/or accrual figures. Any significant change requires PRC approval prior to IRB submission. It is required that a marked document and/or detailed summary of changes and the PRC Amendment Form be provided to the PRC. The PRC form is located at http://horseshoe.musc.edu/hcc/clinical-trials/prc.The PRC Chair will initially review the documents and may approve under expedited review. Should there be additional concerns, the PRC chair has the authority to request full board review of the amendment.

3) <u>Monthly Accrual Updates and Biannual Accrual Review</u>
On a monthly basis, it is required that updated accrual information is provided. In addition, PRC conducts a biannual trial performance review in which the level of accrual is reviewed. Should your predicated accrual period or accrual estimate change from your in initial form submission, please contact the PRC.

4) <u>Changes in Study Status</u>
When the study is closed to accrual or terminated, it is required that the updated status be provided to the PRC. Any applicable IRB letter regarding this change in status should be provided.

5) <u>Copies of all Protocol and/or Consent amendments and Continuing Renewal Applications</u>
The PRC helps ensure compliance to NCI's CTRP reporting requirement by submitting protocol updates on your behalf. Please notify the PRC of any changes to current study documents and related approval letters to the PRC. As an ancillary entity of the MUSC eIRB, PRC may request guest access to eIRB applications. However, should your study use an external IRB, you would be required to notify the PRC of protocol or consent changes and renewal approvals as they occur. All protocol or consent amendments and continuing renewal approvals require submission to the NCI's CTRP. For more information about CTRP please visit http://www.cancer.gov/aboutnci/organization/ccct/ctrp.

Conducting research is a critical component of our University's mission. Thank you for your efforts and should you have any questions regarding PRC, please feel free to contact the PRC chairs or administrator.

Sincerely,

Graham Warren, MD, PhD
Chair, Protocol Review Committee

cc: CTO Binder #103280

APPENDIX C. Study Protocol

SPECIFIC AIMS

Prostate cancer is the fourth most common cancer globally and a tremendous physical, emotional and financial burden for individuals, families, and healthcare systems.[1] From the 3.6 million prostate cancer (PC) survivors living in the United States, 30% suffer from advanced disease stages (regionally advanced-III, metastatic-IV, recurrent or refractory).[2,3,4] *Advanced disease* in survivors, considered treatable but no longer curable, is managed with chemotherapy, radiation, androgen-deprivation, or trials. Although the exact prevalence remains unknown, men with PC report substantial unmet supportive care (SC) needs due to a more prolonged illness pathway and the debilitating effects of therapies, leading to poor quality of life (QOL) and health outcomes.[5] These unmet needs, more widespread in advanced PC, are due primarily to physical, emotional, social, spiritual, informational, and practical impairments such as pain, urinary incontinence, bowel and sexual dysfunction, fatigue, hot flashes, depression, distress, anxiety, isolation, deteriorating bone health, weight changes, risk for suicide, cognitive decline, and financial burdens, costing the U.S. health system more than $9 billion annually.[4,6-13] Extensive research has examined QOL predictors and the impact of PC treatments on survivors who have completed curative treatment.[10,14-17] Research also reports the lived experiences of PC survivors but have not specifically focused on advanced disease. [5,18,19] Most studies attempting to examine unmet SC needs have been conducted with PC patients in earlier stages of the disease and using quantitative or qualitative approaches alone.[7,15,17,19,20] Therefore, there is a major gap surrounding the perceptions of the vulnerable subset of advanced PC survivors regarding their unmet SC needs.[12,13]

A preliminary integrative review revealed a significant lack of SC interventions for advanced disease PC survivors. This finding is supported by recent studies in which 33% - 81% of the surveyed survivors reported inadequate SC care despite guidelines recommending survivorship care for all PC survivors.[5,10] Given the magnitude of the problem, it is essential to develop and implement holistic, cost-effective, patient-centered SC interventions that maximize the QOL of advanced disease PC survivors. However, a *critical first step* is to examine this population's existing unmet SC needs, any additional difficulties faced during crisis such as the 2020 COVID-19 pandemic. Also, it is important to evaluate the feasibility of the research methodology used to measure unmet needs and QOL in this population (recruitment, enrollment, and data collection methods).[7,8,11,15,18-20] The *rationale* for conducting this study with advanced disease survivors solely is that they face different, and often underestimated and underreported, unmet SC needs than survivors at earlier stages.[12,13,21] If demonstrated to be feasible, the study's methodology can provide a more comprehensive picture of the needs in this subset of survivors and contribute as empirical evidence for optimizing their overall cancer survivorship care.

The purpose of this convergent parallel mixed-methods study is to conduct a supportive care unmet needs assessment in advanced disease prostate cancer survivors through the lens of Fitch's Supportive Care Needs for Cancer Care Framework (SCNCCF) while assessing the feasibility of the research methodology. The overarching *research question* that guides the study is:
> "What are the unmet supportive care needs in advanced disease prostate cancer survivors, and how do they relate to the quality of life and disease stage?

The specific aims are as follows:

Aim # 1: To characterize unmet supportive care needs and QOL in advanced disease PC survivors using a nationally administered survey.
   a. Determine the prevalence of unmet needs according to the different SCNCCF domains.
   b. Examine the relationship between SC unmet needs and QOL as well as analyze differences in SC unmet needs by age, race/ethnicity, insurance status, marital status, time since diagnosis, treatments, stage, and confinement for COVID-19.

Hypotheses include: (1) QOL will be negatively correlated to the prevalence of SC unmet needs, and (2) SC unmet needs will be higher in those with more advanced disease stage.

Aim #2: To explore the implications of physical, emotional, social, psychological, spiritual, informational, psychological, and practical needs in advanced disease PC survivors' quality of life.

a. Conduct key-informant, semi-structured interviews with a small subset of advanced disease PC survivors.

b. Perform interviews deductive-inductive content analysis to identify common themes per SCNCCF domains.

Aim # 3: To identify advanced disease PC survivors' unmet SC needs by synthesizing survey and interview findings.

Secondary Aim: To evaluate the feasibility of the research methodology in assessing advanced PC survivors' unmet SC needs for future applicability in similar clinical problems and populations (participant recruitment, enrollment, and consenting strategies as well as the data collection methods - survey and interview).

Impact

The results of this study may provide valuable understanding of the unique unmet SC needs of an understudied population that has been "suffering in silence" the devitalizing effects of cancer, and the prolonged treatments they complete.[20,22] Moreover, the findings will highlight the feasibility of future research utilizing mixed-methods designs and will inform the development of culturally appropriate, patient-centered, comprehensive SC strategies aimed to improve the QOL of this vulnerable and progressively growing population.

A. Significance

A.1. There is limited holistic needs assessment research for advanced-stage prostate cancer survivors.

PC is the leading cause of cancer death in American men.[23] Although the total yearly incidence rate has progressively fallen due to improvements in screening and curative treatments, it is projected that the burden of advanced PC will steadily increase in the upcoming years, particularly in younger men ($\leq$ 69 years).[24,25] It has been well documented that advanced disease PC survivors suffer from a vast array of SC needs as they live with this chronic illness for the remainder of their lives [7,12,14] The available various therapeutic modalities are critical to them for staying alive but are often associated with profound and long-term side effects.[8,9,13,18,20] Past needs assessment studies done with advanced stage PC survivors have focused primarily on physical and informational needs.[18,19,21] However, many *suffer disproportionately* from multiple overlapping SC needs that significantly diminish overall QOL and impact health outcomes negatively. Since up to 30% of all PC patients will eventually progress into advanced disease, it is essential to address this gap by conducting further holistic SC needs assessment research to improve these survivors' QOL.[8,21] The proposed study may provide significant insight into the prevalence and type of specific SC needs in advanced disease PC survivors, which are not being met within the current U.S. health care system. This insight is vital to improving their SC throughout survivorship until the end of life, particularly at times of need such as during the 2020 COVID-19 pandemic or other potential future public health crises.[16]

A.2. Failure to address traditional male roles may prevent optimal supportive care.

An extensive body of evidence indicates that PC is a threat to masculinity.[26,27,28] This is particularly true in men who hold traditional male role identities. One study highlighted that sexual dysfunction, urinary incontinence, and the emasculating way in which these issues are discussed in media and support forums can be particularly threatening and emotionally debilitating for many men.[26] This fact and other individual barriers - such as the need for control, self-blame, a more restricted emotional response, personal perception of the disease, and embarrassment - may hinder the verbalization of their unmet SC needs. Subsequently, there prompt SC may be delayed, leading to *a negative impact* on the QOL and the morbidities associated with more advanced stages of the disease.[27,28] These unmet needs remain largely unknown and unmanaged by healthcare providers. Therefore, this study will examine the prevalence and type of unmet SC needs of this population, so that holistic, patient-centered SC interventions that respect culturally accepted masculine roles can be better informed and developed. These interventions may promote higher engagement and potentially improve the overall QOL of these survivors.

