



Improving adherence and health outcomes in testicular cancer survivors using a mobile health-based intervention: A mixed-methods pilot study

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Julie M Deleemans^{1,2} , Sunil Samnani¹, Chris Lloyd³
and Nimira Alimohamed¹

Abstract

Objective: Testicular cancer (TC) is one of the most common cancers among young men, with survival rates exceeding 97% due to effective treatments. Post-treatment follow-up care is important for long-term survival and monitoring psychosocial symptoms, yet TC survivors (TCS) show poor adherence to post-treatment care. Mobile-health-based interventions show high acceptability in men with cancer. This study will examine the feasibility of using the Zamplo health app to improve adherence to post-treatment care and support psychosocial outcomes in TCS.

Methods: This mixed-methods, longitudinal, single-arm pilot study will recruit N = 30 patients with a diagnosis of TC who finished treatment within ≤ 6 months and are currently aged ≥ 18 years old. Adherence to follow-up appointments (e.g. blood work, scans) will be assessed (primary outcome), and measures for fatigue, depression, anxiety, sexual satisfaction and function, social roles satisfaction, general mental and physical health and body image (secondary outcomes) will be completed at four-time points: baseline, 3, 6 and 12 months. One-on-one semi-structured interviews will be conducted post-intervention (month 12).

Results: Improvements in post-treatment follow-up appointment adherence and psychosocial outcomes will be analyzed using descriptive statistics, paired samples t-tests to determine changes across time points 1 through 4, and correlation analysis. Qualitative data will be analyzed using thematic analysis.

Conclusion: Findings will inform future, larger trials that incorporate evaluation of sustainability and economic implications to improve adherence to TC follow-up guidelines. Findings will be disseminated via infographics, social media, publications and presentations conducted in partnership with TC support organizations and at conferences.

Keywords

digital health, general, testicular cancer, psychosocial health, health behaviors, digital clinical trials, studies

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Background

Testicular cancer (TC) is one of the most common types of cancer among men, particularly in adolescent and young adult (AYA) men aged 15–39, and has increased in incidence over the past two decades.^{1,2} Upwards of 97% of men diagnosed with TC will survive at least 5 years or more post-diagnosis.^{1,2} Previous research has examined

¹Department of Oncology, Cumming School of Medicine, University of Calgary, Calgary, Canada

²Zamplo Research Inc., Calgary, Canada

³OneBall Charitable Cancer Organization, Calgary, Canada

Corresponding author:

Julie M Deleemans, Tom Baker Cancer Centre, 1331 29th Street NW, Calgary, AB, T2N 4N2, Canada.

Email: julie.deleemans@ucalgary.ca



physical aspects of TC survivorship, such as survival and fertility implications. However, less is known about adherence to post-treatment follow-up guidelines and psychosocial challenges in TC survivors (TCS).

TCS follow-up adherence

Limited research has investigated post-treatment follow-up adherence among TCS. However, of the few studies that have investigated this, findings suggest that challenges remain with adherence to follow-up appointments in TCS resulting both from clinician and patient noncompliance to recommended guidelines. Wymer et al.³ examined physician compliance with TCS post-treatment follow-up care guidelines from the National Comprehensive Care Network and found that non-guideline-directed care occurred in 30% of TCS, which was a significant predictor of disease relapse. Similarly, inconsistencies between guidelines and clinical practice in screening TCS post-treatment were found with respect to underuse of imaging and infrequent follow-up exams for cardiovascular, neurological, pulmonary, endocrine, and psychosocial symptoms.⁴ In a sample of 184 men diagnosed with TC, 17% were found to be noncompliant with follow-up appointments. Having an unsatisfactory experience with one's clinician (i.e. patients felt they were not treated as "a person") was the strongest predictor for post-treatment noncompliance.⁵

