A MULTIMODAL INTERVENTION TO SUPPORT INDIVIDUALS ON ORAL ANTICANCER AGENTS: A PILOT RANDOMIZED CONTROLLED TRIAL

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List of Abbreviations

ESAS-r	Edmonton Symptom Assessment Scale revised
IV	Intravenous
MARS	Medication Adherence Report Scale
MASES	Medication Adherence Self-Efficacy Scale
OAA	Oral anticancer agent
PDC	Proportion of Days Covered
PROs	Patient Reported Outcomes
RCT	Randomized controlled trial
SE	Self-efficacy

ABSTRACT

Sixty percent of all anticancer agents currently being developed are in oral form. Oral anticancer agents (OAAs), work as well as or better than their intravenous (IV) counterparts, are less invasive and easier to administer. However, as OAAs are administered outside of supervised clinical settings, the responsibility for their management falls largely onto patients and their families. Individuals on OAAs report distinct needs compared to those on IV treatment such as timely reminders to take OAAs, personalized information and monitoring for side effects, as well as community pharmacy support.

Medication adherence is a primary determinant of cancer treatment success, unforeseen alterations in dose and timing significantly affect treatment-related outcomes. Because OAA adherence has emerged as challenging with rates as low as 46%, the development of highly accessible supportive interventions remains a priority. The present dissertation work aimed to: 1) provide a comprehensive overview of the current evidence concerning OAA-supportive adherence interventions from the literature, 2) develop and test a promising OAA adherence supportive intervention, and 3) explore the potential influence of the intervention on medication adherence self-efficacy, medication adherence, symptom management, and the experiences of individuals receiving OAA treatment.

The dissertation objectives above are met through the provision of three original manuscripts. Manuscript #1 titled **"Patient Adherence to Oral Anticancer Agents: A Mapping Review of Supportive Interventions"** (Ahmed & Loiselle, 2023; published in *Current Oncology*) provides an overview and identifies gaps in the current evidence concerning OAA-supportive adherence interventions by categorizing the theoretical underpinning, study design,

sample characteristic and size, intervention type, and primary outcome(s) of 120 publications. Gaps in the literature point to further exploration of multimodal theory-guided and patient-tailored interventions promoting OAA adherence.

Manuscript #2 titled "**Feasibility, acceptability, and potential effects of a digital oral anticancer agent intervention: A pilot randomized controlled trial protocol**" (Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2024; submitted to the *Journal of Medical Internet Research Protocols*) presents the study protocol, with detailed aims and measures to test the feasibility, acceptability, and preliminary effects of a multimodal OAA supportive intervention. The intervention includes: 1) OAA informational multilingual videos, 2) symptom-related e-handouts and reputable web links, 3) follow-up phone call from a nurse, and 4) e-reminders to take OAAs. The findings of the pilot randomized controlled trial are presented in manuscript #3 titled **"Acceptability, feasibility, and potential effects of a multimodal remote oral anticancer agent supportive intervention: A pilot randomized controlled trial"** (Ahmed & Loiselle, 2024; submitted to the *Journal of Psychosocial Oncology Research and Practice*). Participants (N = 52), 18 years or older, about to start or within the first cycle of OAA treatment were recruited from a university-affiliated cancer centre in Montreal, Qc and randomized to one of two groups, intervention plus usual care (experimental, n = 26) or usual care only (control, n = 26), followed until OAA treatment completion (up to five months). Forty-one participants completed the study (experimental, n = 23; control, n = 18). Mean rating for acceptability post-intervention was 4.13 (from 1 to 5). Videos and e-handouts were the most popular intervention components, accessed by 87% of the experimental group. Medication adherence was 97.8% and 92.9% for the experimental and control groups, respectively. Preliminary findings show statistically non-significant but positive trends toward higher medication adherence self-efficacy, as well as lower

anxiety, depression, and fatigue over time for the experimental group compared to controls. A subset (n = 10 per group) was invited to participate in semi-structured exit interviews. Themes from qualitative analysis included: 1) timeliness of support across key points in the treatment trajectory and immediacy of response, 2) OAA hands-on knowledge as empowering, and 3) connecting and feeling less alone in treatment.

As the use of OAAs continues to grow, the current dissertation demonstrates potentially clinically significant benefits of an OAA supportive remote intervention to meet the needs of individuals on OAAs. Altogether, this work underscores the importance of a theory-guided intervention, rigorous testing, and complementary knowledge gained from in-depth interviews. The intervention's strongest components (i.e., videos and e-handouts) exemplify how remote/digital interventions can provide accessible and timely personalized support at contained costs.

RÉSUMÉ

Soixante pour cent de tous les agents anticancéreux en développement sont sous forme orale. Les agents anticancéreux oraux (AAO) sont aussi efficaces, moins invasifs, et plus faciles à prendre que leur équivalent intraveineux (IV). Cependant, comme les AAO sont administrés en dehors des environnements cliniques supervisés, la responsabilité de leur gestion tombe sur les patients et les proches. Les personnes sur AAO ont des besoins distincts par rapport à celles sous traitement IV, tels que des rappels pour prendre les AAO, de l'information personnalisée et suivi des effets secondaires, ainsi que du soutien provenant de la pharmacie communautaire.

L'adhésion aux médicaments est un déterminant clé du succès d'un traitement et des modifications imprévues à la dose ou à l'horaire affectent significativement les résultats de santé. Étant donné que l'adhésion aux AAO s'avère être un défi, avec un pourcentage aussi bas que 46%, le développement d'interventions de soutien accessibles devient une priorité. Cette thèse de doctorat vise à: 1) fournir un aperçu complet de l'évidence concernant les interventions de soutien à l'adhésion des AAO à partir de la littérature, 2) développer et tester une intervention à distance, prometteuse de soutien à l'adhésion des AAO, et 3) explorer l'influence potentielle de l'intervention sur l'auto-efficacité, l'adhésion aux AAO, la gestion des symptômes, et les expériences des personnes prenant les AAO.

Les objectifs de la thèse sont opérationnalisés à travers trois manuscrits originaux. Le premier manuscrit (#1) intitulé **« L'adhésion des patients aux agents anticancéreux oraux : une revue cartographique des interventions de soutien** » (Ahmed & Loiselle, 2023 ; publié dans *Current Oncology)* fournit un portrait complet de la littérature sur le sujet et identifie les lacunes concernant les connaissances actuelles sur les interventions de soutien à l'adhésion aux

AAO. Les fondements théoriques sont rapportés ainsi que les devis des études, caractéristiques et tailles des échantillons, les types d'interventions et les résultats principaux et ce, provenant de 120 publications. Certaines lacunes pointent sur la nécessité d'explorer de manière plus approfondie, les contributions d'interventions multimodales guidées par la théorie et adaptées aux besoins du patient afin de promouvoir l'adhésion optimale aux AAO.

Le deuxième manuscrit (#2) intitulé **« Faisabilité, acceptabilité et effets potentiels d'une intervention numérique sur les agents anticancéreux oraux : protocole d'un essai pilote contrôlé randomisé** » (Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2024 ; soumis au *Journal of Medical Internet Research Protocols*) présente le protocole de l'étude, les objectifs détaillés et les mesures qui testent la faisabilité, l'acceptabilité et les effets préliminaires de l'intervention. Cette intervention comprend : 1) des vidéos multilingues d'information sur les AAO, 2) des documents pertinents sous forme électronique et des liens internet réputés sur la gestion des symptômes, 3) un appel de suivi par une infirmière, et 4) des rappels électroniques pour prendre les AAO.

Les résultats de l'essai pilote randomisé sont présentés dans le troisième manuscrit (#3) intitulé **« Acceptabilité, faisabilité et effets potentiels d'une intervention de soutien multimodale à distance pour les agents anticancéreux oraux : un essai pilote contrôlé randomisé »** (Ahmed & Loiselle, 2024 ; soumis au *Journal of Psychosocial Oncology Research and Practice*). Les participants (N = 52), de 18 ans ou plus, étant sur le point de commencer ou dans leur premier cycle de traitement AAO, ont été recrutés dans un centre de cancérologie affilié à une université à Montréal, Qc. Ils furent randomisés dans l'un de deux groupes, intervention plus soins de routine (expérimental, n = 26) ou soins de routine seulement (contrôle, n = 26), suivis jusqu'à la fin du traitement (jusqu'à cinq mois). Quarante et un participants ont

terminé l'étude (expérimental, n = 23 ; contrôle n = 18). La moyenne pour l'acceptabilité après l'intervention était de 4.13 (de 1 à 5). Les vidéos et les documents électroniques étaient les éléments d'intervention les plus populaires, consultés par 87% du groupe expérimental. L'adhésion aux médicaments était de 97.8% et 92.9% pour les groupes expérimental et contrôle, respectivement. Les résultats préliminaires montrent des tendances (non significatives) mais positives vers une plus grande auto-efficacité de l'adhésion aux médicaments et l'adhésion aux médicaments, ainsi qu'une diminution de l'anxiété, de la dépression et de la fatigue au fil du temps pour le groupe expérimental par rapport au groupe contrôle. Un sous-ensemble (n = 10 par groupe) a été invité à participer à des entretiens de sortie semi-structurés. Suivant l'analyse qualitative, les thèmes abordés étaient les suivants : 1) l'opportunité de soutien à des points clés dans le parcours de traitement et la rapidité de la réponse, 2) une connaissance des AAO comme source d'autonomisation, et 3) être « connecté » et se sentir moins seul en cours de traitement.