A3. Current guidelines recommend holistic and continuous supportive care throughout survivorship.

The Institute of Medicine (IOM), the American Society of Clinical Oncology (ASCO) and the American Cancer Society (ACS) recommend uninterrupted individualized SC across healthcare delivery settings for PC cancer survivors, including during times of global health pandemics.[29,30] However, the implementation of this SC varies widely across health systems partially due to needs remaining unknown and the differences in screening and care between advanced and localized stages. As a result, advanced disease PC survivors continue to suffer in silence from a considerable number of unmet needs, may not receive the recommended care they require, and many times die from these and other long-term effects of the various cancer therapies.[29,31] Recent evidence indicates that up to 52.9% of PC survivors suffer from unmet emotional needs, 47.1% from physical needs, 23.5% from practical and spiritual needs, and 11.8% from social needs.[29]

Supportive care focuses on person-centered interventions to manage symptoms, improve coping, optimize decision-making, and minimize impairments in overall functioning.[31,32] This study is **_significant_** as it can be a first step to advancing knowledge that can inform the development of more comprehensive, cost-effective, patient-centered SC interventions that lessen the economic burden of cancer care on healthcare systems, while still providing holistic, individualized care.[31] Given current recommendations and guidelines for cancer survivorship care, and the increasing survival rates of patients with advanced disease, SC should become a standard to optimize QOL in this population.

A4. Unmet needs may be related to poorer quality of life.

Several past studies on PC survivors have investigated the relationship between QOL and specific socio-demographic and clinical characteristics such as race/ethnicity, stage of the disease, comorbidities, and time since the initial diagnosis. Results from those studies suggest a significant relationship between lower QOL and the Black race.[16] QOL also decreased -as time since diagnosis or number of comorbidities increased, or as more advanced stage was reached.[12,16,33] However, the relationship between unmet SC needs and QOL in advanced disease PC survivors has not been determined. Some evidence reports that the prevalence of unmet needs increases as age and time since diagnosis increases.[33,34] Further research is needed to validate the hypothesis that QOL in advanced PC survivors varies depending on the prevalence and type of unmet SC needs. This information will be valuable in developing and implementing SC interventions more efficiently.

B. Innovation

This study is innovative in several ways. First, it will be conducted with *all types* of advanced disease PC survivors solely (III, IV, recurrent). Past needs assessment research has combined PC survivors in all stages of the illness or has been limited to advanced disease patients receiving a specific treatment (e.g., androgen-deprivation therapy, chemotherapy).[7,10,31] Second, only a handful of studies have examined the prevalence of a comprehensive set of unmet S0C needs in this subset of PC survivors. However, the relationship between unmet needs and QOL and socio-demographic and clinical variables have not been explicitly investigated, warranting further exploration. It is hypothesized that higher unmet SC needs will be associated with worse QOL and higher disease stage, for example. Results from this study may provide a more comprehensive perspective of the types of unmet SC needs experienced in PC and how they relate to QOL and several socio-demographic and clinical variables, so that future development of more specific, patient-centered, SC interventions can be better informed. Third, the study will be guided by the SCNCCF. This framework has been proven suitable for investigating unmet needs with other conditions such as ovarian cancer or a sample of advanced cancer patients undergoing radiation for symptom control.[35,36] However, it has never guided a mixed-methods study conducted with adult PC cancer survivors. Fourth, as mentioned above, this study is the first to investigate unmet SC needs in advanced disease PC survivors using a *mixed-methods* approach with a large sample. To the best of our knowledge, only one study has used this methodology but with a small sample of 31 survivors.[12]

C. Diversity and Social Determinants of Health

We will recruit a sample of advanced disease PC survivors who are diverse in terms of race/ethnicity, age, disease stage, treatments, time since diagnosis, level of education, marital status,

geographical location to capture the perspective of potentially neglected populations. Statistics show that both the overall incidence of advanced PC and the death rate from the illness are higher in Blacks and Asian Americans/Pacific Islanders than in all other races/ethnicities.[37-39] This trend also holds true for increased age. Prior research has shown that minority race and lower socioeconomic status are associated with increased unmet SC needs and lower QOL in advanced PC cancer, partially due to the influence of masculinity and cancer stigma.[32] Additional studies also showed that stage, clinical treatment, and time since diagnosis usually lead to some common and some very distinct unmet SC needs in this population.[13] All of this evidence emphasizes the need for a deeper exploration of the unmet SC needs in a diverse sample of advanced PC survivors. The results of this study will complement previous research adding a level of insight by addressing person-level factors such as age, race/ethnicity, or stage and *social determinants of health* such as geography. Gender diversity is not achievable because of the male-specific nature of the illness.[40]

D. Guiding Theoretical Framework

This mixed-methods study will use the SCNCCF as the guiding theoretical framework (Appendix A).[41] The SCNCCF outlines a comprehensive taxonomy of seven domains, which include physical, psychological, emotional, informational, social, spiritual, and practical needs. It was developed by Dr. Margaret Fitch as a tool to assist clinicians in meeting the overlapping complex SC needs of cancer patients throughout the various stages of the illness, including survivorship. The SCNCCF is appropriate for this research because it has been used successfully in previous needs assessment studies with various types of cancer survivors.[35,36] The SCNCCF will be employed in the current study for several purposes. During the preliminary integrative review (IR), it was used to identify interventions targeting one or several needs domains (physical and informational) as well as the domains that have been historically neglected in interventional research (spiritual). It has helped identify a validated instrument to measure the SC needs of advanced disease PC survivors due to the similarities between the framework, and the Supportive Care Needs Survey (SCNS) domains (Aim 1).[32] It will help inform the development of the qualitative interview guide because of its holistic view of SC for cancer (Aim 2).[32,42-44] Finally, it will guide the categorization and interpretation of the findings, identifying needs across domains that are particularly prevalent and can impact these survivors' QOL negatively and ultimately, their health outcomes (Aim 3).[29,32,38]

E. Approach
E.1. Preliminary work

The PI conducted an IR previously on SC interventions with reported outcomes for advanced disease PC survivors. Guided by the domains of the SCNCCF, the review showed that SC interventions are limited, often representing the physical and informational domains only, despite the high prevalence of overlapping unmet needs in this population and current survivorship care guidelines and recommendations. SC interventions have the potential to improve the QOL and health outcomes of advanced disease PC survivors. However, advanced PC survivors should be recruited to help inform the development of holistic, patient-centered, multi-domain SC interventions.

E.2. Interprofessional Team

The research team for this mixed-methods study includes a vast array of complementary expertise. Mrs. Alejandra Schimmel is the primary investigator (PI) and has expertise in urological surgical oncology. She has worked with multidisciplinary teams for over 10 years. Dr. Qanungo is the committee Chair and brings unique expertise in both cancer research and overall research methodology. She has investigated physical, emotional, and psychosocial needs in diverse communities, both locally and globally. Dr. Newman brings extensive expertise in qualitative research methodology and has extensively investigated quality of life-related issues in patients with several chronic conditions. Dr. Sterba is a behavioral scientist whose work in cancer survivorship care and QOL has been widely recognized. Dr. Mueller is an advanced nurse expert in conducting complex biostatistical analyses; she will provide statistical support for the study.

E.3. Design Overview

This study will employ a *convergent parallel mixed-methods* design guided by the SCNCCF. This design aims at obtaining a more in-depth understanding of the unmet SC needs of advanced disease PC survivors, as well as the relationship of these with QOL, disease stage, and several other socio-demographic and clinical variables, by collecting and analyzing two independent sets of complementary data concurrently (quantitative and qualitative). Equal priority and importance will be given to both methods in addressing the research question.[45] The quantitative data collection will be done at a national level, and it will include a survey specifically developed to measure the perceptions of unmet SC needs and QOL. The qualitative data collection will focus on the survivors' perceptions of unmet SC needs and QOL through key-informant semi-structured interviews. Deductive-inductive content analysis (coding) of the interviews will then be performed using the SCNCCF as a guide to identify and quantify common themes.[45-47] The merging and integration of the two sets of results will occur during the combined interpretation of the findings. This integration will allow a well-rounded new interpretation about the prevalence and type of unmet SC needs, so future development and implementation of *comprehensive*, *holistic, patient-centered, guideline-based, and culturally appropriate* SC interventions can be better informed.[45] Due to the current COVID-19 extraordinary circumstances, all recruitment and data collection efforts will be performed remotely.

E.4. Mixed-Methods Methodology

The three study aims, and the secondary aim, are presented individually below.

Aim #1: To characterize unmet supportive care needs and QOL in advanced disease PC survivors using a nationally administered survey.

