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Title: Results of a randomized pilot trial of an online psychosocial and physical activity self-management program for men with prostate cancer and their caregivers (TEMPO)

Background: Patient-caregiver dyads facing prostate cancer require support to address burden and optimize health outcomes. Our team used a participatory approach to develop TEMPO, the first dyadic, Tailored, web-based, psychosocial and physical activity self-Management Program, focused on behaviour change processes.

Objectives: To conduct a multicentre pilot RCT to assess feasibility (recruitment, refusal and missing data rates), acceptability (attrition, adherence and satisfaction) and clinical significance (outcomes of anxiety, mental and physical quality of life) of the TEMPO intervention.

Methods: Evidence-informed benchmarks for acceptability, feasibility, and clinical significance were set. Men with prostate cancer and their caregivers were recruited from six sites across Canada and randomized to receive TEMPO or usual care. Baseline and 12-week questionnaires were completed online. Exploratory exit interviews were conducted with a sub-set of dyads.

Results: 49 men and their caregivers were randomized to the study. Feasibility benchmarks were met with the exception of recruitment rate (average 6.1 dyads out of a target of 8 recruited/month). Acceptability targets were met (< 25% attrition and high satisfaction). Adherence criteria were not met, only 45% of participants spent at least 15 minutes on 100% of the online modules; however these criteria may have been too strict. Benchmarks for clinical significance were met for most outcomes.

Conclusion: With minor modification, a larger multisite trial of this behavioural intervention is warranted.