Alors que l'utilisation des OAA continue à augmenter, cette thèse démontre des avantages cliniques d'une intervention de soutien aux AAO. Dans l'ensemble, ce travail souligne l'importance d'une intervention guidée par la théorie et un rigoureux rapport sur l'état des connaissances à date, et les résultats quantitatifs et qualitatifs d'une évaluation de l'intervention à l'étude. Les composantes les plus appréciées et qui font une différence (c.-à-d. les vidéos et les documents électroniques) montrent comment les interventions à distance/digitales peuvent être intégrées dans les soins pour fournir un soutien personnalisé accessible, en temps opportun, et à de moindres coûts.

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“What is meant for you, will reach you even if it is beneath two mountains. What is not meant for you will not reach you even if it’s between your two lips.”

- Al-Ghazali, 11th century philosopher

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This dissertation is organized in a manuscript-based (article-based) format. Chapter 2 includes manuscript #1 titled "Patient Adherence to Oral Anticancer Agents: A Mapping Review of Supportive Interventions" (published in *Current Oncology*). It is the first mapping review to date on the topic, providing a comprehensive review and visual depiction of publication findings on oral anti-cancer agent supportive interventions.

Authors: Saima Ahmed & Carmen G. Loiselle

SA and CGL conceptualized the mapping review and methodology. Under the supervision of CGL, SA conducted the mapping review, analysis, data curation, interpretation of results, and initial write-up of the manuscript. Both authors reviewed and edited the final version of the manuscript.

Chapter 3 includes manuscript #2 titled "Feasibility, acceptability, and potential effects of a digital oral anticancer agent intervention: A pilot randomized controlled trial protocol" (submitted to the *Journal of Medical Internet Research Protocols*) presents the original study protocol. The protocol contributes to OAA adherence research and intervention development by increasing transparency and rigor in reporting. It ensures pre-determined study objectives and measures, as well as the reproducibility of the proposed work for other researchers.

Authors: Saima Ahmed, Christine Maheu, Walter H. Gotlieb, Gerald Batist, & Carmen G. Loiselle

SA contributed to study and intervention design, operationalization, and write-up of the manuscript. CGL wrote the initial study protocol, obtained funding, and supervised the conduct of the write-up. CM, WG, GB provided ongoing study protocol feedback.

Chapter 4 includes manuscript #3 titled "Acceptability, feasibility and potential effects of a multimodal remote oral anticancer agent supportive intervention: A pilot randomized controlled trial" (submitted to *the Journal of Psychosocial Oncology Research and Practice*) presents the results of the study with contributions to theory, clinical practice, and research with the generation of promising results of a remote and sustainable intervention.

Authors: Saima Ahmed & Carmen G. Loiselle

Under the supervision of CGL, SA conducted participant recruitment, data collection, qualitative and quantitative data analysis, and writing of the initial manuscript. Both authors reviewed and edited the final version of the manuscript.

STRUCTURE OF DISSERTATION

The dissertation is divided into five parts. The introductory chapter (Chapter 1) presents the problem, a review of relevant background literature within the context of the study, and the study hypotheses, aims, and objectives. Chapter 2 (Manuscript #1 – "Patient Adherence to Oral Anticancer Agents: A Mapping Review of Supportive Interventions" Ahmed & Loiselle, 2023; published in *Current Oncology*) includes a mapping review of the current evidence concerning OAA-supportive adherence interventions, identifying essential components of the interventions and studies, as well as gaps in the literature. Chapter 3 (Manuscript #2 – "Feasibility, acceptability, and potential effects of a digital oral anticancer agent intervention: A pilot randomized controlled trial protocol" Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2024; submitted to the *Journal of Medical Internet Research Protocols*) describes the research protocol with specifications on study aims and measures, the intervention, as well as the mixed-method methodology. Chapter 4 (Manuscript #3 – "Acceptability, feasibility and potential effects of a multimodal remote oral anticancer agent supportive intervention: A pilot randomized controlled trial" Ahmed & Loiselle, 2024; submitted to the *Journal of Psychosocial Oncology Research and Practice)* presents the qualitative and quantitative findings. Chapter 5 (Discussion) contextualizes the main findings and study contributions, as well as directions for future work.

CHAPTER 1

Problem Statement

Two in five Canadians will develop cancer in their lifetime (Canadian Cancer Society, 2023). Mortality for most cancers, however, continues to decline at a slow yet steady rate; Canadians affected by cancer are living longer than ever before (Brenner et al., 2020) due largely to improved treatments. Certain types of cancers are now considered chronic diseases, being controlled, or managed for extended periods of time (Canadian Cancer Society, 2024).

The increased use of oral anticancer agents (OAAs) persists due to their cost-effectiveness, convenience for patients, and potential to improve health outcomes (Schlichtig et al.,2019; van Dyk et al., 2021). OAAs represent half of all cancer drugs sold in Canada (Government of Canada, 2020) and 60% of oncology drugs in the global development pipeline (Iqvia Institute, 2022). Despite the increasing prevalence of OAAs, there remains a critical deficiency in comprehensive patient support tailored to the unique needs and challenges associated with this relatively new form of treatment (Arber et al., 2015; Wei et al., 2017). Lack of information, inadequate adherence support, and insufficient management of treatment-related side effects contribute to suboptimal medication adherence, compromising the efficacy of treatment, leading to poorer outcomes and increased healthcare costs (Cutler et al., 2018; Greer et al., 2016; Jacobs, 2019; Skrabal Ross et al., 2020). Addressing these gaps in patient support is essential to optimize potential benefits and enhance patient experiences with OAAs.

Oral Anticancer Agents (OAAs)

Cancer treatment is divided into local and systemic categories (American Cancer Society, 2024). Local therapies such as surgery and radiation treat tumors and immediate adjacent tissues (American Cancer Society, 2024; Basik, 2016). Systemic treatment involves drugs that travel through the body to kill cancer cells (American Cancer Society, 2024). Systemic treatment (e.g. chemotherapy) has traditionally been delivered intravenously (IV), directly through the blood stream (American Cancer Society, 2024). However, IV treatment is invasive, requiring medical personnel to administer, monitor, and it can potentially lead to scars and damaged veins (City of Hope, 2021). Advances in cancer treatment have led to the development of a new class of treatment drugs – oral anticancer agents (OAAs). OAAs are pills or tablets administered orally to treat cancer.

There are 3 categories of OAAs, with different mechanisms of action, accompanied by different side effects and unique toxicity profiles (Raymond et al., 2018).

1) Traditional cytotoxic agents are chemotherapy drugs that work by taking advantage of the rapid cell division of cancer to kill all cells in a certain phase in their cycle or by directly damaging their DNA (Raymond et al., 2018).
2) Targeted therapies are precision medicines selectively directed to interfere with specific proteins and pathways that drive cancer growth in the body (National Cancer Institute, 2022).

Hormonal or endocrine therapies are used to treat certain types of breast and prostate cancers by manipulating hormones that those cancer cells need to grow (Raymond et al., 2018).

When OAAs were first introduced in the late 90's (DeMario & Ratain, 1998; O'Neill & Twelves, 2002) their use was limited to metastatic disease (Center for Drug Evaluation and Research, 1998). In recent years, with a greater understanding of cancer, mechanisms of action, and drug targets, the uptake and use of oral treatment continues to increase. Today, OAAs are prescribed as first-line and/or adjuvant treatment for many cancers, taken alone or in combination, demonstrating equivalent or superior efficacy to IV chemotherapy or slowing disease progression in previously untreatable advanced cancers (Jin et al., 2019; Masuda et al., 2017). Thus, it is no surprise that OAAs currently encompass 60% of all cancer drugs in development (Cheng et al., 2019; Iqvia Institute, 2022; Pataky et al., 2018). A complete and up-to-date list of all OAAs, their mechanism of action, pharmacokinetics, Health Canada indication, dosage, and toxicities can be found on the Drug Formulary of Cancer Care Ontario (2024; (https://www.cancercareontario.ca/en/drugformulary/drugs).

Moreover, as OAAs can be taken remotely by patients rather than in the hospital, their use increased during the COVID-19 pandemic. A province-wide survey conducted by the Coalition Priorité Cancer du Québec (N = 402) during the COVID-19 pandemic revealed that about half (51.3%) of individuals treated for cancer were prescribed oral treatment at the time of survey completion (Villalba, Pomey, Guemghar, & Côté, 2020).

Once an OAA is prescribed by the oncologist, the patient is required to visit a pharmacy to fill the prescription. The pharmacy may be a local community one or an oncology specialized (G.Torani, personal communication, February 14, 2020). In Quebec, the majority of OAAs are covered under the province's public drug insurance plan, the Régie de l'assurance maladie du Québec, RAMQ (for a detailed list of OAAs covered as of May 2022, refer to pages 223 to 229 of https://www.ramq.gouv.qc.ca/sites/default/files/documents/liste_med_2022-05-26_en.pdf).