We will administer a cross-sectional online survey nationally using REDCap (Research Electronic Capture Data) with the goal of collecting quantitative data from 200 participants who have advanced disease PC over 3 months. The survey will include a cover page with relevant study information, the PI's contact for questions, and a screening questionnaire with 5 questions. The survey will include a brief sociodemographic and clinical questionnaire and several validated instruments aimed to capture unmet needs and QOL in cancer populations. A descriptive, correlational design will be used to measure the participants' perception of the prevalence and type of unmet SC needs according to the domains of the SCNCCF. We will also examine the relationship between unmet SC needs and QOL, as well as age, race, ethnicity, insurance status, marital status, time since diagnosis, disease stage, treatments, and time confined for COVID-19. Although not suitable to establish a causal relationship, this approach may give a better understanding of the underlying mechanisms accounting for the possible relationship between the study variables.[48]

E.5. Setting

After securing approval from both, the MUSC Hollings Cancer Center Protocol Review Committee (PRC) and the Institutional Review Board (IRB), participants for the survey will be recruited from several settings:

- MUSC urological clinics including Hollings Center Clinics. MUSC is one of the most recognized centers for urological services nationally. It possesses the most modern diagnostic, staging, and multi-modal therapeutic capabilities for PC, providing comprehensive care to more than 2000 PC patients currently.[49]
- Online research volunteer websites such as Research Match (RM).
- Online PC support groups and organizations including but not limited to American Cancer Society (ACS), Prostate Cancer International (PCI), Prostate Cancer Research Institute, Cancer Support Network (CSN), The Reluctant Brotherhood, The South Carolina Cancer Alliance (SCCA), and YANA.
- Online Social Media advertisement (Facebook, Instagram)

E.6. Sample Population and Eligibility

The PI will use a convenience, non-probability sampling strategy to recruit participants. This sampling approach, which prioritizes accessibility and availability, is one of the most applicable and widely used methods in nursing clinical research.[45,50] Inclusion criteria are having an advanced disease PC diagnosis (stages III, IV, recurrent); being 18+ years; being able to read, understand, and

speak English; and residing in the United States. Minors are excluded because it is extremely rare having a PC diagnosis during that stage of the lifespan. Exclusion criteria are being enrolled in palliative/hospice care and having a physical or mental impairment preventing from computer use to complete the survey (Appendix B).

E.7. Sample size determination and Power Analysis

A correct sample size is critical to ensure accurate conclusions and not lose study rigor.[51] The sample size was determined using GPower version 3.1.9.6 to calculate the observable effect size (correlation here r=0.2, based on Alpha=0.05, Power=80% and an expected sample size of at least 200 survey respondents) between unmet supportive care needs and quality of life (both continuous variables).

E.8. Procedures
E.8.1. Recruitment and Retention Strategies
The quantitative component will require a representative cohort of 200 socio-demographically *diverse* men who suffer from advanced PC. For MUSC-wide urological clinics, the PI will submit a SPARC Research Data Request, which will be performed via an Honest Broker, to assist with identification and recruitment of potential eligible participants with PC from MUSC medical records. Through the Honest Broker, the PI will gather the telephone number, and email of prospective participants who have agreed to be contacted for future research by logging their MUSC Research Permissions preferences in MyChart. All MUSC eligible participants who did not opt-out will be recruited by sending the secure link to the survey directly via email. For eligible potential participants who did not opt-out but did not have an email address listed on their chart, recruitment will be done by phone; the PI will verbally explain the study answering any questions and if interested, will ask for an email address to send them the secure survey link. For RM participants, an initial invitation will be sent through the RM electronic site, after the PI fills up a recruitment request. A de-identified "contact volunteers" page will be provided to the PI by RM with all potential participants. The PI will select diverse, potentially eligible participants to send them a contact message with the secure REDCap survey link. Potential participants through PC support groups and organizations will be recruited by posting an electronic flyer with or without the secure survey link (depending on the organization policies) on their social media sites (e.g., Facebook, Instagram), news web site, discussion forums, or invitations to meetings (Appendix C). If the potential participant contacts the PI, all relevant information about the study will be explained. Any questions will be answered and if the potential participant is interested, they will be asked to provide a valid email address so that the secure survey link can be sent.The opportunity to participate in the online survey will be also electronically disseminated through general and public advertising on various social media platforms and outlets (including Facebook and Instagram). For all participants, no matter the setting, the survey will finish with an option to express interest in participating in the qualitative interview (Aim #2). Retention strategies to minimize attrition will include an electronic $10 gift card as compensation upon completion of the entire survey. The participants will be asked to provide an email address of their preference at the end of the survey so that the PI can send them the gift card. The PI will be responsible for funding and sending all the compensation electronic gift cards.
E.8.2. Screening and Assignment of Participants
The eligibility screening, regardless of the setting, will be determined solely on the inclusion and exclusion criteria. The screening will be performed via a screening questionnaire with 5 questions located on the survey cover page. The ones meeting the criteria will be assigned as participants enrolled in the study. For participants who do not meet the criteria, REDCap will take them to a screen that will thank them for their time, and they will automatically exit the survey.
E.8.3. Informed Consent
The PI will request a MUSC Hollings Center PRC since potential participants may be recruited from its urological clinics. The PI will also request a waiver of informed consent to the MUSC IRB under qualifying category 2, since no interventions will be performed during the proposed study. A statement of research will appear on the cover page of the survey, and it will include the study purpose, risks, as well as study aspects being measured, how long the survey should take to complete, and an assurance of confidentiality. Potential participants will also be informed that they are free to

exit the survey at any time and for any reason. To progress to the screening questions, they will need to check a box that indicates their agreement to participate.

E.9. Data Safety and Management

During the MUSC Research Data Request, the Honest Broker will provide the PI with the name, email, and phone number of potential participants who have agreed to be contacted for future research for recruitment purposes only. The data will be kept in a password protected MUSC server. Participant's email address will be requested at the end of the survey so that the gift-card compensation can be sent. A telephone number will also be collected at the end of the survey, but only if the participant records their interest to be contacted for the qualitative interview (Aim #2). REDCap, provided through South Carolina Translational Research (SCTR), will be used to develop and store the survey following MUSC s' data storage requirements. REDCap is a password-secure, web-based application created with the objective to support data capture for research.[52] The PI will perform all the data management procedures (assessment of completeness and analysis). The participants' identifying information (name/email/phone) will not be connected to any survey responses and will not be disclosed to any non-study or non-regulatory personnel. Each participant will be assigned a case number that will be referenced on all study procedures. The PI will be responsible for safeguarding the data (e.g., survey, SPSS files) throughout the study by monitoring the secure data storage daily and appropriately reporting any protocol deviation, including privacy breaches and conflicts of interest, to the IRB and the study team. The passwords for the access to the REDCap study database will be available to the PI, with rights assigned to the study team (for consultations regarding emerging results but not for editing the actual database).

E.10. Data Collection

E.10.1. Instruments

Supportive Care Needs Survey-Short Form 34 (SCNS-SF34): The participants' unmet SC needs will be measured with the SCNS-SF34. The SCNS-SF34 is a self-administered questionnaire that consists of 34 items mapped onto five domains: physical & daily living (5 items), health care & information (11 items), psychological (10 items), patient care & support (5 items), and sexual (3 items). Responses are scored on a five-point Likert scale dichotomized by need level to distinguish between those with "no current needs" (1-2), versus those with "some degree of need" (3-5). Scoring will be done by calculating a Likert summated scale: summing the individual items within each domain. The summated scale can be standardized by summing the individual items, subtracting m (the number of questions within a subscale), and then multiplying the resulting value by 100.[32,42,53,54] This instrument has robust similarities with most relevant domains of the framework guiding this study and was originally created to obtain a direct index of cancer patients' perception of their unmet SC needs.[32,53,55] Although the long and the short forms are recommended for use in assessing unmet needs in cancer patients, the second-generation core SF-34 survey has been recently created from the long-form after further psychometric development.[53] The SCNS-SF34 has been successfully utilized in multiple studies with advanced cancer patients and has an excellent patient acceptance rate. Scores are reported standardized. The SCNS-SF34 possesses high internal reliability, internal consistency, and strong content validity.[55]

SCNS PC Module: This module will be used to measure PC-specific unmet needs. It is self-administered and applies to any PC disease stage, treatment modality and time since initial diagnosis. It consists of 7 additional items (with the same SCNS response set) assessing unmet needs associated with urinary and bowel functions, as well as masculine self-image.[53] Scoring will be done the same way as the SCNS-SF34.

