

Overview of Enrolment and Participation in Research Studies Conducted in a Supportive Care Clinical Program for Prostate Cancer Patients

Olga Arsovska MA, CCRP¹, Eugenia Wu BSc CCRP¹, Monita Sundar MA¹, Michaela Vivar BSc¹, Christopher Pang BSc¹, Maria Spillane MSc¹, Lindsay Hedden, PhD^{1,2}, Larry Goldenberg MD^{1,3}, Celestia Higano MD^{1,3,4}

¹Vancouver Prostate Centre, Vancouver, BC; ²School of Population and Public Health, University of British Columbia; ³Department of Urologic Sciences, University of British Columbia; ⁴University of Washington, Fred Hutchinson Cancer Research Centre, Seattle, Washington

PCSC@vch.ca



Background

Prostate cancer (PC) is the most common cancer and chronic disease diagnosed in men in North America with a relative overall survival of 96% at 15 years¹.

The Prostate Cancer Supportive Care (PCSC) Program was initiated by the Vancouver Prostate Centre (VPC) in January 2013 to address the complex supportive care needs of men with PC and their partners with education and clinical services. PCSC Program enrolment is available to all patients with the disease and not limited to VPC clinic patients.

In addition to providing education and clinical support to patients, an integral mandate of the program is to conduct research that will provide evidence based guidance to better deliver supportive care to patients with prostate cancer.

Objective: to describe the status of the PCSC research program

Methods

- Research studies were grouped by type.
- Screening and enrollment logs were reviewed to tally the total number of patients approached versus enrolled.
- The reasons for non-participation based on data in our enrollment logs were categorized.

Results

Between Feb 2015 and Mar 2019, PCSC Program participated in 22 research studies:

- 9 therapeutic or lifestyle intervention studies (3 RCTs)
- 3 observational studies
- 2 registries
- 1 survey
- 1 genetic study
- 1 databank
- 2 collaborative programmatic studies
- 3 "permission to contact" studies (referral to the study team only)

8 out of the 22 studies included recruitment of dyads (both patient and their partner or caregiver).

Results, cont'd

- PCSC research team referred patients to 3 outside studies for "permission to contact" by outside research team¹
- PCSC collaborated with external programs to run two lifestyle management studies²
- The PCSC Program requests consent from all registrants to participate in the SPIRIT databank.

Table 1. Referral and Recruitment Numbers

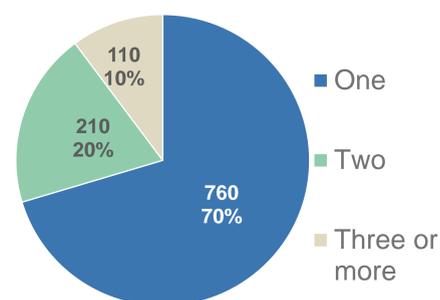
Study	# patients
SRAPC ¹	21
Peer Navigation ¹	16
PR and Men ¹	12
Exercising Together ²	10
Evaluation of PCSC Nutrition Module ²	394
SPIRIT Databank ³	1158

- For the remaining 16 studies, 1080 participants were enrolled in at least 1 research study
- Cumulative enrolment is 1536 over four years (figure 1).
- In 2018, the addition of a research assistant increased recruitment, mainly to registry studies.

Figure 1. Number of Research Consents Obtained Per Year



Figure 2. Number of patients who enroll in 1, 2, 3 or more trials



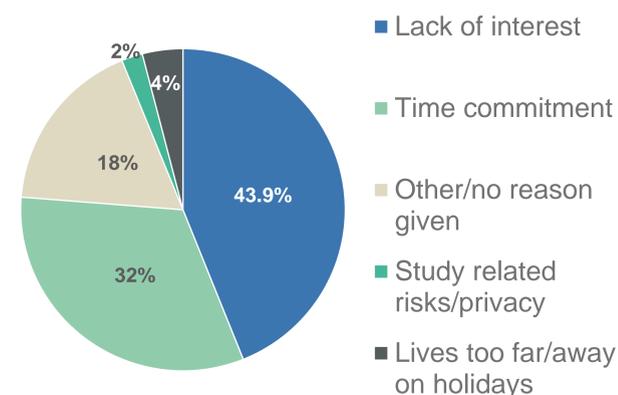
Results, cont'd

- Consent to participate in research varied widely by study (table 2)
- Patients more frequently declined studies that were more demanding of their time eg. frequent group sessions, multiple questionnaire timepoints
- 619 of 3112 approached declined consent

Table 2. Number of patients approached and declined by study

Study	Number Approached	Number declined (%)
Registry		
PC360IS	279	11 (4.0)
TrueNTH	369	17 (4.6)
Therapeutic/Lifestyle Intervention		
SHRAP	152	4 (2.6)
Radiomics	80	5 (6.3)
Cooking	20	3 (15)
Share-C	20	3 (15)
SCP	94	29 (30.1)
Introspect	700	338 (48.3)
TEMPO	21	13 (61.9)
EMMPC	65	45 (69.2)
IMPACT	52	38 (73.1)
Observational		
LPC	42	0
PCSC-1	162	13 (8.0)
Sleep	28	15 (53.6)
Others		
OOP	279	10 (3.6)
ASGS	749	77 (10.3)

Figure 3. Primary Reasons for declining consent



Summary & Conclusions

- The PCSC education and clinical program is offered to all PC patients independent of their participation in research.
- Unlike programs that start as research projects and often cannot survive after the funding has run out, our program, started first as a clinical program and now provides a rich environment in which to conduct many types of research.
- Outside of treatment intervention trials, patients are more willing to participate in trials that are simple and are less time intensive.
- Integration of our research team into the clinical setting appears to be a successful model that meets the needs of patients as well as the mission to advance knowledge to provide more evidenced based supportive care for prostate cancer patients.

Future Directions

- The PCSC Program is actively engaged in assessing the impact of the program on patient outcomes and patient satisfaction.
- The program continues to work on expanding services to BC Cancer sites across the province, and to increase awareness of the program within the community of providers and patients.

References

1. Canadian Cancer Society. Prostate cancer statistics [Internet]. 2017 [cited 2017 Jun 22]. Available from: <http://www.cancer.ca/en/cancer-information/cancer-type/prostate/statistics/?region=sk>

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