All individuals whose primary residence is in Québec, who are present for at least 183 days per calendar year, and who possess authorization to remain in Canada (e.g., citizens, permanent residents, refugees, or protected persons) are eligible for coverage under the RAMQ (Gouvernement du Québec, 2020a). Depending on their income and insurance status, patients may still be responsible for co-payments or deductibles, though provisions for financial assistance are available for low-income individuals (Gouvernement du Québec, 2020b). Additionally, patients with private insurance may have access to further coverage options, potentially reducing their out-of-pocket expenses (Gouvernement du Québec, 2020b). Similar public drug insurance plans exist for every province in Canada, although specifics with regards to amount of coverage per individual may vary by province (Government of Canada, 2021). Patients are advised to initially consult their pharmacist for any questions or concerns regarding their OAA (E.Cooke, personal communication, January 9, 2019). Should the pharmacist be unable to provide the necessary assistance, patients are then encouraged to contact their assigned pivot nurse (if applicable) or their oncologist (E.Cooke, personal communication, January 9, 2019).

Patient Perspectives on Oral vs IV Cancer Treatment

Patient preferences for oral versus IV administration of drugs are well-documented. In a review of the literature by Eek et al. (2016), 11 of 13 articles (84.6%) reported patients preferring oral over IV treatment. Reasons for these preferences go beyond simple convenience and relate to feeling in control of treatment, less work/social interference, fewer or no hospital visits for treatment, past experiences such as wait times while receiving IV treatment, trouble finding a suitable vein, and problems related to infusion, compared to the perceived simplicity of taking a

pill orally (Ciruelos et al., 2019; Eek et al., 2016; Wood, 2012). However, the convenience and potential benefits of taking one's treatment orally is accompanied by a reduction in face-to-face interactions and support from the cancer care team, and fewer opportunities for connections with other patients that occurs while at the cancer centre (City of Hope, 2021). Patients are now responsible for taking their cancer treatment, including handling, administrating, and disposing of the drugs (American Cancer Society, 2019). Consequently, as patient autonomy increases while on OAAs compared to IV treatment, new responsibilities are placed on them and their caregivers. In addition, side effects and toxic reactions from OAAs can be particularly high, especially at the beginning of treatment, they should be monitored and managed at the onset as they can lead to complications and in extreme cases, death (Alloway, 2020). However, many patients and their families have misconceptions regarding OAA side effects and efficacy before beginning treatment, that OAAs may be less potent and side effects may be minimal (Halfdanarson & Jatoi, 2010; Talens et al., 2021). In a study of the experiences of patients with various cancer diagnoses taking OAAs (N = 149), the most commonly reported symptoms were fatigue (88.6%), drowsiness (76.5%), disturbed sleep (68.2%), memory problems (63.1%), and emotional distress (60.8%) (Jacobs, 2019). Moreover, participants who reported higher symptom burden had lower medication adherence (Jacobs, 2019).

A survey of adults having been treated for cancer within the last six months (N = 3300) at one of three McGill University partner hospitals in Montreal, Quebec, Canada assessed cancer care experiences and patient satisfaction (Rossy Cancer Network, 2018). Participants completed the Ambulatory Oncology Patient Satisfaction Survey (AOPSS) which covers six dimensions of care: 1) emotional support, 2) continuity and coordination of care, 3) respect for patient preferences, 4) physical comfort, 5) information, education, and communication, 6) access to

care. Findings revealed that the two domains with the lowest satisfaction levels were emotional support and information, education, and communication (Rossy Cancer Network, 2018). Moreover, compared to those receiving IV chemotherapy and radiation treatment, individuals on OAAs reported receiving less information about potential side effects and how to manage them, as well as ranked lowest in feeling that their care providers did everything to help with side effects (Rossy Cancer Network, 2018).

Regardless of the treatment mode, medication adherence remains a key concept in assuring therapeutic goals are met, the disease is optimally controlled, and patients have the best outcomes possible (Specialist Pharmacy Service, 2023).

Medication Adherence

Medication adherence is often reported as the primary determinant of treatment success, as unauthorized alterations in dose and timing affect treatment outcomes (C. St-Pierre, personal communication, March 1, 2020; Early Breast Cancer Trialists' Collaborative Group, 2019, G.Torani, personal communication, February 14, 2020). Yet medication adherence has emerged as a central challenge for OAAs, with studies reporting adherence as low as 46% (Greer et al., 2016). Often construed as a treatment-related outcome (Morinsky & DiMatteo, 2011), adherence itself is a behavior, defined as the extent to which patients “correspond with agreed upon recommendations from their healthcare provider” for taking medicine optimally (Chakrabarti, 2014; Specialist Pharmacy Service, 2023). Examples of medication adherence in OAAs include obtaining the prescription from the pharmacy, its initiation and continuation, taking the recommended dose at the recommended time(s), obtaining medication refills, as well as following medical advice such as foods to avoid and not crushing OAA tablets (Schlichtig, Dürr,

Dörje, & Fromm, 2021; Vrijens et al., 2012). Furthermore, medication adherence is seen as distinct from compliance – where individuals act in accordance with their healthcare provider recommendations for "prescribed interval, and dose of a dosing regimen"– a passive act, characterizing a paternalistic attitude, or persistence which is the duration of time from starting to stopping therapy (Aronson, 2007; Cramer et al, 2008). In contrast, adherence emphasizes patient-provider partnership and the active role of patients (Bosworth et al., 2017). The concept of medication adherence, capturing the pro-active role of individuals taking OAAs will be alluded to throughout this dissertation.

A World Health Organization (WHO) report called *Adherence to Long-Term Therapies: Evidence for Action* – provides an exhaustive review of medication adherence defined as the result of relationships among five domains: patient-, condition-, treatment-, healthcare system-, and social/economic-related, Table 1-1 (World Health Organization, 2003). Adherence is dynamic, influenced by each of these domains, with their combinations being unique for each patient (World Health Organization, 2003).

Table 1-1. Five domains that influence medication adherence (WHO, 2003).

Patient-related Resources, knowledge, attitudes, beliefs, perceptions, and expectations of the patient. Forgetfulness, psychosocial distress, knowledge and/or skill to manage symptoms and side effects, knowledge and beliefs about the illness, motivation, confidence (self-efficacy) in ability to manage and adhere, treatment expectations and beliefs.	**Condition-related** Severity of symptoms, level of disability (physical, psychological, social and/or vocational), as well as disease stage and progression.
Social and economic Socioeconomic status, poverty, illiteracy, level of education, unemployment, lack of effective social support networks, unstable living conditions, and out of pocket cost of medication.	**Treatment-related** Complexity of the regimen, duration of treatment, previous treatments, changes in treatment, treatment side-effects, and the availability of healthcare provider support to help manage them.
	Healthcare system-related Patient-provider relationship, medication reimbursement, the knowledge and training of health care providers.

Lower adherence poses a significant challenge; for OAAs to be as effective as possible and demonstrate outcomes equivalent to those seen in clinical trials, patients must follow best practices. As per classic tumor regression models, tumor cell growth is highest when tumor burden is lowest (West & Newton, 2017). Poor adherence resulting in longer time between treatments and/or lower dose than indicated signifies fewer cancer cells being killed and/or rapid tumor regrowth (West & Newton, 2017). Thus, poor adherence leads to decreased effectiveness of treatment (Marin et al., 2010), often resulting in increased healthcare utilization and costs such as more emergency room visits, higher hospitalization rates, longer hospital stays, and decreased survival (Cutler et al., 2018; DiMatteo et al., 2002; Ganesan et al., 2011; Wu et al., 2010). A review of factors influencing adherence specific to oral cancer drugs by Skrabal Ross et al. (2020), incorporated evidence from three past systematic reviews and two randomized controlled trials to further classify reasons into modifiable and non-modifiable factors. The modifiable factors identified (Table 1-2), are consistent with the unmet information and support needs reported by individuals on OAAs, being both patient- and treatment-related domains (World Health Organization, 2003) These factors present promising areas for developing supportive OAA strategies and/or interventions.

Table 1-2. Reasons for non-adherence to oral anti-cancer drugs (Skrabal Ross et al., 2020).

Modifiable factors	**Non-modifiable factors**
1. Side effects and toxicities • *Treatment-related* 2. Forgetfulness • *Patient-related* 3. Lack of patient education/knowledge on disease and treatment • *Patient-related*	1. Co-payment • *Social and economic* 2. Age • *Patient-related* 3. Regimen and complexity • *Treatment-related* 4. Time since diagnosis and the duration of therapy • *Condition- and treatment-related*

Patient Information and Support

As its development and use expands, adherence to OAAs continues to receive a substantial amount of interest from multiple stakeholders including policymakers, insurance companies, drug makers, healthcare providers, and researchers. The American Society of Clinical Oncology (ASCO) and Oncology Nursing Society (ONS) initially released guidelines and safety standards for the administration of OAAs (Jacobson et al., 2009). These were revised in 2011, 2013, and 2016 (Jacobson et al., 2012; Neuss et al., 2013; Neuss et al., 2016) to highlight the importance of patient education at the initiation of treatment, given that starting on a new treatment may be potentially complex and confusing, and patient information seeking behavior is known to be highest at the start of treatment and decreases over time (Alloway, 2020; Eheman et al., 2009; Vogel, Bengel, and Helmes, 2008). In addition, ongoing monitoring throughout enables for the prompt identification of early, delayed, and long-term side effects and toxicities, preventing complications (Howell, 2016; Neuss et al., 2016).

In a qualitative study, women with breast cancer receiving OAAs (n = 9), and their healthcare providers (n = 8; 4 oncologists and 4 nurses) were asked to assess women's needs (Wei et al., 2017). Symptom management was the only common theme identified by both groups. Unbeknown to providers, women reported feeling helpless at home, with insufficient knowledge to manage their treatment, and wanting positive and encouraging information as well as support from other patients with similar experiences (Wei et al., 2017). Thus, there is a need for timely and accessible information and support for individuals on OAAs (Arber et al., 2015; Wei et al., 2017).