Functional Assessment of Chronic Illness Therapy - Spiritual Well- Being (FACIT-Sp): The integrative review findings showed that the *spiritual domain* is as influential for this population as the other 6 domains, primarily as a coping resource. However, so far, this domain has been neglected in advanced cancer needs assessment questionnaires and interventional research. Since the SCNS-SF34 does not include a spiritual domain, the PI will use the FACIT-Sp 12 questionnaire. The FACIT-Sp 12 is a subscale of a longer questionnaire and it is the most widely used scale for spiritual well-being in patients with cancer.[56] It contains 12 items with summary scores ranging from 0 to 48. The instrument identifies the items that must be reversed before being summed. Once reversed, all subscale items are

summed to a total. A higher subscale score indicates greater spiritual well-being. This subscale has been validated across multiple cultures and has strong reliability.[56,57]

European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): Participants' health-related QOL, will be measured with the EORTC QLQ-C30. The EORTC QLQ-C30 is an integrated system consisting of 30 items and intending to measure global health in patients who have cancer. It is composed of multi-item subscales and single-item measures. It includes 5 functional scales (physical, role, cognitive, emotional, social), 3 symptom scales (fatigue, pain, nausea & vomiting), a global health status (1 item) and a QOL (1 item) scale, and 6 single items for symptom measures. It uses a 4-point response set for all the items except for the health status and QOL scales, which are measured on a 7-point scale. Scores are calculated by scale or by item and transformed into a 0 to100 scale with higher summary scores representing higher QOL or higher level of symptomatology. The mean score, standard deviation, and range will be reported. The EORTC QLQ-C30 is considered an excellent instrument to measure QOL and has been widely employed in studies with different cancer populations, including PC.[4,12,58]

E.10.2. Data Collection

The PI will collect quantitative data through a survey distributed electronically using REDCap. The actual survey will have two sections: first, a brief sociodemographic and clinical questionnaire, and then, several reliable and validated instruments (Appendix D). To adapt the instruments for this study, the PI made a minor change to the FACIT-Sp questionnaire, modifying its time frame from 7 days to one month so that all the unmet needs findings are meaningful around the same specific timepoint.[59] If possible, The PI will pretest the survey with 1-2 volunteers for clarity and flow. Data will be collected at a single point in time. To overcome commonly existing survey low response rates, participation and completion will be encouraged by ensuring confidentiality, by reposting the advertisement on support groups and organizations sites every 2 weeks, by sending 3 friendly reminders to potential participants who did not complete the survey the first time (after 3, 6 weeks, and 9 weeks) and by offering compensation for their time.[48,60] The survey will be available for potential participants for 3 months. Table 1 summarizes a description of the variables in this study, as well as the data sources for all the variables and the psychometric properties of all the instruments. The completion of the survey will take approximately 15-20 minutes.

Table 1- Study variables and measures

VARIABLE	MEASURE	PSYCHOMETRIC PROPERTIES
Age, race, ethnicity, marital status, education level, employment status, insurance status	Brief socio-demographic/clinical survey	n/a
PC stage at diagnosis, time since initial diagnosis, treatments received, current stage	Brief socio-demographic/clinical survey	n/a
Quality of Life (subjective)	- EORTC QLQ-C30	- EORTC QLQ-C30: Cronbach's α coefficients between .70 and .96.[58]
Perceived Unmet Needs (subjective)	- SCNS-SF34 - SCNS PC module - FACIT-Sp 12	- SCNS-SF34: Reliability coefficients Cronbach Alpha .86-.95 and internal validity coefficients .87-.96 [53] - SCNS-PC: Preliminary evidence indicates internal consistency & reliability [53] - FACIT-Sp 12: Cronbach's α coefficient .87 [57]

E.11. Data Analysis

Rigorous data analysis in mixed-methods research involves several steps: 1) prepare the data for analysis, 2) explore the data, 3) analyze the data, 4) represent/display the data, 5) interpret the results, and 6) validate the data and results.[45] The PI will prepare the quantitative data for analysis by exporting the data from REDCap into SPSS v26 software, by visually checking for errors in the database, and by recoding variables as appropriate. The exploration of the data will include creating frequency distributions to determine missing data and checking the amount and pattern of the missing

data, which is paramount to maintain the overall integrity of the research. If the missing data represent less than 5% of the entire data, SPSS will use listwise deletion by default.[51,63] If missing data are between 5% and 30%, multiple imputation (MI) will be performed using SPSS so that participants are not lost due to SPSS deletion. MI uses available data to predict respondents' missing values, given their observed values on other variables. This procedure has been demonstrated to yield the best estimations of missing data. Its benefits include no loss in statistical power and maintenance of internal and external validity against biases resulting from nonresponse.[51,63] If more than 30% of the data are missing, the variable will be deleted altogether.

The PI will analyze the data using the SPSS v. 26 software package. Descriptive statistics will be used to summarize the sample characteristics – means and standard deviations for continuous variables and frequencies, proportions, and ranges for categorical variables – and the level of unmet needs – by reporting the prevalence (%, mean, standard deviation, range) per domain and individually per item, as well as the total score.

The PI will also assess the frequency with which respondents reported each item as moderate/high need (at least 25% of the sample).[34] Assuming normal distribution, a bivariate correlational analysis with Pearson's r computation will be performed to determine the strength and direction of the linear relationship between each domain of unmet SC needs and QOL as well as between each domain of unmet needs and several socio-demographic and clinical variables (age, race/ethnicity, marital status, insurance status, stage, time since diagnosis, treatments received, and confinement time for COVID-19). If data are non-normally distributed but the sample is large (above 20), type I and II errors will be minimized by calculating non-parametric Spearman s'rank-order instead. [51] The PI will also conduct appropriate statistical analyses to compare socio-demographic (age, race/ethnicity, insurance status, marital status, confinement time), and clinical characteristics (disease stage, years since diagnosis, treatments received) by SC unmet needs domain. In addition, the PI will perform a series of regression analyses to examine whether unmet SC needs can be predicted by age, stage, treatment received, years since diagnosis, race/ethnicity, insurance status, marital status, and confinement time. Also, linear regression will be conducted to investigate if QOL is predicted by SC unmet needs. The results of both, the descriptive statistics and the inferential statistical tests, will be represented using tables and graphs for a better visualization. The results of the tests will be compared and contrasted with the two Aim 1 hypotheses and interpreted with reference to prior studies from the literature, considering the limitations of the proposed study. Data validation will rely on the already established construct validity and reliability of all the instruments used during the data collection.[45,51]

Aim #2: To explore the implications of physical, emotional, social, psychological, spiritual, informational, psychological, and practical needs in advanced disease PC survivors' quality of life.

This component will follow a qualitative descriptive methodology and involves a separate brief socio-demographic and clinical questionnaire and an individual semi-structured key-informant interview conducted via telephone or Doxy.me, a secure telehealth platform that uses encryption protocols ensuring data integrity and privacy. Doxy.me is free, user-friendly, and HIPAA compliant platform that enables real-time audio-visual communication.[64] Qualitative description is the optimal methodology as the proposed study has a mixed methods design and it seeks information to understand and to describe the phenomenon under investigation from those directly experiencing it.[45,65]

E.12. Setting

The participants will be recruited from several settings. All of the participants enrolled in the quantitative component of the study (Aim #1) will be invited to participate in the qualitative component (Aim #2). In addition, the online PC support groups and organizations will advertise the study via flyer as described in Aim #1 for both, the survey and /or the qualitative interview. For this qualitative portion, the PI will solely interview PC survivors who suffer from advanced disease PC (stages III, IV, recurrent).

E.13. Sample and Eligibility

To ensure a *diverse* representation of all PC advanced stages, ages, and races/ethnicities, the PI will use a purposive sampling plan. The PI will select and recruit up to 30 participants until data saturation - no new information from the participants' interviews - is achieved.[65] The primary inclusion criteria will be advanced disease PC (stages III, IV, recurrent); being +18 years; being able to read, speak, and understand English; and residing in the United States. Exclusion criteria will include being enrolled in palliative/hospice care and having a physical or mental impairment that prevents telephone or computer use (Appendix B).

E.14. Procedures
E.14.1. Recruitment and Retention Strategies
The PI will select and contact a *diverse* sample of enrolled participants who have completed the survey (Aim #1) and who have provided a phone number. Participants will also be recruited via flyer from online support groups and organizations, until data saturation is achieved. The PI will schedule the key-informant interview at a day/time of the potential participant's choice, either via telephone or electronically (Doxy.me). The PI will maintain a recruitment log to track all participants who were selected, contacted, recruited, screened, and enrolled for the interview.

Retention strategies will include scheduling the interview at a day/time of the participant's choice. Interviews will be held by telephone or Doxy.me based on availability and participant's preference. Attrition will be minimized by obtaining additional contact information during the first contact (a family member or friend), by offering a $20 electronic Amazon gift card as compensation upon completion of the socio-demographic questionnaire and interview, and by sending an electronic thank-you card as a way to leave a more long-term positive effect.[66] The PI will request an email address of their preference at the end of the interview so that the gift-card compensation and the electronic thank-you card can be sent. The PI will be responsible for funding and deliver all the electronic gift cards and the thank-you cards.