Additionally, pilot data from our team indicates that TCS adherence to post-treatment follow-up appointments in Alberta, Canada, is sub-optimal and reveals a clear need to focus more research and effort on TCS specifically. Appointment "no-shows" occurred in approximately 20.6% of patients, with only about half (50.6%) of the TCS adhering to all post-treatment follow-up guidelines.⁶ This has implications for survival, as long-term follow-up is crucial for monitoring for recurrence, secondary cancers, and other health conditions related to cancer treatments.⁷

Technology use in cancer care

Digital communication and use of technology have become the norm in present society, particularly among young people, with increasing diversity in the patient populations engaging with technology to improve their health.⁸ Since the COVID-19 pandemic, health technology use and acceptance have increased in North America. A recent survey found that 84% of Canadians felt they would use technology-based tools to manage their health, while 90% of Canadians expressed a need for technology that would allow them to have more control over their health.⁹

Mobile-Health (m-Health) refers to the use of emerging mobile communications and network technologies within the context of healthcare.¹⁰ Klasnja and Pratt⁸ outline five

basic, m-Health-based intervention strategies that have been used successfully in people with different health conditions, including cancer.¹⁰ The strategies include: (a) Tracking health information, which involves using one's phone to track health behaviors, symptoms and other outcomes relevant to health, and may include native journaling applications (apps) or automated sensors; (b) Involving the health care team, which may include remote coaching, remote symptom monitoring and/or automated feedback; (c) Leveraging social influence through peer-to-peer connections (e.g. social support or competition), support from family and friends and/or peer modeling; (d) Increasing health information accessibility via informational messages, reminders and/or graphical displays and (e) Employing entertainment or "fun" to enhance engagement through games or integration of interesting or amusing non-health-related content in addition to health information.⁸ Previous studies using these or similar strategies in the context of m-Health-based interventions in men with cancer have generally shown high acceptability and participant satisfaction.^{11,12}

Psychosocial challenges in TCS

Research suggests that a subset of TCS will experience psychosocial challenges such as anxiety, depression, cancer-related fatigue (CRF) and distress in intimate relationships associated with a TC diagnosis and subsequent treatments.¹³⁻¹⁵ Moreover, TCS may experience challenges related to bodyimage,^{13,15} sexual function^{13,15-17} and diminished quality of life (QOL).^{16,18,19}

A review found that TC can compromise survivors' bodyimage, however, there is limited research examining bodyimage in younger (i.e. teenagers and early young adults) TCS,¹³ who may be at greater risk for distress around body image during this critical developmental stage. Moreover, sexual experiences can be influenced by a TC diagnosis and subsequent psychosocial issues related to this may develop. Sexual satisfaction among TCS was found to be lower relative to healthy men, which was mediated by psychosocial factors.¹⁶ Among long-term TCS, the incidence of erectile dysfunction was higher relative to the general population and was associated with negative changes in body image.¹⁵

While most studies on TC-related infertility were conducted with older men, younger males, especially adolescents may experience relationship distress that goes undetected.¹³ Aspects of sexuality and bodyimage can interact to affect TCS psychosocial health and QOL, particularly in younger, single TCS.^{14,20} Sexual and marital satisfaction of TCS and their partners are also mutually correlated.^{20,21} For instance, TCS who developed a relationship following TC treatment reported more marital concerns and lower sexual satisfaction relative to healthy men and TCS in relationships pre-dating a TC diagnosis.²¹

The impact of TC on survivors' QOL is variable and depends on several factors including age, relationship status, and employment status. Importantly, some studies suggest that the general QOL among TCS does not differ significantly from healthy men in the general population.^{22,23} Conversely, some TCS experience a plethora of long-term treatment-related issues such as peripheral neuropathy, hearing loss, tinnitus, chronic fatigue, cognitive dysfunction and Raynaud-like phenomenon, all of which may contribute to diminished psychosocial health and QOL^{23,24} and changes in sexual function.^{14,20} Importantly, TCS QOL may also be mediated by differences in coping strategies. In long-term TCS, avoidant coping styles were associated with significantly more psychosocial problems relative to those who used an approach coping style.²⁵ Additionally, passive coping strategies, being single, unemployed, and low socioeconomic status were associated with TC patients experiencing increased physical symptoms (comorbidities, severe side-effects), and poorer psychosocial health outcomes.²⁶