Given the home-based nature of OAAs, a remote approach is promising as it is patient facing and has the potential to overcome barriers patients face by offering real-time, tailored support, driven by their needs and preferences (Whitehead, 2016). In view of the complex nature of medication adherence and multiple interacting components of information and support required, a theoretically grounded multimodal support intervention was designed and will be evaluated in this dissertation. The intervention was developed through a multi-stakeholder development process. First a thorough search was conducted of existing interventions and evidence, with special attention paid to the Quebec and/or Canadian context. As no OAA relevant interventions were found, Dr. Loiselle initiated to write a grant on the topic for which funding was subsequently provided by the Rossy Cancer Network (Cancer Care Quality & Innovation Program Research Fund - Grant title: Implementation and testing of a sustainable support program as a complement to an ongoing RCN patient-reported outcomes initiative) and began designing the content of the intervention through the development of relevant e-handouts addressing all potential side effects and complications. Next, Dr. Loiselle and the doctoral candidate met with Precare, a company providing educational video resources to patients

(https://precare.ca/) and began a consultation process with pivot nurses in oncology to prepare the text for the video. Next other clinicians (nurses and doctors), researchers, pharmacists, patients, and informal caregivers as well as local and National cancer community non-profit organizations provided feedback on videos and e-handouts. In anticipation of study commencement, a final round of feedback was sought from all previously involved parties, particularly the pivot nurses in oncology. The final versions videos and e-handouts were reviewed one last time by Dr. Loiselle and the doctoral candidate. Next, all intervention components were integrated into Belong – Beating Cancer Together, a CIUSSS du Centre-Ouest-de-I'Île-de-Montreal platform.

Prior to clinical implementation, the intervention requires high-quality and current evidence to its effectiveness to support informed decisions about patient care and how to best allocate available limited resources. In addition, the successful implementation of this intervention is dependent on both its acceptability and feasibility, which provide valuable insights to clinicians and researchers as well as increase its likelihood of success (Sekhon et al., 2017).

Main Objective, Aims, and Hypotheses

The main purpose of this dissertation is to generate preliminary insights and evidence into the implementation potential of a remote supportive OAA intervention to address the unmet needs of individuals on OAAs. More specifically, this dissertation aims to: 1) provide a comprehensive overview of the current evidence concerning OAA-supportive adherence interventions from the literature, 2) develop and test a promising OAA adherence supportive intervention, and 3) explore the potential influence of the intervention on medication adherence

self-efficacy, medication adherence, symptom management, and the experiences of individuals receiving OAA treatment.

The hypotheses are that the study is feasible, the intervention is accepted by its target sample – individuals with cancer about to start OAA treatment, and that over time, compared to usual care only, those exposed to the intervention demonstrate a trend toward higher medication adherence self-efficacy, higher medication adherence, and lower symptom distress.

CHAPTER 2

Preface

Chapter 2 presents the first manuscript of the dissertation, providing a comprehensive overview of the current evidence concerning oral anticancer agent (OAA) supportive adherence interventions. The manuscript is titled **"Patient Adherence to Oral Anticancer Agents: A Mapping Review of Supportive Interventions"** (Ahmed & Loiselle, 2023) published in *Current Oncology*.

OAA medication adherence is a well-established challenge that must be addressed to ensure optimal cancer-related outcomes. Treatment side effects and toxicities, forgetfulness, and lack of patient education/knowledge regarding OAA uptake have been identified as modifiable factors, aligning with unmet needs reported by individuals on OAAs. To address these, supportive interventions (i.e., actions or strategies implemented to help or encourage individuals experiencing difficulties or challenges arising from cancer) hold much promise as they offer informational, practical, physical, and emotional support in the promotion of medication adherence (Jones, 2023).

A review of past and current approaches to supportive interventions aimed at promoting OAA adherence provides a comprehensive understanding of OAA-related issues from the literature, highlighting potential gaps in addressing modifiable factors and unmet needs (Campbell et al., 2023). The complex nature of OAAs (e.g., systemic, targeted and/or hormonal drugs), OAA user profiles (such as age, cancer diagnosis, etc.), medication adherence

measurement (including self-report, chart review, etc.), intervention type (whether pharmacist-led, nurse-led, digital health, etc.) and mode/domain (behavioural, educational, medical, technological) must be captured extensively. This mapping review provided a complete overview of current evidence and followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. It categorized the theoretical underpinnings, study design, sample characteristics, sample size, intervention type, and primary outcome(s) of publications. In addition, the search strategy utilized was PICO, corresponding to evidence-based clinical questions: Population (P) being oral anticancer agent, Intervention (I) being supportive intervention, and Outcome (O) being medication adherence (Richardson, Wilson, Nishikawa, & Hayward, 1995).

Manuscript #1

Patient adherence to oral anticancer agents: A mapping review of supportive interventions

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Abstract

The development and use of oral anticancer agents (OAAs) continue to grow, and supporting individuals on OAAs is now a priority as they find themselves taking these drugs at home with little professional guidance. This mapping review provides an overview of the current evidence concerning OAA-supportive adherence interventions, identifying potential gaps, and making recommendations to guide future work. Four large databases and the grey literature were searched for publications from 2010 to 2022. Quantitative, qualitative, mixed-method, theses/dissertations, reports, and abstracts were included, whereas protocols and reviews were excluded. Duplicates were removed, and the remaining publications were screened by title and abstract. Full-text publications were assessed and those meeting the inclusion criteria were retained. Data extracted included the year of publication, theoretical underpinnings, study design, targeted patients, sample size, intervention type, and primary outcome(s). 3175 publications were screened, with 435 fully read. Of these, 315 were excluded with 120 retained. Of the 120 publications, 39.2% (n = 47) were observational studies, 38.3% (n = 46) were quasi-experimental, and 16.7% (n = 20) were experimental. Only 17.5% (n = 21) were theory-based. Despite the known efficacy of multimodal interventions, 63.7% (n = 76) contained one or two modalities, 33.3% (n = 40) included 3, and 3.3% (n = 4) contained four types of modalities. Medication adherence was measured primarily through self-report (n = 31) or chart review/pharmacy refills (n = 28). Given the importance of patient tailored interventions, future work should test whether having four intervention modalities (behavioral, educational, medical, and technological) guided by theory can optimize OAA-related outcomes.

Introduction

Driven by ease of administration, patient convenience, potential cost-effectiveness, and enhanced quality of life, oral anticancer agents (OAAs) are being rapidly developed, tested, and approved for patient use. Able to be taken by patients at home rather than in the hospital, OAA use increased substantially during the COVID-19 pandemic, as drugs that can be taken at home, orally, were favored over intravenous ones when possible (Moujaess, Kourie, & Ghosn, 2020; Villalba et al., 2020). Currently, OAAs represent half of all cancer drugs sold in Canada (Government of Canada, 2020) and 50–60% of the global oncology drugs in the development pipeline (Iqvia Institute, 2022).

Compared to intravenous (IV) chemotherapy, OAAs refer to pills or tablets taken by mouth to treat cancer and are classified under three categories: (1) traditional agents, a systemic approach taking advantage of the rapid division of cancer cells to kill all cells within certain phases of the cell cycle (e.g., Capecitabine), (2) targeted agents, referred to as "precision medicines" that are genetically driven, inhibiting a specific pathway in the cancer cell (e.g., Imatinib or Ribociclib), and (3) hormonal agents, manipulating the hormones in cancer cells that require them to grow (e.g., Anastrozole) (Raymond et al., 2018).

The transfer from in-hospital to home-based OAA treatment presents a paradigm shift in cancer care, with the administration and management of treatment now falling to the patient and informal caregivers rather than within the healthcare team. For OAAs to be as effective as possible, patients must follow best practices (e.g., dosage, timing, foods to avoid, etc.), as well as manage their treatment, side effects, and be alert for toxicities. Medication adherence is the primary determinant of treatment success (Thomas et al., 2019), whereby medication-related

behaviors “correspond with agreed upon recommendations from their healthcare provider” (Chakrabarti, 2014) . In addition to taking medication as prescribed at the same time every day—as alterations in dose and timing can affect treatment outcomes (Early Breast Cancer Trialists’ Collaborative Group, 2019) —adherence also includes obtaining the prescription(s), medication initiation and continuation, refills, and following medical recommendations related to medication intake, side effects, and potential complications (Vrijens, 2012). However, medication adherence can be challenging (Thomas et al., 2019), with studies reporting OAA adherence ranging from 46 to 100% (Greer et al, 2016). Lower than prescribed adherence can cause reduced medication effectiveness, increased healthcare service use, and higher costs, such as more medical visits, higher hospitalization rates, longer hospital stays, and possibly lower survival (Cutler et al., 2018; DiMatteo et al., 2002; Ganesan et al., 2011; Wu et al., 2010). A review of factors influencing non-adherence to OAAs (Skrabal Ross et al., 2020) for instance, identified three modifiable factors across studies that interventions may focus on: side effects and toxicities, forgetfulness, and the provision of reliable information. As OAAs have grown exponentially in popularity, supportive interventions promoting medication adherence have been developed and tested. Published studies vary in scope in terms of participant profiles, OAA types, intervention theoretical underpinnings and modalities, study design, outcomes of interest, as well as operationalization of the medication adherence construct. While systematic, meta, and scoping reviews have been published, and offer in-depth analyses and specificity on the evidence on this topic (Dang et al., 2022; Lafata et al., 2023; Waseem, 2022), there remains a need for a wider-scope appraisal of the OAA literature in terms of study type, design, and intervention quality, as well as outcomes of interest. A mapping review provides a useful structured overview of relevant research by “categorizing, classifying, characterizing patterns, trends or themes in evidence

production or publication" (Booth, 2016; Campbell, 2023). Despite increased interest and a growing body of literature on this topic, a mapping review has never been conducted to assess gaps for future work to address. Cataloguing relevant information into domains, such as theoretical underpinnings, targeted samples, and outcomes of interest, can provide further insights into broader questions, such as, what work has been done so far, and what needs to be done in the future (Grant & Booth, 2009; Khalil & Tricco, 2022). Using visual displays to summarize data makes similarities and differences among studies clearer while explicitly addressing potential issues (Grant & Booth, 2009).