E.14.2. Screening and Assignment of Participants
Eligibility screening will vary according to the recruitment setting. For the participants enrolled via quantitative survey, the PI will explain the study purpose and risks involved and answer any questions during the initial contact. Once the potential participant expresses interest in participating in the interview, the PI will screen for eligibility based on the inclusion/exclusion criteria by asking the same 5 screening questions than on the survey. If agreed, the participant will be enrolled in the qualitative part of the study. For potential participants who contact the PI via electronic flyer through support groups and organizations, the PI will explain all the pertinent aspects of the study (purpose, risks, confidentiality) and answer any questions during that first contact. If interested, the PI will screen them for eligibility based on the inclusion/exclusion criteria by asking the 5 same screening questions. If the criteria are met, the PI will enroll the potential participant for the semi-structured interview.

E.14.3. Informed Consent
The PI will secure a PRC from the Hollings Center and a waiver of informed consent under qualifying categories 2 for both aims since no interventions will be performed. Regardless of the interview method, prior to start, the PI will provide a statement of research to inform the enrolled participants about all pertinent aspects of the study, including risks, benefits, special protections, audio recording, and assurance of confidentiality. The PI will answer all of their questions. The PI will also inform them how long the interview will take to complete and that they can take a break or withdraw from the interview altogether at any time and for any reason. The participant will have to provide verbal consent to continue with the interview.

E.15. Data Safety
The PI will perform all the data management procedures. The participant's name will be collected during the interview for addressing purposes only. The participants' telephone and email will be collected during the recruitment for eligibility screening, and interview scheduling purposes. However, all identifiable information used prior and during the interview will not be connected to any data on the interview transcripts or the brief socio-demographic and clinical questionnaire files. The brief socio-demographic survey will be computer-based and will be uploaded securely into a password protected REDCap database according to MUSC storage requirements. Interview audio

recordings will be transcribed for analysis using Rev.com (MUSC-approved), and then, uploaded, de-identified, to a password-protected MUSC Box storage folder to maintain participants' confidentiality. Afterwards the hard copies of the recordings will be erased from the portable device. The recruitment log and the reflective journal notes (de-identified) will be uploaded into password-protected secure Box files. Each participant's transcription will be assigned a case number to be referenced on all study procedures. Data safeguarding and passwords handling are described above on E.9.

E.16. Data Collection

Up to 30 semi-structured, in-depth, one-time interviews will be performed over 3 months to explore the implications of physical, emotional, social, psychological, spiritual, informational, and practical needs in advanced PC survivors' QOL. The interviews will take place via telephone or Doxy.me. The interviews will be scheduled at a day/time that is convenient to the participants. Before the interview, the PI may ask every participant to complete a separate brief demographic and clinical questionnaire, which will include race/ethnicity, age, education level, marital status, employment status, insurance status, PC stage at the time of diagnosis and currently, time since the initial diagnosis, treatments received, and some COVID-19-related questions. The PI developed an interview guide informed by the literature and guided by the SCNCCF with the objective to capture the seven domains of needs (Appendix E). Two open-ended, non-directive questions will encourage participant's free expression regarding life with PC and current needs. The remaining guided questions will allow participants to elaborate on what is relevant to them about their current unmet needs, including any existing differences during COVID-19 pandemic, and care planning based on the 7 domains of the framework. The PI will use probes throughout the interview to elicit clarifications and/or additional explanations or to redirect the participant.[45,67] Notes on a reflective journal will also be taken to describe the PI's impressions and feelings about the interview. The interview will take between 45-60 minutes to complete. All interviews will be audio-recorded with an external portable recorder and transcribed using a professional MUSC-approved transcription service (Rev.com). The transcripts will be de-identified, uploaded into a secure folder in Box, and entered into NVivo12 data analysis software for coding and analysis.

E.17. Data Analysis

E.17.1. Demographic characteristics

The socio-demographic and clinical data collected via the brief survey will be stored securely in REDCap and analyzed using the NVivo12 software. The PI will use descriptive statistics to analyze and present the sample characteristics. Measures of central tendency (mean & standard deviation), frequencies, and measures of dispersion (range) will be reported for all the participants' demographic and clinical variables.

E.17.2. Analysis of the survivors' interview

The unit of analysis will be the interview. After each interview is transcribed using Rev.com, the PI will perform a comparison between the transcript and the original audio-recording to ensure content accuracy. Qualitative deductive-inductive content analysis will be conducted as soon as possible after the interview using NVivo12 qualitative data analysis software to provide a rich account of the data collected during the interviews.[68,69] Commonly used in nursing research, deductive-inductive content analysis aims at both, quantifying and describing the phenomenon under investigation so that new insight or knowledge can be established.[70,71] For each interview, the PI will use the following analytic strategies: (1) read the transcript, (2) deductively-inductively code the data until common themes related to unmet SC needs emerge, (3) consider the emergent needs within the domains of the SCNCCF, (4) look for commonalities and differences among the data and the codes, (5) determine on common themes generated from the data/codes, (6) use the analysis of each interview to inform subsequent interviews, by adding questions to the interview guide based on the data collected/analyzed from prior interviews.[45,70,71] The PI will follow an iterative comparative method throughout the entire data collection and analysis period until data saturation is achieved. The PI will keep a codebook with coding schemes and definitions as part of the study audit trail. The outcome of the qualitative component of the study will include a descriptive summary of the data contents organized according to the SCNCCF domains of needs. The representation of the qualitative

data analysis results will include a thematic description of the examples of participants' vivid quotes for each of the emerging theme categories.

Aim # 3: To identify advanced disease PC survivors' unmet SC needs by merging and synthesizing survey and interview findings.

E.18. Overview

In Aim 3, the results from the surveys (Aim 1) and the semi-structured interviews (Aim 2) will be merged for analysis. Both strands of data will be given equal emphasis. The goal is to compare both quantitative and qualitative data to find similarities, differences, and/or inconsistencies (Figure 1).[45] The PI expects to identify the prevalence and type of unmet SC needs in advanced disease PC survivors, to determine a correlation between those needs and QOL/disease stage, and how some socio-demographic and clinical characteristics may affect or predict SC unmet needs so that future research and development of holistic, patient-centered SC interventions can be informed.

Figure 1. **Merging of both sets of data.**
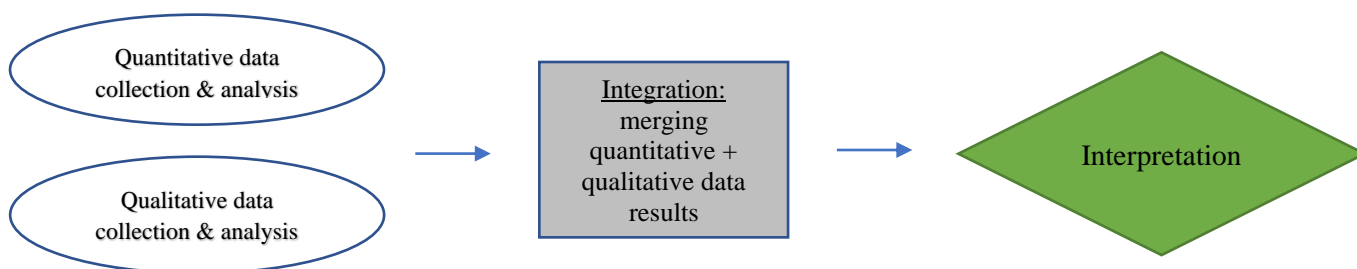
E.19. Data Analysis

The data from Aims 1 (quantitative) and 2 (qualitative) will be collected concurrently but analyzed independently. Merging and integration of both threads of results will occur in a separate, subsequent step. The PI will review and synthesize both sets of results to compare and contrast emerging themes and understand mechanisms underlying unmet needs experiences, which will be organized according to the domains of the SCNCCF. For example, a SC need that appears disparately burdensome seen during an interview will be compared/looked for evidence in the quantitative data and vice versa.[45,68] A joint display will be created to assist with the interpretation of the results – focusing on the extent to which both sets of results produce a more comprehensive understanding of the prevalence and type of unmet SC needs in advanced disease PC survivors.[45]

Secondary Aim: To evaluate the feasibility of the research methodology in assessing advanced PC survivors' SC unmet needs for future applicability in similar clinical problems and populations (participant recruitment, enrollment, and consenting strategies as well as the data collection methods - survey and interview).