Some TCS experience psychosocial challenges and reluctance to adhere to longer-term cancer follow-up. Research suggests that AYA in particular experience more isolation and loneliness as a result of their cancer experience,^{2,27} in addition to other unmet needs (e.g. adequate psychosocial support, information about fertility) which can lead to long-term distress if not addressed.²⁸ There is a need for tailored interventions that use age- and sex-appropriate strategies for TCS by providing them with the tools to support their psychosocial health and post-treatment follow-up adherence in a pro-active manner.

Interventions that focus on self-help, action-oriented strategies, and positive support from peers have been shown to be particularly effective for young men,²⁹ and would therefore be highly applicable for a TCS population. Improving TCS outcomes requires overcoming barriers to uptake of behavioral interventions among men in general. Barriers to psychosocial care among patients and poor uptake of available evidence-based interventions continue to be challenging,³⁰ and these barriers are significantly greater among men compared to women, particularly for psychosocial interventions.³¹ Despite evidence for the effectiveness of psychological interventions in cancer patients and related recommendations within clinical practice guidelines, stigma regarding psychosocial health-related needs is still a key barrier to uptake of these aspects of cancer care.³²

Present study

Previous studies have found that men, particularly younger men, prefer interventions that employ action-oriented strategies, are self-managed, technology-based, compatible with masculine ideals (e.g. stoicism), and leverage the importance of peer relationships.^{29,33} TCS tend to be understudied

within oncology literature, but young men in particular tend to show high acceptability of m-Health-based treatment paradigms specifically.²⁹ Given this, there is a need for the development and implementation of a technology-based intervention specifically for TCS that are consistent with men's preferences for support services.

The present longitudinal pilot study is a novel intervention that aims to use a patient-reported outcomes (PRO) driven health application, Zamplo, to: (a) determine the feasibility and acceptability of the Zamplo digital health app intervention for TCS; (b) improve TCS adherence to post-treatment screening and follow-up appointments; (c) determine whether using the Zamplo app may support psychosocial health specifically cancer-related fatigue, fertility concerns, sexual function and satisfaction, satisfaction with social roles, body-image, global mental and physical health, anxiety and depression following treatment and (d) explore participants experience with using the Zamplo app and whether TCS perceived usage of the app impacts their screening care and psychosocial health. The psychosocial outcome measures were selected based on the literature and expert opinion from collaborators, including a patient advocate with a lived experience of TC.³⁴

Methods

This pilot study will follow the ORBIT model,³⁵ and use a QUANT-qual mixed-methods research design. The ORBIT model provides a framework that emphasizes using a set of studies to form a chain of evidence that ultimately indicates readiness for a larger trial and is ideal for developing and testing novel behavioral interventions, such as the one in the present study.³⁵ Phase 1 involves defining and refining the scientific foundation and potential basic treatment elements, which has already been achieved through review of the literature and preliminary data from work done by our team.⁶ This study fits into Phase 2 of the ORBIT model, where preliminary testing through pilot and feasibility studies is conducted. Results from the pilot testing will ultimately serve to develop, implement and evaluate a larger randomized controlled trial of the intervention.

Participants

Participants (N = 30) will be TCS (i.e. have finished treatment within the past 6 months or less), currently aged 18 years of age or older, with a diagnosis of TC (e.g. patients who are on surveillance after curative-intent chemotherapy and/or radiation therapy and/or for patients who are on surveillance after orchidectomy).³⁶ As seen in Figure 1 of the study schematic, we will use a single-arm, repeated measures design wherein all participants will be allocated to the treatment group (n = 30; i.e. Zamplo app intervention). This sample size was determined based N's used in previous mixed-methods research with TCS cohorts³⁷ and the expected