Objectives

The main objectives of this mapping review are to identify, describe, and provide an overview of the body of literature on supportive interventions promoting OAA adherence, and identify gaps and avenues for future work. The recommended evidence-based PICO model, used to formulate a clinical question (Richardson et al., 1995), guided the search strategy for this review, as presented in Table 2-1.

Table 2-1. PICO search strategy guiding the mapping review (Richardson et al., 1995).

Concept 1 **Patient/Population**	**Concept 2** **Intervention/Exposure**	**Concept 3** **Outcome**
Oral anticancer agent	Supportive intervention	Medication adherence

Methods

The reporting of this mapping review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Moher, Liberati, Tetzlaff, Altman, 2009; Page et al., 2021).

Search Strategy and Eligibility Criteria. PubMed/Medline, EMBASE, CINAHL, PsycINFO, and the grey literature were searched for articles published between January 2010 and December 2022. An initial search strategy of Medical Subject Headings (MeSH), key text word(s), or text phrases was formulated. Upon consultation, the university-based librarian, an expert in reviews specialized in medicine, helped further strategize the terms used in the search. The finalized search strategy carried out by the first author included: antineoplastic agents, administration oral, oral (chemotherapy* or anti?neoplastic or anti?tumo?r,) neoplasms/or carcinoma/or (cancer* or tumo?r* or carcinoma* or adenocarcinoma* or neoplas* or oncolog* or metasta* or maglignan* or choriocarcinoma* or sarcoma* or lymphoma* or melanoma* or myeloma*), cancer oral* (agent* or medication* or medicine* or therap* or treatment* or drug* or deliver*), oral oncolytic*, medication adherence or patient compliance or health behavior or attitude to health or adherence or compliance or self-efficacy, patient (complian* or activat* or engage* or empower*), health behevio*r.

Quantitative, qualitative, mixed-method studies, theses/dissertations, reports, and conference abstracts were included. Study protocols and review publications were excluded to avoid duplicate data (e.g., separately published protocols and results).

Study Selection and Review. A member of the research team first identified publications by title for their relevance to the review topic and publication eligibility (i.e., quantitative,

qualitative, mixed-method studies, theses/dissertations, reports, or conference abstracts). The retained publications were then screened by their abstracts. Once duplicates were removed, those with all inclusion criteria were retained for full-text review and synthesis.

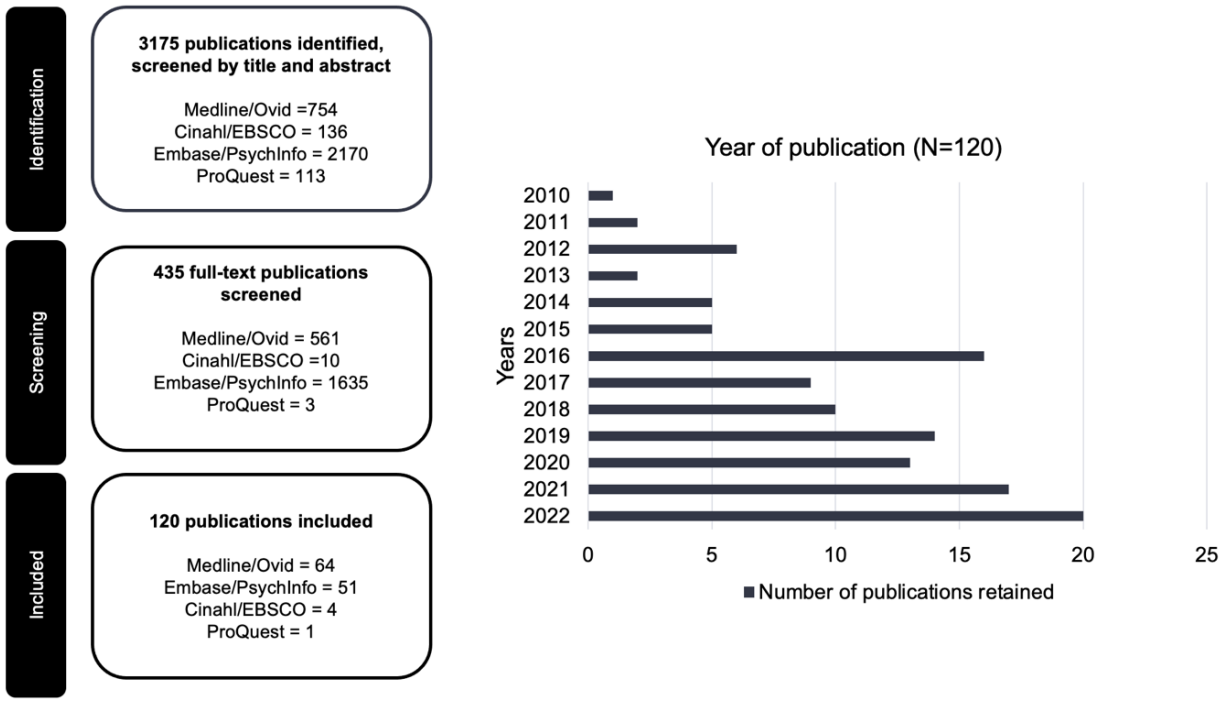
Data Extraction. This mapping review provides a visual overview of the existing evidence related to the topic by coding, cataloguing, and describing the evidence. For each publication, data were extracted using the following categories: (1) year of publication, (2) conceptual or theoretical framework used for study and/or intervention, (3) design, (4) sample, (5) sample size, (6) intervention type and modalities, and (7) primary outcome(s).

Results

Here, 3175 publications were initially identified and screened by the title and abstract. Of these, 435 were kept for full-text review, and following this, 315 were excluded as duplicates or for not being relevant or meeting the inclusion criteria. A final sample of 120 publications was retained. The PRISMA flow chart (Figure 2-1) summarizes the study selection process in detail. A list of all included 120 publications can be found in the Supplementary Material.

Year of Publication. Publications from January 2010 to December 2022 were retrieved. Nearly 82% (n = 99) were published from 2016 onward. The year of publication is illustrated in Figure 2-1 as: 2010 (n = 1, 0.8%), 2011 (n = 2, 1.7%), 2012 (n = 6, 5%), 2013 (n = 2, 1.7%), 2014 (n = 5, 4.2%), 2015 (n = 5, 4.2%), 2016 (n = 16, 13.3%), 2017 (n = 9, 7.5%), 2018 (n = 10, 8.3%), 2019 (n = 14, 11.7%), 2020 (n = 13, 10.8%), 2021 (n = 17, 14.2%), and 2022 (n = 20, 16.7%).

Figure 2-1. PRISMA flowchart of the publication selection process and years of publication (N = 120).



Conceptual or Theoretical Framework. Of the studies and/or interventions reported, 17.5% (n = 21) were explicitly theory-based, with the Plan-Do-Study-Act (PDSA) model (n = 4), self-efficacy (n = 3), motivational interviewing (n = 2), and one intervention using motivational interviewing to increase self-efficacy (n = 1). Table 2-2 presents a summary of the theories and frameworks used to inform the interventions of the retained publications.

Table 2-2. Theories and frameworks used in study and/or intervention development of the included publications (N = 120).