E.20. Overview

To the best of our knowledge, the SC unmet needs of advanced disease PC survivors have not been examined using a mixed-methods design with a large sample. Several sources of data will be used to measure and evaluate the preliminary feasibility of the research methodology in assessing the unmet SC needs of this population. The feasibility components and quantifications for are displayed in Table 1. These quantifications will be measured for both, the quantitative and qualitative components using logs.

Table 1. Feasibility components/Quantification measures

	Study component	Feasibility quantification
Recruitment plan & procedures	Recruitment (survey & interview)	Number of participants sent the survey/ contacted the PI or by the PI

	Attempts to contact / reminders (survey & interview)	Number of attempts necessary more than initial
	Approaching (survey & interview)	Number of participants being informed about study
	Screening (survey & interview)	Number of eligible & ineligible participants
	Response (survey & interview)	Response rate
Data collection procedures	Completion rate	Number of surveys/interviews with complete data & reasons for not completion
	Psychometric properties (survey only)	Established reliability & convergent validity coefficients
	Reliability of questionnaires (survey only)	Calculation of Cronbach Alpha for existing sample
	COVID-19 response	Number respondents shared COVID-19 info versus PC info

E.21. Data Collection

Data collection on the recruitment and procedures will be an iterative process and will last 3 months. As potential participants for Aims 1 and 2 are approached, contacted, recruited, screened, and enrolled, entries will be recorded on logs (for the quantitative and qualitative aims). As surveys are received or interviews are conducted, the data (response and completion) will also be recorded on the same logs, which will be securely stored in Box. The psychometric properties of the instruments will be obtained from the literature and recorded on the log as well. The PI will calculate the reliability coefficient Cronbach's alpha to determine the suitability of the questionnaires for this specific sample.

E.22. Data Analysis and Reporting

The feasibility outcomes, their definition, and the results will be represented as a table or figures for a better visualization. All the rates will be calculated and reported as amounts and percentages. The PI will also provide a 95% confidence interval (CI) for means for all continuous feasibility outcomes.

E. 23. Potential Problems and Alternate Approaches

The study faces several challenges: convenience and purposive sampling plans, unequal quantitative and qualitative sample sizes, participants' fatigue/boredom, erroneous data, recall bias (inability to recall properly due to a prolonged illness pathway) , social desirability response bias (responses to survey and/or interview questions are intended to please the study team), failure to resolve conflicting results, and study rigor.[71,72] To minimize these challenges, the PI's recruitment plans include several and varied settings to add diversity. The PI has secured support from several PC support groups and organizations gatekeepers to advertise the electronic study flyer on their sites. The survey and the interview are designed to be completed in the least amount of time to prevent fatigue or boredom from happening. Erroneous data will be overcome by exploring the data carefully and implementing the appropriate strategies as needed (e.g., deletion). The social desirability response bias will be mitigated by establishing appropriate rapport with the participants, educating them about the importance to respond to all the questions honestly, by emphasizing that there are no right/wrong responses, and by ensuring them that all the responses will be treated confidentially.[71] To overcome recall bias, the interviews will be scheduled as soon as possible after the recruitment and with the participants preferences in mind (method, day, time). The PI will also engage in strategies to explain and represent potentially conflicting results from both components.[45]

Quantitative rigor will be maintained by recruiting a *diverse* sample of participants, by reaching the sample size target, by applying sound statistical processes, and by using previously validated instruments to collect the data. Qualitative study rigor will be maintained in several ways. The PI will ensure trustworthiness through credibility, dependability, confirmability, and transferability. Credibility will be established by the statement of research conducted before the interview to create rapport and by conducting several levels of data coding. Dependability and confirmability will be achieved through an audit trail of data collection and analysis procedures, description of the sample characteristics, and the inclusion of direct quotations as evidence of the raw data collected. Transferability will be ensured by applying the sampling strategy, and by providing sufficient details regarding the data collection process, so that replicability can be achieved.[48,65,67]

E.24. Study Timeline

Table 1. **Study timeline**

Study Objectives	Anticipated Time of Completion
Secure PRC approval	4/2020-5/2020
Secure IRB approval	5/2020-6/2020
Participant recruitment	6/2020-9/2020
Data collection	7/2020-9/2020
Data analysis	7/2020-9/2020
Manuscript preparation	9/2020-10/2020
Submission of entire compendium	10/2020-11/2020

F. Human Subjects
F.1. Risks to the Subjects

a. **Human Subjects Involvement and Characteristics**

There will be 200 study participants for Aim #1 who will be recruited from MUSC urological clinics, RM, several online support groups and organizations as well through general and public advertising on various social media platforms and outlets (including Facebook and Instagram). Eligibility screening will be performed via the 5 questions on the survey cover page. To ensure *diversity*, the sample will include various adult ages, races/ethnicities, disease stages, current treatments, time since diagnosis, level of education, marital status, and national locations. A preliminary feasibility report done at MUSC urological clinics in February 2020 determined that there were 2,490 potentially eligible participants, with ages ranging from 36 to 90 years. The races were distributed as 57% White, 40% Black, and 3% unknown. Ethnicity was 96% non-Hispanic (Appendix F). We anticipate recruiting a sample with similar sociodemographic characteristics.

For Aim #2, all of the participants enrolled for Aim #1 will be invited to participate in the qualitative component (Aim #2). Additionally, study participants will be recruited from online support groups/organizations. A purposeful sampling approach will be used to select and recruit a *diverse* sample with regard to age, race/ethnicity, and advanced stage. The PI will attempt to recruit up to 30 participants for semi-structured interviews until data saturation is achieved. The interviews will be conducted via telephone or Doxy.me according to the participant's preference and availability. We will request a PRC to the Hollings Center and an exemption of the informed consent based on qualifying category 2 to the MUSC IRB prior to sending any survey or conducting any interview.

b. **Sources of Materials**

The PI will collect potential participants' name, email, and telephone from the SPARC Research Data Request (conducted by an Honest Broker service) if they have indicated on MyChart that they would like to be contacted for future research. The only sources of data obtained from human subjects are described in the above research protocol. These include:

- Sociodemographic and pertinent clinical data
- Electronic data from survey information
- Audio-recordings, transcriptions, and reflective journal notes from the qualitative interviews
- A telephone number on the survey only if the respondent is interested in participating in the interview
- A preference email address to send the electronic gift card and the thank-you cards
- A name for addressing purposes during the interview

This information will be stored in password protected MUSC servers REDCap and Box. All data will be used for research purposes only and the PI will make every effort possible to keep these data confidential. No identifiers will be connected to any survey or interview data. Neither will identifiers

be used in any publications resulting from this study. However, the survey and/or interviews transcripts data may be used in future studies and/or publications.

c. Potential Risks

The PI does not expect significant risks to human subjects related to the completion of the electronic survey and the semi-structured interviews. It is possible that collecting this information poses a minimal risk to confidentiality. There is also minimal risk that participants may experience emotional distress, boredom, or fatigue as they reflect on past experiences or as they answer a specific question or survey item. But the study poses no physical, social, or legal risks.

To mitigate potential risks, the PI will provide participants with a statement of research with all the pertinent study information before the survey/interview. The PI also will conduct a debriefing session after the semi-structured interview. In case the debriefing fails to relieve any emotional distress that a participant experiences, the PI will arrange a referral to an available health care provider or an emergency room for further evaluation. All participants will be reminded that they can discontinue their participation in the study at any time and for any reason. In the event of a life-threatening emergency, the PI will call emergency services (911).

F.2. Adequacy of Protections Against Risks

a. Recruitment and Informed Consent

Aim #1: For MUSC-wide urological clinics, the PI will submit a SPARC Research Data Request via an Honest Broker, to assist with the identification and recruitment of eligible participants (who have advanced prostate cancer diagnosis - stages III, IV, recurrent) from MUSC medical records. The Honest Broker will provide the PI with the name, telephone number, and email of prospective subjects who have agreed to be contacted for future research by logging their MUSC Research Permissions preferences in MyChart. These participants will be approached, recruited screened, and enrolled directly by sending the secure link to the REDCap survey via email. For MUSC eligible participants who did not opt-out but did not have an email address on file, approaching and recruitment will be done by phone; the PI will verbally explain the study answering any questions, and if interested, the PI will ask for an email address to send them the secure survey link. Screening and final enrollment will be done via the survey link. RM participants will be sent an initial invitation via electronic flyer through RM, after the PI fills up a recruitment request. RM will provide the PI with a de-identified "contact volunteers" page with all potential participants. The PI will select diverse, potentially eligible participants to send them a contact message with the secure REDCap survey link. Potential participants through PC support groups and organizations will be recruited by posting an electronic flyer with or without the secure survey link (depending on the organization policies) on their social media, news web site, discussion forums, or invitations to meetings, as described in E.8.1. If the potential participant contacts the PI, all study pertinent information will be explained, and any questions will be answered. If interested, a valid email address will be asked to send the secure survey link. The opportunity to participate in the online survey will be also electronically disseminated through general and public advertising on various social media platforms and outlets (including Facebook and Instagram). Regardless of the setting, the survey participants will have the choice to indicate their willingness to participate in the qualitative semi-structured interview by selecting the option at the end of the survey. REDCap will notify the PI of all participants interested in doing the interview so that the PI can select them based on age, stage, and race/ethnicity *diversity* and contact them via telephone to screen for eligibility. Participants who complete the entire survey will receive an electronic $10 Target gift card as compensation.