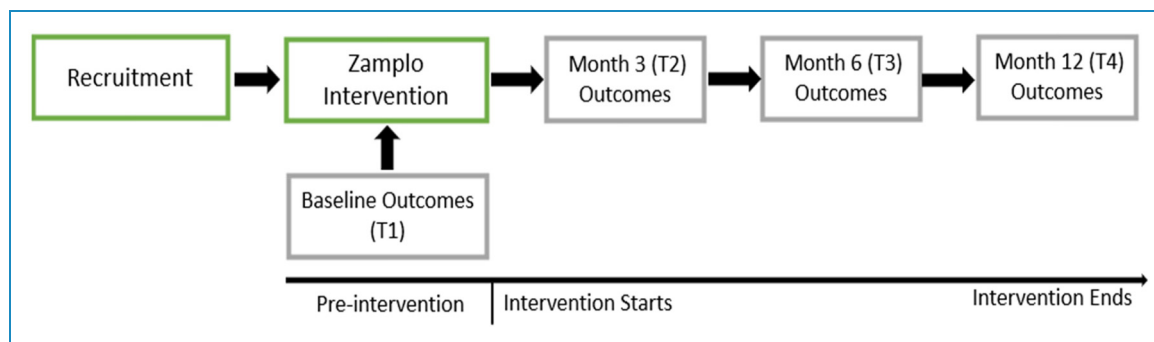


Figure 1. General schematic for single-arm, repeated measures pilot study.

availability of these participants at two major cancer centers in Alberta, Canada where there are approximately 200 patients per year seen in the testicular follow-up clinic. We estimate that we will be able to recruit approximately 4 patients a month to the study (between two sites: Calgary and Edmonton) over a period of approximately 1 year. Participants must also have access to a smartphone, Internet connection and be able to read, write and speak English.

Our research team has partnered with patient advocacy partner representatives from the TC community through “OneBall,” a not-for-profit organization composed of TCS who are actively involved in increasing awareness of TC and supporting the psychosocial well-being of men with TC.³⁴ This patient partnership will enhance the applicability of and participation in the intervention by the TCS community, as they are involved as a collaborator in the development of the research questions, data collection, interpretation and dissemination of findings. Collaboration with patient partners and advocacy groups results in greater success in the development, implementation, and dissemination of intervention programs by ensuring that patient perspectives and priorities are included throughout the research process, which leads to better patient outcomes.³⁸

Procedure

Clinic: TCS will be recruited through physician and nurse practitioner referrals from TC clinics at the Tom Baker Cancer Center and Holy Cross Hospital in Calgary, Alberta and Cross Cancer Institute in Edmonton, Alberta. Participants will receive a consent to contact form in clinic and will subsequently be contacted by a member of the research team who will screen them for eligibility.

Social Media and Community Organizations: Recruitment will also take place through OneBall, relevant community organizations (e.g. Wellspring) and social media. Potential participants recruited via community and social media may reach out to the research coordinator directly to arrange a time for screening and to discuss consent.

Informed Consent: If eligible, all participants will be asked to read and sign a secure digital informed consent

form sent through email to the participant. Both the participant and the research team will retain a copy of the signed consent form. Once admitted to the study, participants will receive the Zamplo app and a full tutorial on how to use the app.

Intervention

The study will last 12 months from the time the participant is admitted into the study. All participants will be asked to complete PRO measures at four time points: baseline, 3, 6 and 12 months. Participants will also be asked to use Zamplo to document attendance at all scheduled follow-up appointments (e.g. scans, blood work), any unscheduled appointments related to their TC diagnosis (e.g. emergency department visits), and may enter additional data daily if they choose, such as symptoms, exercise or supplement use, during the 12-month period. All PRO outcome measures will be completed via the Zamplo app. Research personnel will use electronic medical records to confirm participant attendance at scheduled follow-up appointments during the study. Details of the outcome measures, time points, and expected time commitments are shown in Table 1.

Consistent with strategies used to optimize other m-Health interventions,⁸ the Zamplo app will use notifications to enhance participant engagement. In addition to using the Zamplo app for free (a value of \$100), in appreciation for their participation all participants will receive a gift card valued at \$25 or a donation of \$25 made by OneBall and the research team on their behalf to a charity of their choice at the end of the study.