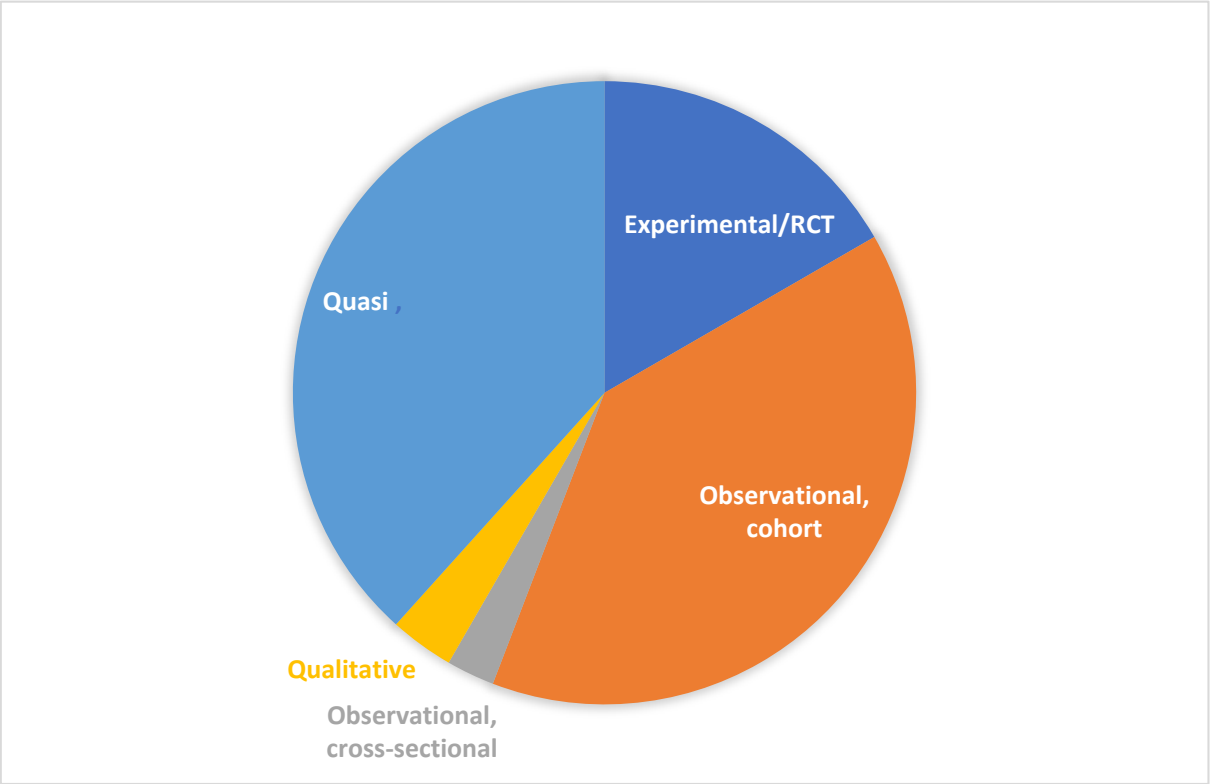
Theory/Framework	**Number of Publications N = 120, *n* (%)**
Plan-Do-Study-Act (PDSA) Model	4 (3.3)
Self-efficacy	3 (2.5)
Motivational interviewing	2 (1.6)
Self-efficacy and motivational interviewing	1 (0.83)
Acceptance and Commitment Therapy (ACT) and self-affirmation theory	1 (0.83)
Concordance and shared decision-making	1 (0.83)
Conceptual framework created to study med adherence	1 (0.83)
Health belief model and the stress process model	1 (0.83)
Intervention for Symptom Management Model	1 (0.83)
Motivation Theory	1 (0.83)
Self-Care-Deficient Nursing Theory	1 (0.83)
Self-Regulatory Model of Antiretroviral Adherence	1 (0.83)
Social Representation (SR) theory	1 (0.83)
Synergy Model of Patient Care and Ottawa Model of Research Use	1 (0.83)
UK Medical Research Council's Self-Management Framework	1 (0.83)

Study Design. Among the publications, 39.2% (n = 47) used observational cohort designs, 38.3% (n = 46) were quasi-experimental, and 16.7% (n = 20) were experimental, such as randomized controlled trials (RCTs) or pilot RCTs. Only 3.3% (n = 4) relied on qualitative designs and 2.5% (n = 3) were observational cross-sectional studies (Figure 2-2 and Table 2-3)

Table 2-3. Summary of study designs (N = 120).

Study Design	**Number of Publications, N = 120, *n* (%)**
Observational, cohort	47 (39.2)
Quasi-experimental	46 (38.3)
Experimental	20 (16.7)
Qualitative	4 (3.3)
Observational, cross-sectional	3 (2.5)

Figure 2-2. Pie chart of the study design of the retained publications (N = 120).



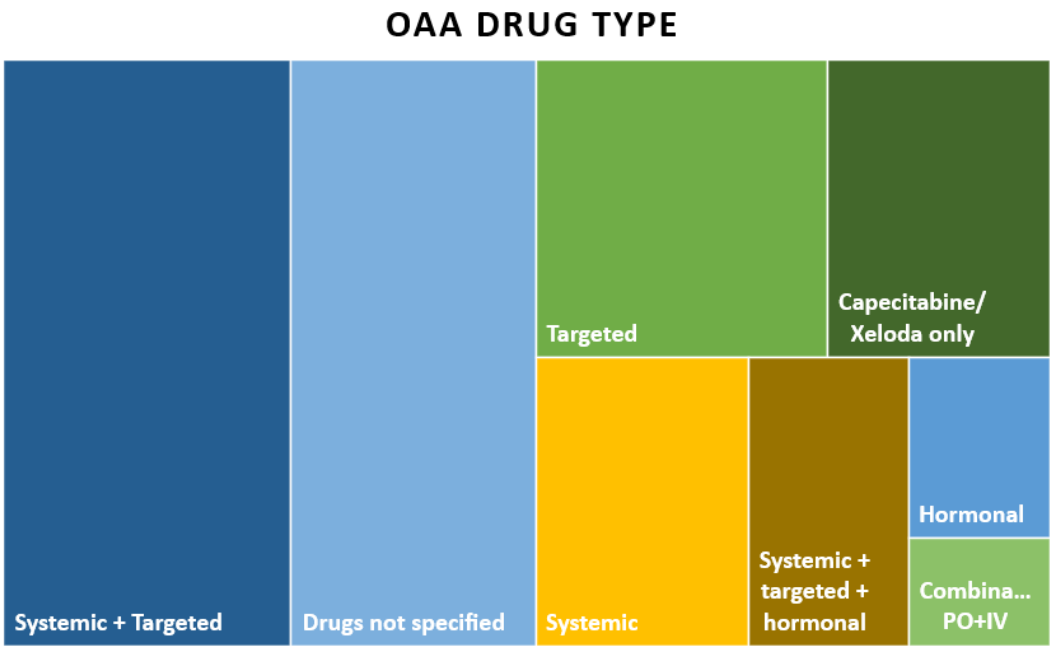
Study Sample. Most of the publications (n = 89, 75%) used samples with participants diagnosed with various cancers (on OAAs). Only a few publications focused on a particular cancer diagnosis, such as hematological (n = 12, 10%), gastrointestinal (n = 10, 8.3%), breast (n = 5, 4.2%), lung (n = 3, 2.5%), or prostate cancer (n = 1, 0.8%).

In terms of OAA type, systemic and targeted drugs together were the most common (n = 33, 27.5%), followed by targeted only (n = 17, 14.2%), Capecitabine/Xeloda only (n = 13, 10.8%), mixed systemic therapy (n = 12, 10%), all three together—systemic, targeted, and hormonal (n = 9, 7.5%), hormonal only (n = 5, 4.2%), and a combination treatment of IV and PO (n = 3, 2.5%). Of note, 23.3% (n = 28) of the publications did not specify OAA drug(s) taken by patients in their study. The distinct study population OAA types are illustrated in Figure 2-3 and Table 2-4.

Table 2-4. Summary of OAA types (N = 120).

OAA Drug Types	Number of Publications, N = 120, *n* (%)
Systemic and targeted	33 (27.5)
Drugs not specified	28 (23.3)
Targeted	17 (14.2)
Capecitabine/Xeloda only	13 (10.8)
Systemic, targeted, and hormonal	3 (2.5)
Hormonal	5 (4.2),
Combination treatment of IV and PO	3 (2.5)

Figure 2-3. Tree map chart of OAA types (N = 120).



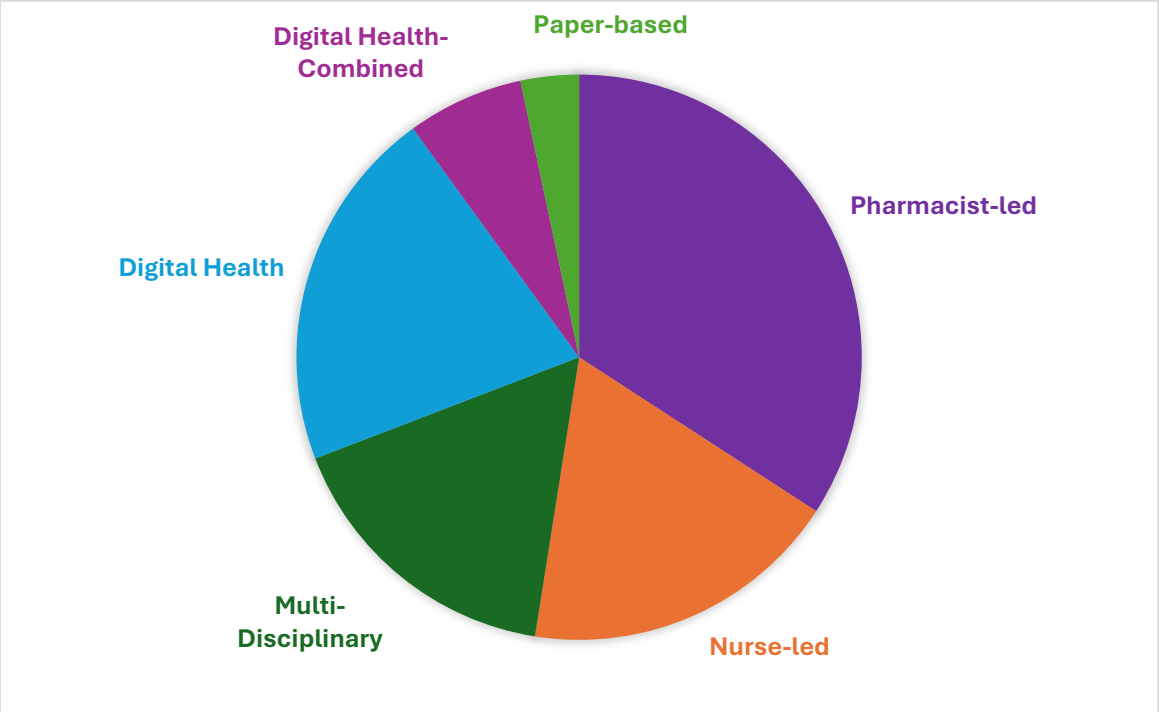
Sample Size. Sample sizes varied across studies, with more than half (62.5%; n = 75) having less than 100 participants. Sample sizes were categorized as follows: 1–10 (n = 3, 2.5%), 11–30 (n = 25, 20.8%), 31–50 (n = 18, 15%), 51–100 (n = 29, 24.2%), 101–150 (n = 13, 10.8%), 151–200 (n = 7, 5.8%), 201–250 (n = 4, 3.3%), 251–300 (n = 7, 5.8%), 301–350 (n = 2, 1.7%), more than 400 (n = 10, 8.3%), and not specified (n = 2, 1.7%).

