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Preferences, barriers and facilitators regarding virtual pelvic healthcare in individuals with gynaecological cancers: protocol for a patient-oriented, mixed-methods study

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ABSTRACT

Introduction Vaginal pain during intercourse and urinary incontinence are common complaints after gynaecological cancer treatments. Pelvic health physiotherapy treatments aim at optimising function through education on the use of vaginal moisturisers, dilation therapy programme and pelvic floor muscle training. Given that barriers such as time, travel, and costs are known to limit access to physiotherapy services, a virtual pelvic health physiotherapy programme may help to facilitate access. The primary objective of this study is to identify preferences, barriers and facilitators from individuals with gynaecological cancer regarding virtual pelvic healthcare survivorship care.

Methods and analysis This patient-oriented, mixed-methods study will involve an online cross-sectional survey data (phase I) and qualitative data from a series of virtual focus groups (phase II). Phase I: an anonymous survey will be used to assess the demographics, health status, prevalence of urogenital symptoms, as well as knowledge, barriers and facilitators to pelvic health services of people with gynaecological cancer. A total of N=50 participants from Canada will be recruited through convenience and self-selection sampling. Phase II: a series of virtual semi-structured focus groups will be conducted with 10–15 participants on key topics related to virtual pelvic healthcare. Interviews will be audio-recorded and transcribed, from which key themes and quotes will be identified. An interpretive description qualitative method will guide analysis and implementation of results.

Ethics and dissemination Approval from the Health Research Ethics Board of Alberta—Cancer Committee (HREBA.CC-21-0498) and of the CISSS Bas-Saint-Laurent (CISSSSBL-2021-10) have been obtained. Informed, electronically signed consent will be required from all participants. Results from this work will be published in a peer-reviewed journal and will be used to inform the development and implementation of a new Pelvic eHealth Module for individuals treated for gynaecological cancers. This module will be incorporated into a comprehensive educational and exercise programme offered by a web-based application.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of this study is the patient-oriented strategy that informed its design and development.
⇒ Another strength of this study is the diversity and inclusivity strategy: the survey and study material were developed and reviewed to ensure the inclusion of people from all backgrounds, cultures and sexual orientations, in addition to being offered in two languages.
⇒ The proposed recruitment strategy may not ensure equal representation of those who support and do not support virtual pelvic healthcare.
⇒ Due to the anonymity of the responses to the survey, a comparison of the medical characteristics, impairments or motivation between the participants taking part in the focus groups and those who responded to the survey will not be possible.
⇒ Generalisation of results may be limited to residents with internet access.

INTRODUCTION

Each year, more than 1 300 000 individuals in the world are newly diagnosed with gynaecological malignancies.1 Surgical removal of the reproductive organs and radiation therapy remain the two most frequently recommended treatments for gynaecological cancers.2–5 Five-year net survival rates have been increasing for most gynaecological cancers, estimated to be as high as 83% for people who have been diagnosed with endometrial cancer.1 As such, individuals living with the physical, psychological and emotional sequelae of the cancer and its treatments are more numerous than ever.1 6 Various urogenital dysfunctions have been reported following gynaecological cancer treatments, such as urinary incontinence (UI), urinary urgency (U), sexual dysfunctions and dyspareunia, as well as faecal incontinence.7–14 Prevalence
rates for UI and UU vary between 40% and 83% and tend to increase over time.7–11 Sexual dysfunction, including dyspareunia, is estimated to affect 40%–100% of individuals treated for gynaecological cancers.12 13 Prevalence rates for faecal incontinence after gynaecological malignancy treatment vary greatly across tumour sites and treatments received; however, rates as high as 34% have been reported in individuals with cervical cancer treated with surgery, brachytherapy and external-beam radiation therapy.14 Thus, there is a growing need to address challenges related to the pelvic health of individuals with gynaecological cancer.

There is an expanding body of evidence suggesting that pelvic health therapies can help urinary continence and sexual functioning after gynaecological cancer treatments. Using pelvic floor muscle exercises and bladder training education, recent evidence indicates that urinary continence and pelvic floor muscle strength were preserved15 or improved16 17 in groups of individuals treated for gynaecological cancers. A multimodal pelvic health physical therapy programme, including education, pelvic floor muscle relaxation exercises and dilation therapy, was reported to improve patient-reported sexual functioning and pain severity, as well as psychosexual outcomes in individuals with gynaecological cancer experiencing dyspareunia.18–21 Unfortunately, access to pelvic health physical therapy services remains limited across many communities. This is especially true for individuals living in rural areas given barriers such as time, travel and costs that are known to limit access to specialised physiotherapy services.22 With the high prevalence of survivors and identified gaps in rehabilitation services in rural and remote areas, in-person interventions may not be the optimal mode of delivery of pelvic health therapies to respond to the increasing needs. As such, providing pelvic health education and exercises virtually could be a viable option for the remote delivery of these interventions.23

This study aims to identify the preferences, barriers and facilitators to virtual delivery of pelvic healthcare for individuals treated for gynaecological cancers to inform the design and delivery of a comprehensive Pelvic eHealth Module. By identifying issues from the perspective of individuals who have undergone treatment for gynaecological cancer, our goal is to ensure that the proposed content and mode of delivery align with, and appropriately meet their needs.