Following the intervention, participants will be invited to participate in a one-on-one semi-structured interview (approximately 45–60 min in length) to provide feedback on the Zamplo app experience, and whether there are any additional supports they want/need, and if so, which ones. Interviews will be audio-recorded and transcribed verbatim. This study has been approved by the Alberta Health Research Ethics Board (HREBA.CC-22-0016).

Table 1. Outcome measures and expected time commitments for participants.

Outcome measure	Assessments
Demographics/clinical data survey	Completed on Zamplo app at baseline (T1) only. Estimated time to complete: 7 min
Psychosocial surveys	Completed on Zamplo app at 4 time points: baseline, 3, 6 and 12 months . Will ask about potential symptoms/concerns of fatigue, depression, anxiety, sexual satisfaction and function, social roles satisfaction, general mental and physical health and body image. Estimated time to complete: 15–20 min
Attendance at follow-up appointments (e.g. blood work, scans)	Reminder of appointment and confirmation of attendance documented in Zamplo app on date of appointment. Estimated time to complete: 5 min after each appointment
Other health care visits (optional)	Can choose to document any emergency visits, blood test results, etc. in Zamplo app. Estimated time to complete: 10–20 min
Other health notes (optional)	Can choose to document other health activities (e.g. exercise, symptoms, medications, supplements, etc.) in Zamplo app. Estimated time to complete: 10–15 min daily (or weekly)
Individual semi-structured interview (optional)	Completed by a research assistant at 12 months (T4) to gain feedback on the intervention and outcomes of interest, and desired supports for TCS. Estimated time to complete: 45–60 min

Data collection

Zamplo and Data Security: Zamplo is an m-Health app endorsed by the Alberta Cancer Foundation and Alberta Health Services, that allows participants to record all aspects of their medical conditions, medication regimes, self-observations on their condition, symptoms and activity participation. Zamplo is unique from other platforms in that it allows individuals to track and analyze their health information, and empowers patients with the resources, knowledge, and tools to mobilize and understand their personalized health data. Moreover, individuals can connect privately and securely to family, friends, healthcare practitioners and others who have a similar diagnosis. Through the Zamplo app participants will also have access to a health library that will have links to supportive resources, such as Oneball and psychosocial support services.

The developers, Hanalytics Solutions, are not data custodians. As participants interact with the Zamplo application, all data is communicated over secure (encrypted) connections and stored in an encrypted database using industry leading security. Only consented and enrolled participants using Zamplo and their appointed caregivers have access to their personally identifiable information and no data is shared with any third party without the user's consent. The Zamplo application is entirely Hanalytics Solutions Inc.'s intellectual property. Hanalytics have complete control over its functionality, integrations, access, data and communication models. This allows us to ensure privacy and security requirements for participants, research partners and regulators alike.

Quantitative measures: study metrics, demographics and clinical outcomes

Data on recruitment, retention, accrual, completeness and acceptability of the intervention for participants will be collected. Clinical and demographic factors including current age, age at diagnosis, income, occupation, ethnicity, education, living arrangements, relationship status, cancer diagnosis and treatments received will be collected at baseline. Concerns about fertility, dating and intimate relationships will be collected at all four-time points.

Psychosocial outcomes

Fatigue, sexual function and satisfaction, satisfaction with social roles, global physical and mental health, anxiety, and depression outcomes will be measured via the NIH Patient-Reported Outcomes Measurement Information System (PROMIS).³⁹ PROMIS is a set of person-centered measures that evaluate physical, mental and social health, and is a validated measure of psychosocial and physical health outcomes among different populations with chronic health conditions, including cancer.^{40,41} Body image will be assessed using the Body Image Scale for people with cancer, which is a reliable and validated scale that has been used to evaluate changes in body image in various cancer cohorts, including TC.⁴²

Fatigue will be measured using the PROMIS: Item Bank v1.0-Fatigue-Short Form 6a scale, which includes six statements related to fatigue frequency and intensity. Statements

are rated on a five-point scale from 1 (Not at all or Never) to 5 (Very much).