For Aim #2, participants will be invited to participate via the quantitative survey, which will provide a checkmark at the end as well as a space to submit a phone number for contact. Participants will also be recruited by electronic flyer via several online support groups and organizations. Regardless of the setting, all study pertinent information will be explained, and any questions will be answered during the initial telephone contact. If interested, screening will be conducted as described

in E.14.2., and the interview will be scheduled at a day/time of the participant's choice via telephone or Doxy.me depending on availability and/or preference. Participants who complete the brief socio-demographic and clinical questionnaire interview will receive an electronic $20 Amazon gift card as compensation for their time.

The PI will request a PRC to the Hollings Cancer Center and a waiver of informed consent for the entire study to the MUSC IRB based on qualifying category 2, since the proposed study does not involve any interventions. On the survey, a cover page will serve as a written statement of research and it will include the study purpose, potential risks, the study aspects being measured, time that the interview will take to be completed, and an assurance of confidentiality. Participants will also be informed that they are free to exit the survey at any time without any reason. Respondents will need to check a box to agree to participate and continue on the survey (Appendix D).

For the qualitative component, the PI will provide a verbal statement of research before the interview by informing the potential participants about all aspects of the study, including potential risks, special protections, topics discussed, time needed to complete the interview, and assurance of confidentiality. The PI will answer all of the questions and inform them that they can take a break or withdraw from the interview at any time and for any reason. The participant will need to provide verbal consent to participate All participants, from both, the survey and the interviews, will be provided with the PI telephone and email address in case they need to contact the PI at any time.

The PI and all other study team members have completed the required human participants research training courses (e.g., Miami CITI) as well as the mandatory HIPAA training. A log will be kept in a password-protected Box folder and will include information regarding participant's date of approach, recruitment, screening, enrollment, and survey/interview completion as well as the survey completion rate for analysis purposes of the secondary aim (feasibility).

b. Protection Against Risk and Data Management

The PI anticipates minimal risk of adverse events (AE) based on the study design and the absence of interventions and invasive procedures. However, if an AE occurs, the participant will be instructed to contact the PI immediately. Any AE or protocol deviation will be recorded and reported to the IRB as well as the study team members, following all MUSC institutional requirements and procedures. There are no anticipated physical, social, or legal risks from participating in the survey or the interviews.

The PI will undertake every possible measure to ensure the safety of all study participants. Before the survey, participants will be instructed how to contact the PI and how to exit the survey if they feel fatigued, or do not want to continue answering the questions. The PI will provide breaks during the interviews to participants that feel fatigued or frustrated. The interview will also be rescheduled or interrupted if the participant feels that he cannot continue, with no consequences. All participants will be reassured that they do not have to answer to any question they do not want to answer. In the event of a study-related question illness or injury, participants will be instructed on how to contact the PI and how to access appropriate health care. The participants will be assured that taking part in this study will not interfere with the clinical care that they are receiving at MUSC or elsewhere.

Several plans are in place to protect all participants' data confidentiality. For the quantitative component, personal identifiers (name/email/phone number) will be collected from the Honest Broker and from the participants at the end of the survey, for recruitment, interview scheduling, and sending the gift card purposes only. The potential participant's contact information (name/email/phone) will not be connected to any data on the survey and will be stored in password protected MUSC servers. Each participant will be assigned a unique case number that will be referenced on all study procedures. All the survey data will be stored in the secure password-protected REDCap database. The password to that database will be accessible only to the PI, with rights assigned to the study team members for consultations regarding emerging results.

For the semi-structured interviews, confidentiality will be assured by conducting the interview in a privately connected session via telephone or Doxy.me (from a private office). The interview transcript data will be de-identified for analysis. The PI may collect the email address and phone number of participants, but for recruitment and scheduling the interview purposes only. The contact information will not be connected to any data on the interview transcripts or the brief socio-demographic and clinical survey. Each transcript will be assigned a unique case number that will be referenced on all study procedures. The interview audio recordings will be uploaded and transcribed for analysis from a portable recorder into an MUSC-approved transcription service (Rev.com) after each interview session. The resulting transcripts will be de-identified and uploaded into a secure password-protected storage file in Box. Afterwards, the recordings will be erased from the portable device. The enrollment log and the reflective journal notes taken during the interview will be also confidential and will also be kept in a password-protected storage file in Box. The data from the brief sociodemographic and clinical survey will also be de-identified and kept in a REDCap database following all MUSC storage requirements. Access to the password-protected REDCap database and the Box storage files will be limited only to the PI, with rights assigned to the study team members for consultations regarding emerging results. To further ensure participants' confidentiality, there will be no paper copies of any data. However, the digital audio recording transcripts will be stored in a secure database for a minimum of 6 years.

The PI will perform all the data management procedures for both, the survey and the interview components, and will ensure that the study is being conducted following the written proposal. The PI and the study team will adopt all possible measures to ensure that any data and private personal information are not disclosed to anyone outside the study team. Caution will be used when presenting the findings from the qualitative interviews. We will provide participants' quotations from the transcripts that can support the study results while avoiding unintentional disclosure of the participant's identity.

F.3. Potential Benefits of the Research to Human Subjects and Others

The participants may not benefit directly from the proposed study. The minimal risks of the study outweigh the inconvenience to the participants in terms of the anticipated new knowledge that may be gained from the study. Participant contributions may hopefully provide health researchers and clinicians with a better understanding of the unmet SC needs in advanced disease PC survivors so that more culturally appropriate, patient-centered, efficient SC interventions can be informed and developed to improve their QOL and health outcomes. In addition, all participants, from both the quantitative and the qualitative components, will receive compensation for completion of the survey and the interview.

F.4. Importance of the Knowledge to be Gained

The knowledge to be gained from the proposed study may provide significant insight into the prevalence and type of unmet SC needs in advanced disease PC survivors. The information obtained from the study participants may provide a foundation for the development of more culturally acceptable, comprehensive, cost-effective, and patient-centered SC interventions that improve this vulnerable population's QOL and overall health outcomes. The findings may also help validate two hypotheses: first, that QOL will be negatively correlated to the prevalence of SC unmet needs, and second, that SC unmet needs will be higher in those with more advanced disease stage. In addition, the data collected may help evaluate the feasibility of the study methodology.

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ARE YOU A
PROSTATE CANCER SURVIVOR?

WE CAN USE YOUR INPUT!
Currently Recruiting

A **research study** is being conducted to better understand the supportive care needs and quality of life in individuals with **ADVANCED disease prostate cancer**. Individuals with advanced prostate cancer are invited to participate in an online survey and/or interview. Some compensation may be available.

Below you will find the direct secure survey link (copy and paste into your browser) or if you prefer, you can use the QR Code above:

https://redcap.musc.edu/surveys/?s=WKK4A9NDAE

For more information, please contact:
Alejandra Schimmel
schimme@musc.edu

APPENDIX E. Advanced Disease Prostate Cancer Survivors Interview Guide

STATEMENT OF RESEARCH

My name is Alejandra Schimmel and I am a doctoral student at the Medical University of South Carolina College of Nursing. You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. *You are being asked to participate in this study because you have diagnosis of advanced prostate cancer.* The purpose of this study is gathering information about the different supportive care needs that advanced prostate cancer survivors may have. By surveying survivors like you, we hope to understand better the unmet needs that you may have related to your prostate cancer and help you to care for them better. I am very interested in knowing how important each of these needs are for you right now.

Thank you very much for speaking with me today about your illness. I would like to talk to you for about 45 to 60 minutes if that's OK. Our conversation will be private. The interview will be digitally recorded. The digital audio files will be transferred from the external recorder to a secure password protected computer for storage within 48 hours after the interview is completed. The digital audio files will be deleted from the recorder after that. We will transcribe the digital recordings, removing any identifying information such as individual names. These are standard procedures for interviews.

Taking part in the study should not put you at risk for any physical harm. You *may* feel uncomfortable, fatigued, or frustrated discussing certain aspects of your cancer. You will be reminded several times that you are *not* required to respond to any questions that make you feel uncomfortable. You may ask for a break or to stop the interview at any time and for any reason (if you feel fatigued, or bored, or frustrated…).