**METHODS AND ANALYSIS**

**Study design**

For this multi-centre study, a patient-oriented, mixed-methods sequential approach will be used to develop a better contextualised Pelvic eHealth Module. To collect quantitative data relative to preferences, barriers and facilitators regarding pelvic health issues and the virtual delivery of pelvic health interventions, phase I will involve a cross-sectional, mixed-methods online survey. To develop an in-depth and more comprehensive understanding of those findings, phase II will involve an exploratory qualitative methodology using a series of online focus groups (see figure 1). The study will be conducted in two Canadian provinces (Alberta and Quebec) and in two languages (French and English). This work is funded by the 2021 Patient Involvement in Cancer Research Programme Small Grant Competition from the Canadian Cancer Research Alliance. The research project is currently in its recruitment phase and data collection has begun (February 2022). The study is expected to be completed within 18 months (July 2023).

**Population and recruitment procedures**

To be included in this study, participants will need to (1) have received a diagnosis of a gynaecological cancer (any stage) including—uterine, cervical, vulvar or vaginal, (2) be 18 years old or older, (3) reside in the provinces of Alberta or Quebec, (4) be able to read and understand English or French, (5) have undergone at least one treatment for their cancer, regardless of treatment type (surgery, radiation therapy, chemotherapy or hormonal therapy) and (6) have access to internet, either from a smart device or a computer, to complete the survey online from their home or their community centre. Exclusion criteria: individuals will not be eligible for this study if they present with (1) any active concomitant cancer and (2) any cognitive impairments limiting the ability to complete the questionnaire.

Participants will be sought through the Cancer Rehabilitation Clinic (Edmonton, Alberta) and the CISSS Bas-Saint-Laurent (Rimouski, Québec). Participants from the former region will be identified from previous research patient databases, during medical follow-ups and through a social media campaign (phase I: convenience sampling). Furthermore, participants from remote northern communities will be reached out by on-site community nurses. Participants from Quebec will be asked if they are willing to participate during medical follow-ups, as well as through poster announcements in various patient groups and social media campaigns. Social media campaigns will be posted on Facebook, Instagram and Twitter on the Cancer Rehabilitation Clinic, the CIUSSS Bas-St-Laurent and the researchers accounts. With the help of our
To target the respective component, the COM-B model was developed to understand behaviour change and contains three main factors: (1) capability: individuals need to be psychologically and physically capable of performing behaviour; (2) opportunity: individuals need to have the physical (environment) or social (interpersonal influences) opportunity to perform a behaviour and (3) motivation: individuals need to be motivated in performing behaviours. Once interested in participating, the individual will be directed to a separate REDCap form where they will be asked to provide their name and contact information (ie, email or phone number). The contact information will be sent via REDCap to the study research coordinator. The research coordinator will contact the participant to provide more information on the second phase of the study and to confirm their eligibility. Participants will be required to complete a second consent form prior to participating in the semi-structured interview/focus group session.

Phase I: survey
Conceptual framework
The online survey comprises a maximum of 50 multiple choice and open-ended questions spanning five main categories: demographics and health status, prevalence of urogenital symptoms, pelvic health knowledge, environmental factors and motivational factors. The formulation and relevance of survey questions were guided by clinical experience of the researchers, evidence from the literature, input from patient-advisors and key knowledge-users. The questions were then mapped according to the Theoretical Domains Framework (TDF), a framework which stems from organisational behaviour change theories and implementation science principles (see online supplemental table 1).26 27 The TDF itemises several domains that influence health-related behaviour in a practical scheme for the subsequent development of an intervention.26 This framework enables the identification of barriers related to 14 spheres of behavioural change including knowledge, skills, emotion, environment or memory.27 A key benefit of using the TDF is that each domain can be mapped to a component of the Capability, Opportunity, Motivation- Behaviour (COM-B) model.27 The COM-B model was developed to understand behaviour change and contains three main factors: (1) capability: individuals need to be psychologically and physically capable of performing behaviour; (2) opportunity: individuals need to have the physical (environment) or social (interpersonal influences) opportunity to perform a behaviour and (3) motivation: individuals need to be motivated in performing behaviours. Once mapped, implementation strategies can be selected to target the respective component. The COM-B model provides a systematic approach of determining target behaviours and the most effective techniques to modify such behaviours. The results of the survey will guide the development of a meaningful and theory-driven intervention for the new Pelvic eHealth Module.

Materials and procedures
The survey will be administered through the secured and encrypted REDCap system to ensure protection and management of data. REDCap is specifically designed for research study data collection, for building surveys and for managing data. The server is hosted at the University of Alberta’s Faculty of Medicine and Dentistry’s data centre.