Sexual function and satisfaction will be measured using the PROMIS Global Satisfaction with Sex Life Scale which assesses both sexual function and satisfaction in men and is a reliable and validated measure in cancer populations.⁴¹ The instrument includes 10 statements related to sexual function and satisfaction that are rated on a Likert scale.

Social Roles PROMIS Item Bank v2.0-Satisfaction with Social Roles and Activities-Short Form 6a which contains six items related to one's ability and satisfaction with participation in social roles. Items are rated on a five-point Likert scale from 1 (not at all) to 5 (very much).

Global mental and physical health will be assessed using the PROMIS *Global Health-Scale v1.2*, which includes 10 statements about physical and mental health that are rated on a five-point Likert scale, with the exception of pain severity which is rated on a scale from 0 (no pain) to 10 (worst pain imaginable).

Depression will be measured using PROMIS Item Bank v1.0-Emotional Distress-Depression-Short Form 4a, which contains four items to assess the presence and severity of depression symptoms. Statements are rated on a five-point scale from 1 (never) to 5 (always).

Anxiety will be measured using the PROMIS Item Bank v1.0-Emotional Distress-Anxiety-Short Form 4a, which contains 4 items that relate to symptoms of anxiety. Statements are rated on a five-point scale from 1 (never) to 5 (always).

Body Image will be measured using the Body Image Scale which consists of 10 items used to evaluate body image changes in people with cancer.⁴² Items are rated on a four-point Likert scale from "not at all" to "very much". Examples of items include "during the past week... Have you been feeling self-conscious about your appearance?"

Qualitative semi-structured interviews

Content of interest will be informed by existing literature and engagement with patient partners from One Ball. Specific content of interest will include bodyimage, relationship status, sexual and relationship satisfaction, sexual function, satisfaction with the intervention and Zamplo app and potential additional support needs for TCS.

Data analysis

Objective 1 will determine whether it is feasible to recruit TCS to a m-Health-app intervention. This will be evaluated by number of patients recruited and retained, as well data completeness. Objective 2, improvements in TCS adherence to post-treatment follow-up appointments will be analyzed using descriptive statistics including paired samples t-tests to determine changes across time points 1 through 4, and correlation analysis to explore post-treatment

appointment adherence. Objective 3, psychosocial outcomes, will be analyzed using descriptive statistics including paired samples t-tests to determine changes across time points 1 through 4, and correlation analysis to analyze changes in cancer-related fatigue, sexual function and satisfaction, satisfaction with social roles, global health, body-image, anxiety and depression.

Objective 4, exploring participants' experience with using the Zamplo app and whether TCS perceived usage of the app to impact their follow-up care and psychosocial health will be analyzed using quantitative data obtained via semi-structured interviews. Interviews will be transcribed and content-coded using Thematic analysis procedures. Narratives will be coded by two independent coders, based on a coding scheme. Narratives will be characterized based on the narrative codes. Exploratory cluster analysis will be conducted to determine whether it is possible to reduce the number of narrative codes, yielding meaningful narrative styles or profiles. Exploratory analyses will then be performed to determine whether there are differences between clusters with respect to key variables.

Discussion

To our knowledge, this study will be the first to use a novel m-Health app intervention, Zamplo, to improve TCS adherence to post-treatment guidelines. Additionally, the app will be used to collect PRO data on TCS psychosocial health outcomes during the first year after cancer treatment completion and will determine if engagement with the app is associated with better health outcomes.