There is a risk of loss of confidentiality of your information that is used in this study. To minimize this risk, we will maintain the confidentiality of your information in accordance with all national and local regulations. All digital recordings and interview transcripts will be stored on a password protected MUSC server with access limited to the study team only. Your name will not be on the transcripts. In return for your time and effort, you will receive $20 by gift card for participation in this study.

I will first ask you some questions about you and your cancer, if that´s OK. Then, we will continue on with the interview. Are you ready to start?

First, we will go through a few screening questions:

1. HAVE YOU BEEN DIAGNOSED WITH ADVANCED PROSTATE CANCER BY A MEDICAL PROFESSIONAL (stages 3, 4, recurrent)?
2. ARE YOU 18 YEARS OF AGE OR OLDER?
3. ARE YOU ABLE TO READ, UNDERSTAND, AND SPEAK ENGLISH?

4. DO YOU RESIDE IN THE UNITED STATES OR ITS TERRITORIES?
5. ARE YOU CURRENTLY ENROLLED IN PALLIATIVE OR HOSPICE CARE?

(If eligible, I will go ahead with the brief questionnaire and interview)

PART 1. BRIEF SOCIO-DEMOGRAPHIC AND CLINICAL QUESTIONNAIRE

I am aware that you may have already completed this questionnaire, but if you don´t mind, I would need to gather this information again.

What is your age?

  ------ Prefer not to respond

What is your current marital status?
 ------- Never married
 ------- Partnership (unmarried)
 ------- Married
 ------- Separated
 ------- Divorced
 ------- Widowed
 ------- Prefer not to respond

Are you Hispanic or Latino?
 ------ Yes
 ------ No
 ------ Prefer not to respond

What is your race (check all that apply)?
 ------ Black / African American
 ------ White
 ------ American Indian/Alaskan
 ------ Asian
 ------ Pacific Islander
 ------ Other
 ------- Prefer not to respond

 If you identify yourself with Other regarding your race , please, specify:

How many years of school have you completed?
 ------ Elementary school/Junior high

------ High school graduate or GED
------ Some college
------ College graduate and beyond
------ Prefer not to respond

What is your employment status?
------ Full-time
------ Part-time
----- Unemployed-Actively looking for employment
------ Unemployed-Not looking for employment
------ Disabled
------ Retired
------ Student
------ Prefer not to respond

Do you have medical insurance?
------- Yes
------- No
------- Prefer not to respond.

What treatment have you received for your prostate cancer (check all that apply)?

------- Surgery
------- Radiation therapy
------- Chemotherapy
------- Androgen Deprivation Therapy (hormonotherapy)
------- Radioactive seeds implantation
------- Cryotherapy
------- Other (clinical trial, vaccine)
------- Prefer not to Respond

If Other treatment(s), please, specify:

What year were you first diagnosed with prostate cancer?

------- Prefer not to respond

What was the stage of your prostate cancer at the time of your initial diagnosis?
------- I – very localized cancer inside the prostate only
------- II – cancer has not spread outside the prostate
------- III – cancer has not spread outside the prostate but has spread to surrounding tissues or the lymph nodes
------- IV – cancer has spread to lymph nodes or other organs

------- Unknown
------- Prefer not to Respond

What is the stage of your prostate cancer right now?
------- I - very localized cancer inside the prostate only
------- II - cancer has not spread outside the prostate
------- III - cancer has not spread outside the prostate but has spread to surrounding tissues or the lymph nodes
------- IV - cancer has spread to lymph nodes or other organs
------- Unknown
------- Refuse to Respond

What is your state of residence? --------------------

Thank you very much for answering these questions. We will now start with the interview questions regarding your prostate cancer experiences and needs.

PART 2. INTERVIEW GUIDE

Opening, non-directive questions:

1. Can you please tell me what is a typical day like for you?
2. What is different in your life related to living with prostate cancer?

*The following questions will be formulated based on the (7) domains of the Supportive Care Needs for Cancer Care Framework. Aside from the listed probes, a **general probe** will be used as needed in case the PI needs to re-direct the participant to talk about more current needs: "...that sounds like a challenging time, ...can you comment on any emotional/physical/social...challenges you currently have?"*

PHYSICAL NEEDS:
3. What physical changes in your regular daily functions have you experienced related to your prostate cancer treatments?
    - **PROBE** - needs from the illness or the medical treatments, for example, fatigue, pain, urinary or sexual symptoms, changes in bowel habits, difficulty sleeping, weight changes, or hot flushes, changes in sexuality.
    - **PROBE** – are you able to maintain the same hobbies, activities as before?
    -
EMOTIONAL NEEDS:
4. Tell me about any emotional issues or concerns that you have experienced related to your PC?

177

- **PROBE** – do you experience excessive worry, anger, fear about cancer spreading, distress, anxiety, depression.
- **PROBE** – Do you see or are you willing to see a provider regarding your emotional health?

SOCIAL NEEDS:
5. Tell me about your social life.
6. How has your prostate cancer impacted your relationships and roles towards others?
    - **PROBE** - communicating with others?
7. What support systems do you have? Family? Friends? Community?

SPIRITUAL NEEDS:
8. What role does spirituality have for you in your life?
    - **PROBE**: Have you experienced any changes regarding your spirituality since your diagnosis – changes in personal values, any spiritual crisis?
    - **PROBE** – do you maintain the same spirituality (religion…)?

PRACTICAL NEEDS:
9. Tell me about any practical issues or needs that you may have.
    - **PROBE**- like inability to work, assistance at home, access to support services, or difficulties with transportation (not being able to drive to your medical treatments or check-ups)
    - **PROBE** – any major changes at home/car?
10. Do you have any financial needs or worry about paying the bills, or not being able to work, or not having enough income/pension?

INFORMATIONAL NEEDS:
11. What information have you received regarding your prostate cancer and treatments? Is there any information that you wished you had but did not received?
    - **PROBE** - Do you know where to go for resources or help?
    - **PROBE** - Do you know what information to trust?
    - **PROBE** - Have you received information about all your treatment choices? From who?

PSYCHOLOGICAL NEEDS:
12. How do you cope with your illness?
13. Please, tell me how you feel about your body and how your PC has affected your body image.
14. What is the most difficult aspect of your condition?
    - **PROBE -** How do you handle or care for it?

15. What information might have helped you better adapt and make choices that felt right for you?
    - **PROBE -** Did you have or currently have help making decisions regarding your illness and treatments?

COVID-19 QUESTIONS:

16. Did you or anyone in your household get COVID-19?
------- YES

------- NO

------- Prefer not to Respond

17. If YES, who was it?

----

18. Do you believe your needs regarding your prostate cancer have changed due to the
    COVID-19   pandemic?

-------- YES

-------- NO

-------- Prefer not to respond

19. If **YES**, how have those needs changed? ¿Can you tell me how you have lived this
    confinement in terms of your prostate cancer?

Closing Questions:

20. Is there anything else that you would like to tell me today?

21. Do you think that you could have been more supported regarding your needs in any
    way?

We have finished the interview. I greatly appreciate you sharing this information about your
illness with me. If necessary, would it be acceptable for me to contact you for further
clarifications during the transcription and analysis of the information? I will provide you with
a brief summary of the study results once the study is finalized.

Could I ask you your zip code please? -------------------

Also, if you could provide me with an email address, I will be happy to send you the
electronic gift card as compensation for your time.

APPENDIX F. Permission to Use Quantitative Measurement Instruments

1) EORTC-QLQ-C30

Dear Alejandra Schimmel,

Thank you for registering on the EORTC Quality of Life Group website.

Your registration to obtain permission to use our tools has been approved. During the registration process you agreed to our terms and conditions regarding the academic use of our questionnaires. You can review the terms and conditions here.

Please find below the links to the requested tools:

QLQ-C30 Core Questionnaire - English

Scoring Manuals:

C30 Scoring Manual

EORTC

http://www.eortc.org

http://qol.eortc.org

NOTE:
This email was automatically generated. Since this email is an automatic notification, we are unable to receive replies. Please do not respond to this email address.

2) **FACIT-SP 12**

FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY (FACIT) LICENSING AGREEMENT

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Issued on: January 15, 2020 by:

Shannon C Romo
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Ponte Vedra, FL 32082-4161 USA
www.FACIT.org

3) SCNS-SF34 & PC-module

Hi Alejandra,

Thank you for your email. Attached are a copy of the long and short versions of the SCNS for use in your study, as well as the User Manual.
Please don't hesitate to contact me if you have any questions.
Best wishes with your research.

Regards,
Allison

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Re: Framework

Marg Fitch <marg.i.fitch@gmail.com>
Fri 10/16/2020 6:35 AM

Hello Alejandra

Thank you for your email and interest in the Supportive Care Framework. I am pleased to know it is helpful to you.
I am happy for you to make use of it and adapt the diagram with the appropriate reference/acknowledgement.

Regards