Intervention Type and Approach. Interventions that were professionally led were at the forefront (n = 83, 69.2%), with pharmacists (n = 41, 34.2%), nurses (n = 22, 18.3%), and multiple disciplines involved (doctor, nurse, and/or pharmacist combined; n = 20, 16.6%). In addition, 20.8% (n = 25) were digitally based, 6.7% (n = 8) were digital health/healthcare provider combined, and 3.3% (n = 4) were paper-based. Figure 2-4 and Table 2-5 summarizes the intervention types.

Table 2-5. Summary of intervention modalities (N = 120).

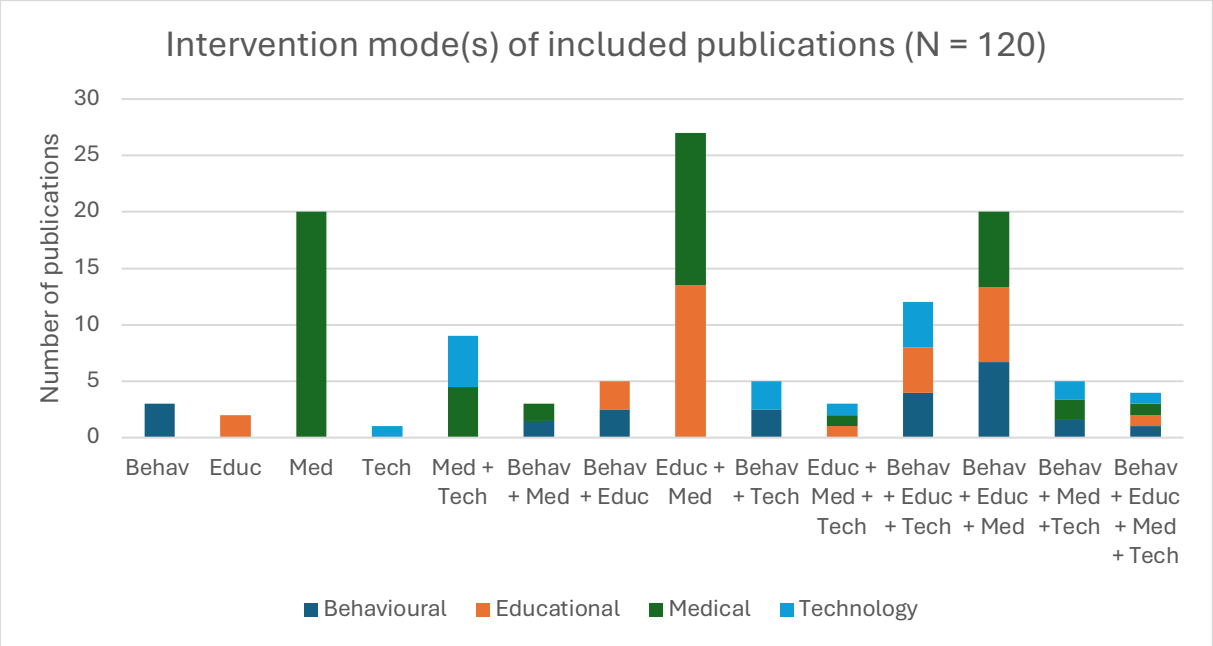
Intervention Modality	**Number of Publications, N = 120, *n* (%)**
Pharmacist-led	41 (34.2)
Nurse-led	22 (18.3)
Digital health	25 (20.8)
Multi-disciplinary	20 (16.6)
Digital health/healthcare provider combined	8 (6.7)
Paper-based	4 (3.3)

Figure 2-4. Pie chart of intervention modalities (N = 120).



Interventions were further classified into four main approaches: medical—any act with preventative, diagnostic, therapeutic, or rehabilitative claims carried out by a physician or healthcare provider (Mednis, 2020); educational—the provision of information to increase knowledge and skills to help patients better manage their treatment (Ricci et al., 2022); behavioral—"designed to affect the actions that individuals take" (Anderson, Bulatao, & Cohen, 2005); and/or technological—relying on the internet and/or smartphones (De Witte et al., 2021). About one-quarter were medical and educational (n = 27, 22.5%), followed by medical only (n = 20, 16.7%), medical, educational, and behavioral (n = 20, 16.7%), and medical and technological (n = 9, 7.5%). Of note, only 3% (n = 4) of studies contained all four approaches. Figure 2-5 presents a summary of the interventions by the prevalence of approaches.

Figure 2-5. Interventions classified by medical, behavioral, educational, and/or technological approaches (N = 120).



Primary Outcome(s). Most publications had multiple outcomes of interest, and these included (not mutually exclusive) medication adherence (n = 74); side effects, toxicities, or adverse events (n = 29); number of consults, interventions, or healthcare service use (n = 22); knowledge and/or understanding (n = 13); quality of life (QoL or HRQoL, n = 12); satisfaction and/or perceptions (n = 11); and self-efficacy (n = 6). A summary of all publications included (n = 120) and the corresponding outcome(s) for each is available in the Supplementary Material. Medication adherence, more specifically, was measured through self-report (n = 31), pill count (n = 1), electronic/smart pillboxes (n = 6), chart review/pharmacy refills (n = 28), or a combination of two or more measures (n = 7). Figure 2-6 depicts methods of measuring adherence, while Table 2-6 further elaborates on the measures used, including self-report, chart refill, and combined methods.

Figure 2-6. Pie chart of measurement methods for OAA adherence (*n* = 74).

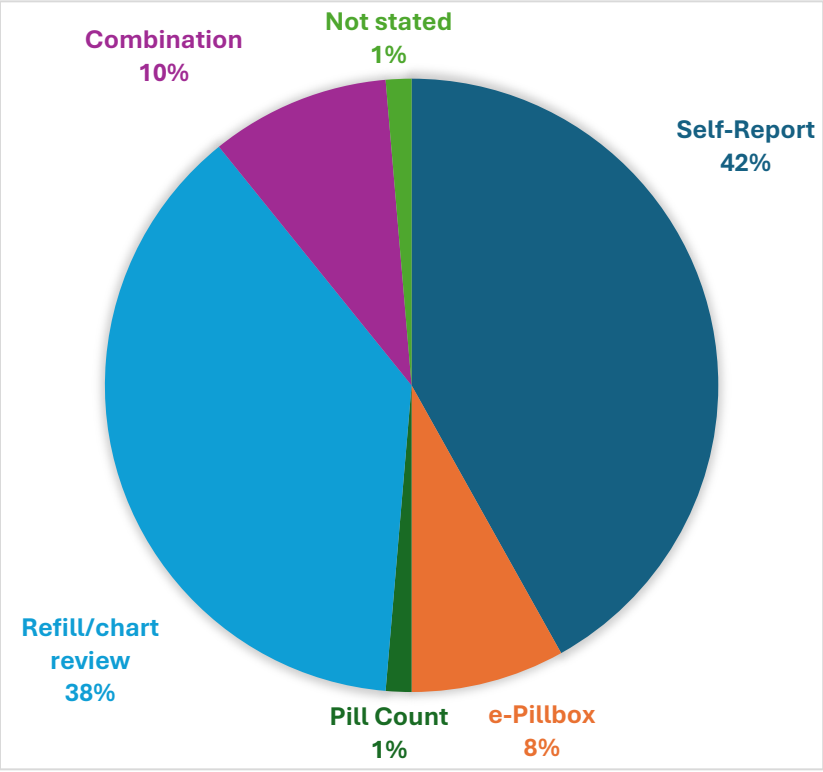


Table 2-6. List of measures, including self-report, chart refill, and combined methods of adherence.

Self-Report (*n* = 31)	Refill/Chart (*n* = 28)	Combination (*n* = 7)
Study-specific questionnaire (*n* = 16)	Medication possession ratio: MPR (*n* = 16)	Diary + pill count (*n* = 1)
Morisky Medication Adherence Scale: MMAS-8 (*n* = 7)	Details not available: NA (*n* = 7)	Self-report (Basel Assessment of Adherence Scale: BAAS) + pill count (*n* = 1)
Via telephone (*n* = 2)	Proportion of days covered: PDC (*n* = 2)	Self-report (MARS-5) + e-pillbox (*n* = 1)
Medication Adherence Report Scale: MARS-5 (*n* = 1)	Relative dose intensity: RDI (*n* = 2),	Self-report (MMAS-8) + e-pillbox (*n* = 1)
Oral Chemotherapy Adherence Scale: OCAS (*n* = 1)	MPR/PDC/TTT (*n* = 1)	Self-report (study-specific) + refill (NA) (*n* = 1)
Medication Adherence Questionnaire: MAQ (*n* = 1)		Plasma drug concentration + self-report (study-specific) (*n* = 1)
Morisky Green Levine Medication Adherence Scale (*n* = 1)		RDI + pill count (*n* = 1)
Patient diary (*n* = 1)		

Discussion

This mapping review sought to identify, describe, and provide an overview of the body of literature on supportive interventions related to OAAs. To our knowledge, this is a first in providing a comprehensive review and visual depiction of publication findings on the topic. The current state of the literature on OAAs is congruent with their rise in popularity over the past few years, with the greater part of publications produced between 2016 and 2022. This reflects the approval timeframe of commonly prescribed oral cancer drugs and their subsequent rapid uptake as routine cancer treatment (FDA, 2018; Levin, 2013; Pfizer, 2013).

