

# Results of a randomized pilot trial of a Tailored, web-based, psychosocial and physical activity self-Management Program for men with prostate cancer and their caregivers (TEMPO)

## Authors, Affiliations, and References

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## BACKGROUND

- Prostate cancer most common cancer diagnosis among men.<sup>1</sup>
- Family caregivers key role in meeting patients' needs, often assuming their role with no formal training = high burden.<sup>2,3</sup>
- Many interventions developed for men with prostate cancer and their caregivers, but these often do not get implemented in the real-world due to their high-cost.<sup>4</sup>
- A web-based format was used to hopefully facilitate subsequent integration in care, at a low cost of TEMPO.

## DESCRIPTION TEMPO

- TEMPO actively engages men with prostate cancer and their caregivers to work together as a dyad to learn effective skills for self-managing physical and psychosocial challenges that affect their well-being and to integrate physical activity as a general strategy to enhance mental and physical health.
- Five modules: 1- identifying needs, 2- goal setting & action planning, 3- Goal monitoring and managing barriers, 4- mobilizing social support, and 5- celebrating successes.
- TEMPO also includes a health library with 49 factsheets based on the most up-to-date evidence on self-management strategies and physical activity supports participants in coping with challenges and achieving goals.

## OBJECTIVE

- Conduct a multicentre randomized pilot trial to assess TEMPO's:
- ✓ Feasibility (recruitment, refusal and missing data rates)
  - ✓ Acceptability (attrition, adherence and satisfaction)
  - ✓ Clinical significance (outcomes of anxiety, mental and physical quality of life)

## METHODS

- Evidence-informed benchmarks for acceptability, feasibility, and clinical significance were set.
- Men with prostate cancer and their caregivers were recruited (N = 49) and randomized to receive TEMPO or usual care.
- Baseline and 12-week follow-up questionnaires were completed online. Exploratory exit interviews were conducted.

## RESULTS

### ACCEPTABILITY

Attrition rate	Adherence rate	System usability
19%	45%	75% 82%
		Men with prostate cancer    Caregivers
Benchmark of < 25% met	Benchmark of 75% not met, but still acceptable	Above average satisfaction reported

### FEASIBILITY

Recruitment rate	Refusal rate	Missing data
6.1 dyads	34%	<10%
Benchmark of 8 dyads (or patients) per month not met*	Benchmark of < 45% met	Benchmark of < 10% met

\*recruitment amidst COVID-19 1<sup>st</sup> wave

## CLINICAL SIGNIFICANCE

Primary outcome improvements	Effect sizes exceeds 0.2 benchmark
Quality of life - mental 33% of men    22% of caregivers	0.38
Quality of life - physical 24% of men    33% of caregivers	0.30
Anxiety 43% of men    44% of caregivers	0.24

## Key Findings

The focus on both psychological needs and health behavior was acceptable	Caregivers seem to benefit more on mental health outcomes	Dyads favored modules over factsheets in the health library
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## CONCLUSION

Pilot study was successful, and the acceptability, feasibility, and clinical significance of TEMPO was supported. Even if the results of this pilot are promising, a larger trial needs to be conducted prior to concluding that TEMPO is efficacious. Minor modifications will allow this behavioral intervention to be tested in a larger multisite trial.

## Participating Organizations



Références: 1. CCS's Advisory Committee on Cancer Statistics. Canadian Cancer Statistics 2016: Toronto, ON, Canada, 2016. 2. Northouse, L.L.; et al. Spouse Caregivers of Cancer Patients. In Psycho-Oncology; Oxford University Press: New York, 2015. 3. Lambert, S.D., et al., Impact of Cancer and Chronic Conditions on Caregivers and Family Members. In Cancer and Chronic Conditions; Koczwara, B., Ed.; Springer, 2016; pp. 159–202. 4. Northouse, L., et al., Psychosocial Care for Family Caregivers of Patients with Cancer. J. Clin. Oncol. 2012, 30, 1227–1234.

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