Consistent with previous m-Health-based interventions in cancer cohorts, we expect that participants in our study will report satisfaction with the Zamplo app, and that the data will reveal improved post-treatment surveillance appointment adherence, paralleling findings from previous research. For example, Kenfield et al.¹¹ conducted a technology-based, 12-week intervention for men with prostate cancer that used multiple tools including a study website, a Fitbit activity tracker, and text messaging with the aim of improving specific health behaviors, such as exercise and diet. Study completion rates were high, with 94% in the intervention group versus 82% in the control group completing all assessments, and diet was significantly improved following the intervention.¹¹ Another technology-assisted 10-week intervention in racially diverse men with advanced prostate cancer compared a virtual cognitive behavioral stress management (CBSM) program to a health promotion attention (control) program, and similarly found high rates of retention (>85%) and study attendance (>70%).¹² Men in the CBSM group reported significant improvements in depressive symptoms and relaxation self-efficacy at 6 months post-intervention follow-up.¹²

Despite promising findings in other studies, careful consideration in the design of our study was warranted as poor success rates have also been found in studies using m-Health-based interventions for men with cancer. Specifically, Heiniger et al.³³ reported lower rates of success with a technology-based intervention using evidence-based information and psychological intervention to reduce anxiety, depression, and fear of cancer recurrence in TCS. Only 56% of the men completed at least 80% of the program, and barriers to success included a lack of time and failure to screen for clinically meaningful levels of distress as inclusion criteria for participation.³³

Hence, while evidence suggests that m-Health-based interventions for men with cancer can be effective, careful consideration of study design and implementation is critical. For this reason, we worked closely with a patient advocate with a lived experience of TC to design our study so as to optimize the utility and accessibility of the intervention for survivors of TC. While recruitment and data collection is currently underway, so far the response of men enrolled in our study and using the Zamplo app has been positive.

Limitations and future directions

While care and consideration were taken in designing this study, it is not without limitation. Specifically, the small sample size for the pilot design, while consistent with recommended sample sizes for pilot studies,⁴³ may increase the likelihood of a Type II error during analysis. Additionally, since we are using a single-arm design with no control group, the effectiveness and generalizability of the study findings relative to standard-of-care treatment cannot be determined. Since our study is only recruiting patients in the province of Alberta, and healthcare system practices and delivery differ between Canadian provinces and countries, the potential lack of generalizability of our results outside of the province of Alberta will be an important consideration and potential limitation. Nevertheless, despite these limitations data from the present study will provide important information regarding the potential use of m-Health-based interventions for supporting the health and wellbeing of men with TC.

Findings from our study will ultimately inform the development and implementation of a future, larger randomized controlled trial which will also incorporate sustainability and cost-effectiveness evaluations. Future studies may also utilize our findings when designing similar m-Health-based interventions for other cancer cohorts. Additionally, as part of our commitment to patient-oriented research, findings from the present study will be disseminated via infographics and presentations conducted in partnership with OneBall and shared on social media and with relevant community stakeholders such as Young Adult

Cancer Canada and Wellspring, community groups that support persons affected by cancer. Finally, to inform potential clinical practice strategies and future research in this area, the results of this pilot study will be presented at grand rounds within the cancer centers in Alberta, at national and international scientific conferences, and published in peer-reviewed journals.

Conclusion

TC is one of the most common diagnoses in men. Post-treatment surveillance for recurrence, late effects and psychosocial concerns is important to optimize patient wellbeing, yet TCS show poor adherence to post-treatment care. m-Health-based strategies may help improve this. Hence, this protocol describes a study that examines the feasibility of using a patient-centered, mobile health app, Zamplo, to improve adherence to post-treatment care in TCS. Results from this mixed-methods, single-arm pilot study will inform future, larger trials, with implications for employing clinically relevant strategies that may improve patients' adherence to TC follow-up guidelines.

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Contributorship: JD conceptualized the study designed, drafted the protocol, submitted all ethics materials, and prepared the protocol manuscript for submission. SS reviewed final draft of the manuscript and is responsible for overseeing study operations. CL is a patient advocate who provided valuable lived experience insights to inform development of the study protocol and outcome measure selection, and reviewed final drafts of the manuscript. NA is the principal investigator, and contributed to study conceptualization, design, writing, obtaining ethics, and reviewing final drafts of this manuscript.

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ORCID ID: Julie M. Deleemans  <https://orcid.org/0000-0001-8645-0990>

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