Phase II: focus groups
Conceptual framework
Focus groups will allow the collection of verbal accounts of patients’ experiences, as well as inform a general consensus on the topic of pelvic health interventions and virtual format of service provision. Following Thorne’s qualitative methodology of interpretive description (ID), these focus groups will provide qualitative data, that will be coded and analysed, to explore and better understand the rationale behind the results of the survey.29 ID addresses clinical questions using an inductive approach to describe a phenomenon and aims to understand the phenomenon from the perspective of those experiencing it. ID is consistent with our intent to provide an in-depth understanding of the experiences of individuals treated for gynaecological cancer with pelvic health concerns and supports the inclusion of illustrative participant quotes describing their experiences. Philosophical underpinnings of the ID design and this research are that: (1) reality is subjective, constructed, contextual and complex; and (2) the researcher and researched interact to coproduce new understandings of a phenomenon. A series of open-ended questions will be used to facilitate in-depth discussions on identified key topics of survivorship care related to pelvic health and to identify shared perspectives and preferences on the virtual delivery of pelvic health interventions. Focus groups will allow the collection of several verbal accounts of patients’ experiences, as well as consensus on the topic of pelvic health interventions and virtual format of service provision. Possible drawbacks from group discussions are acknowledged to include a lack of comfort in sharing perspectives that are notably different from the rest of the group, as well as discouragement of outlier perspectives.

Materials and procedures
The focus groups will be conducted using the encrypted Zoom platform using the Focus privacy mode. Attending these focus groups will require an additional 90 min of the participants’ time. Participants will be invited to join a group according to their preferred language, as both English and French sessions will be available. Focus groups will be audio recorded and transcribed verbatim, from which the key themes and quotes will be identified.30 Collected data from the interviews conducted in French will be translated into English language for analyses.
Sample size
Recruitment is targeted at a minimum of N=50 eligible participants as a convenience sample to answer the online survey, from which we will aim to recruit n=10–15 participants (or until saturation is achieved) in the subsequent focus groups. Sample size was estimated based on prior work conducted in cancer rehabilitation, considering the proportion of gynaecological cancer diagnoses in Canada among overall cancer diagnoses.31–33

Patient and public involvement
This study was designed to follow the Strategy for Patient-Oriented Research to adapt research methods and means used to represent and disseminate results to patients fairly and effectively. As such, patient advisors (PAs) from different provinces, who speak either French or English and have been diagnosed with different gynaecological cancers were recruited to collaborate on this research study and share their experiential knowledge. PAs are actively involved and have been consulted throughout the various research activities of this study, including the design. According to their preferred level of engagement, PAs have been involved in reviewing the proposal and proposing edits, as well as providing comments and suggestions to the protocol according to their point of view. PAs have contributed to the development of the study instrument by identifying important questions to address, as well as reviewing all survey questions and recruitment materials for their inclusivity, relevance and appropriate formulation. PAs are invited to participate further in upcoming research activities such as the interpretation of the data analyses and findings phase by assisting in reviewing themes from data, and sharing their perspectives and interpretation of data, for both the survey and the focus groups analyses.

Analysis
Phase I
Responses to the survey will provide quantitative data from both nominal and ordinal scales as well as qualitative data from open ended questions. Medical and demographic variable will be presented as the mean and SD for continuous data, and frequencies and percentages for nominal data. Further, frequency and percentages will be determined for quantitative questions related to needs, barriers and facilitators items of the survey. Basic descriptive analysis will be generated by REDCap, while the SPSS program (version 29 or later) will be used for calculating ranges, means and SD, as well as percentages to finalise data description.

Phase II
Digital recordings of interviews will be transcribed verbatim by a trained transcriptionist. Transcripts will be cleaned for accuracy by an experienced team member. Consistent with the ID design, the six steps of inductive thematic analysis will be used as an analytic approach. In becoming familiar with the data (step 1), two research team members (SB, MLM) will read through all transcripts and make notes of possible themes. In performing coding (step 2), they will develop a coding scheme inductively derived from the data to reach agreement on the final coding scheme. In seeking themes and reviewing themes (steps 3 and 4), the two team members will meet to identify recurring and converging themes. The entire research team will then review the themes and data within each theme and make suggestions for the final themes, as well as watch again the recordings to validate data and themes. At this point, theme definition will be created and named (step 5). In the final step, a written report of the final themes will be produced (step 6). This analytic process is in accordance with the methods described by Braun and Clarke.34 The identified themes will be further organised to align with the TDF framework and COM-B model. As such, an ID qualitative method will guide the step-by-step analysis of the semi-structured interviews and allow for future actionable implementation strategies related to the development of the Pelvic eHealth Module.30

ETHICS AND DISSEMINATION
Approval from the Health Research Ethics Board of Alberta—Cancer Committee (HREBA HREBA.CC-21-0498) and of the CISSS Bas-Saint-Laurent (CISSBSBL-2021-10) have been obtained. All participants will be required to provide informed consent after being informed of the purpose and procedures of the study, risks and benefits, the right to withdraw, confidentiality and privacy regulations. A numerical code will be attributed to each participant to protect their identity. Our end-of-study dissemination and knowledge-translation goals are: (1) to inform the research community and individuals with gynaecological cancer about our findings to foster a future interventional trial through publication of the results in a peer-reviewed journal; and (2) to highlight these individuals’ preferences in terms of delivery using a virtual format, which will help us to develop a comprehensive, meaningful and tailored Pelvic eHealth Module to better support pelvic health survivorship care.

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