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

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## 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 years[1].

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.

The program was designed in a modular fashion with clinical and educational interventions to address treatment decision making, sexual rehabilitation, diet and exercise lifestyle changes, adaptation to androgen deprivation therapy, urinary incontinence and psychological/psychosocial issues.

An integral principle of the program's mandate is to support research into PC supportive care.

**The objective of this analysis is to describe the metrics of our research program in the context of our PCSC Program**

## Methods

- 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

Since February 2015, 22 research studies were initiated by the PCSC Program:

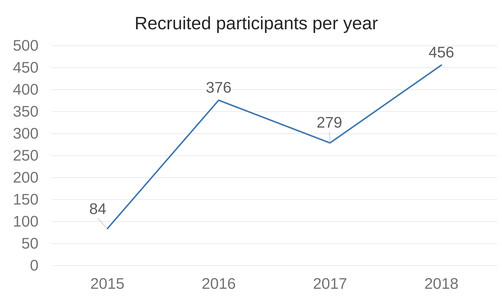
- 10 therapeutic or lifestyle intervention studies (3 RCTs)
- 3 observational studies
- 3 "permission to contact" consenting studies
- 2 registries
- 2 surveys
- 1 databank
- 1 genetic study (collecting saliva samples)

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

## Results, cont'd

A total of 851 participants have been recruited to at least 1 research study (figure 1).

**Figure 1. Number of Research Participants Recruited Per Year**




A total of 1195 study consents were obtained from 851 participants, with majority (657, 77%) participating in one study (figure 2).

**Figure 2. Number of studies which participants enroll in**

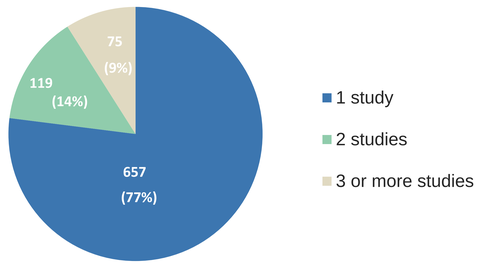



Figure 3 below shows that 450/851 (52.9%) of study participants were enrolled in the PCSC Program and seen at the VPC clinic, 347/851 (40.8%) of study participants were seen in VPC clinic but were not enrolled in PCSC.

**Figure 3. Breakdown of study patients' involvement in the program**

| | | VPC | |
|---|---|---|---|
| | | Yes | No |
| PCSC | Yes | 450 (52.9%) | 44 (5.2%) |
| | No | 347 (40.8%) | 10 (1.2%) |

## Results, cont'd

Consent to participate in research varied widely by study (table 1).

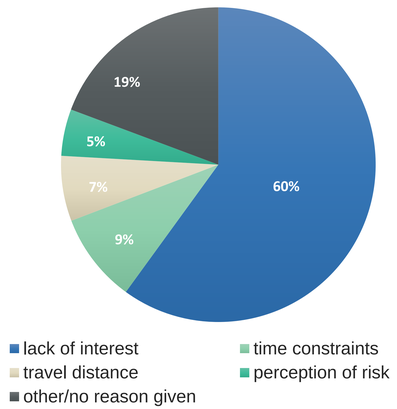
Therapeutic/Lifestyle Intervention studies which were more time-intensive in terms of participation had higher rates of patients declining enrolment compared to observational and registry studies.

Common reasons given for declining to take part are shown in figure 4.

**Table 1. Breakdown of Percentage Declined by Study**

| Study | Total Approached | Total Declined | % Declined |
|---|---|---|---|
| **Registry** | | | |
| TrueNTH | 152 | 5 | 3.3 |
| PC360IS | 166 | 6 | 3.6 |
| **Therapeutic/Lifestyle Intervention** | | | |
| SCP | 90 | 27 | 30 |
| EMMPC | 114 | 14 | 12.3 |
| Introsppect | 428 | 91 | 21.3 |
| IMPPACT | 52 | 38 | 73.1 |
| TEMPO | 21 | 13 | 61.9 |
| Cooking | 20 | 3 | 15 |
| Radiomics | 80 | 11 | 13.8 |
| Share-C | 20 | 3 | 15 |
| SHRAP | 152 | 4 | 2.6 |
| **Observational** | | | |
| Sleep | 20 | 2 | 10 |
| LPC | 42 | 0 | 0 |
| PCSC-1 | 162 | 13 | 8.0 |
| **Others** | | | |
| ASGS | 749 | 77 | 10.3 |
| OOP | 188 | 9 | 4.8 |

**Figure 4. Primary reasons for declining consent**




## Summary & Conclusions

- The PCSC program is offered to all PC patients whether or not they are research subjects.
- Our data shows that establishing a clinical program based on known patient needs and layering research on top can provide a rich environment in which to conduct research and clinical trials.
- This is in contrast to other approaches where supportive care is only provided in the context of research with the care intervention no longer available when the study is complete.
- Accrual was higher in trials that were simpler and less intensive.
- Based on our experience, we hypothesize that our successful enrollment metrics are related to 1) integration of our research team into the clinical setting, 2) patient acceptance of trials that resembled or were adjunct to usual care, and 3) the PCSC Program being a clinical & educational program that embraced and promoted research to patients from day 1.

## Future Direction

- The PCSC Program is actively engaged in assessing the impact of the program itself on patient outcomes.
- Increase awareness of the PCSC Program to participants who are seen at the VPC Clinic but not enrolled the program thereby increasing the pool of patients who will hear about the program's active research program.

## 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

## Acknowledgements

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