Taken together, findings from this mapping review emphasize the importance of well-thought-out intervention development, testing, and implementation, as well as transparent reporting of OAA-related outcomes (Mir, 2023; WHO, 2003). As multiple factors contribute to

optimal adherence, single-mode interventions are not found to be as effective as multimodal interventions (studied among people with chronic conditions) (Dang et al., 2022; Rosenberg et al., 2020; Spoelstra & Sansoucie, 2015). In addition, interventions should ideally follow established theoretical models or frameworks addressing behavioral factors and underlying processes involved (Irwin, 2015; Kahwati et al., 2016). Whereas several studies herein contained a behavioral component, only 17.5% (n = 21) were explicitly theory- or model-based. The three most popular models/frameworks were Plan-Do-Study-Act (PDSA), motivational interviewing (MI), and self-efficacy (SE). The PDSA model has been widely used in quality improvement projects; however, it is not a theoretical behavioral model by which an intervention should be developed, but rather a four-step, structured cyclical approach to test the outcome of a change that has been implemented (Knudsen et al., 2019; Agency for Healthcare Research and Quality, 2020). The intended use of the PDSA model is small scale, where the cycle is rapidly repeated multiple times to test and refine a single element within a short duration and a small sample size (Agency for Healthcare Research and Quality, 2020; Health Quality Ontario, 2023). Two separate systematic reviews of the model found that although widely used, many projects that use PDSA report improvements while not adhering to its methodology of four steps (Agency for Healthcare Research and Quality, 2020; Taylor et al., 2014). In addition, the model itself is more rooted in healthcare processes than patient outcomes (Agency for Healthcare Research and Quality, 2020). In contrast, MI is a behavior change counselling technique developed by clinical psychologists (Center for Substance Abuse Treatment, 1999). It is best described as a "person-centered, goal-oriented style of communication" with the goal of behavior change (Bischof, Bischof, & Rumpf, 2021). Originally derived to help those with alcoholism and addiction, robust data exist of MI working across various demographics and in the promotion of treatment

adherence in chronic diseases (Rubak, Sandbaek, Lauritzen, & Christensen, 2005). With an emphasis on communication, MI requires direct patient contact, as it revolves around conversations between the patient and a trained healthcare provider (Center for Substance Abuse Treatment, 1999).

Last, SE, developed by Bandura (1977), is an individual's belief in their own ability to successfully perform a specific task related to a specific behavior (i.e., taking their medication on time to adhere to treatment). High self-efficacy is associated with a sense of mastery, accomplishment, and feeling in control (Bandura, 1977). Thus, an individual with a high level of self-efficacy toward a particular task is more optimistic about their ability to cope with unexpected events and challenges that may occur, whereas an individual with low self-efficacy may give up easily or avoid the task altogether. There exist both internal and external sources of self-efficacy, providing potential mechanisms for interventions (Bandura, 1977). A systematic review of the relationship between self-efficacy and medication adherence found a positive link between them in 59 out of 66 studies (Náfrádi, Nakamoto, & Schulz, 2017). One publication included in this mapping review combined both SE and MI, as SE is a theory of human behavior, while MI is a technique. Interestingly, SE theory, with its significant positive associations with medication adherence (Náfrádi, Nakamoto, & Schulz, 2017), was mentioned in only three studies, while SE was used as an outcome measure in six studies, suggesting that theory-driven work may not be explicitly identified in reporting.

We found a limited number of studies to be experimental, whereas the majority were quasi-experimental or observational. Prior to clinical implementation of OAA interventions, higher levels of evidence should be required. Studies should also consider mixed-method designs, as they may generate more comprehensive and complementary knowledge on

intervention effects. Interestingly, nearly one-quarter of publications (23.3%) did not specify the types of OAAs used. Moving forward, researchers must be more explicit when reporting on OAAs so that replication studies and projects can be more easily carried out.

As expected, medication adherence was the most prevalent outcome used across studies. Methods to measure OAA adherence were primarily self-report or pharmacy refill rates. Self-report questionnaires are convenient and may allow adherence-related factors and behaviors to be considered. However, they may be subject to recall, response, and desirability biases that may overestimate adherence rates. Of the 30 studies that relied on self-report, only 11 (37%) used validated questionnaires. The use of study-specific questionnaires may be due in part to the large copyright and licensing fee researchers are asked to pay for the most commonly used validated self-report measure, the Morisky Medication Adherence Scale (MMAS-8) (Marcus, 2017). Originally developed in the context of anti-hypertensive drugs, the scale has been validated and widely used across various populations and languages (De Las Cuevas & Peñate, 2015). The Medication Adherence Report Scale (MARS-5) and Medication Adherence Questionnaire (MAQ) are both free alternatives to the MMAS-8 (Office of Research Services at the University of Pennsylvania, 2020; Chan et al., 2020). Developed in 2023 by Talens et al., the Oral Chemotherapy Adherence Scale (OCAS) specifically assesses adherence to oral chemotherapy. Validated in Spanish, the scale has yet to be validated in an English-speaking sample. If successfully validated, this scale may be the best option for OAA researchers. With questions such as “do you sometimes think that another intravenous drug would produce better results than the current drug?”, the scale captures elements specific to the OAA experience that generic adherence scales miss.

Pharmacy refill rates, while being objective, do not measure the uptake of medication itself. The two common refill measures, the medication possession ratio (MPR) and proportion of days covered (PDC), vary slightly, but with significant ramifications. The MPR—the sum of days' supply for all fills in the period/number of days in the period—may overestimate adherence if a patient refills their medication a few days before the end of the previous period, thus making it possible to be higher than 100%. The PDC—the number of days covered/number of days in the period—adjusts the calculation and shifts overlapping days and is, therefore, the more accurate measurement (Pharmacy Times, 2015). However, of the 28 studies that relied on refill data, only 2 used PDC. To best mitigate risks associated with each indicator and obtain a more complete picture of adherence, a combined objective and subjective approach is ideal.

In the past two years, a systematic review (Lafata et al., 2023), a systematic review and meta-analysis (Waseem, 2022), as well as an overview of reviews (narrative synthesis) (Dang et al., 2022) were published to guide clinical practice on what interventions may improve medication adherence to OAAs. All three found the level of evidence to be too low, lacking in quality, as well as presenting a high-risk of bias among studies. Our findings are indeed consistent with their recommendations for more rigorous, large-scale studies of theory-based interventions. As interventions continue to be developed and tested, this mapping review may serve to guide the first step of their process. The findings inform current gaps in the literature and the discussion provides context. Specific takeaways include self-efficacy as a potential intervention guiding model to be further explored, the four intervention modes (behavioral, educational, medical, and technological) to consider, linking the theory used to carefully selected outcome measures, and the variability that exists in the measurement of medication adherence.

Limitations

Despite a rigorous methodology (PRISMA) and efforts to ensure transparency in coding, there are a few limitations to this review. All publications were identified, screened, and data were extracted by one author, a doctoral student, as part of their dissertation work. The defined coding framework for each category of data extracted did not go further into study details, such as sample characteristics (e.g., age, sex, or gender), as the purpose of this review was not comparative. Due to the scope of a mapping review, many publications were included with the main intervention components and testing described; however, specific study results were not included. There already exist many systematic reviews and meta-analyses on the topic, focusing exclusively on results. This mapping review is not meant to guide clinical practice in terms of what interventions may work best, but rather guide future work in the field. Last, the publications stemmed from four well-established databases with large repositories, though it is possible that studies from other databases were missed.

Conclusions

As cancer care increasingly involves precision medicine, more anticancer agents will be taken orally. As such, we are likely to see more OAA studies with new drugs. It is critical that research on this topic be thoroughly conducted, favoring theory-driven experimental and mixed-method approaches, with careful consideration to outcome selection. The rigorous accumulating evidence will help determine if (and which) supportive interventions significantly optimize OAA adherence and health-related outcomes for patients.

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Conflicts of Interest

The authors declare no conflict of interest.

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Supplementary Material

Publications included in the mapping review (N = 120): year, reference, outcome(s) of interest, and adherence measure.

Year	Reference	Outcome(s) of Interest
2022	Accordino M.K., Ulene S., Honan E., Trivedi M.S., Crew K.D., Harden E., Law, C., Hershman, D.L. (2022). Feasibility and patient satisfaction with a smartphone application to improve medication adherence among patients with breast cancer. Cancer Research, 82(4 SUPPL), no pagination. https://doi.org/10.1158/1538-7445.SABCS21-P4-11-16	• Feasibility: Intervention completion rates • Patient satisfaction: User Mobile Application Rating Scale (uMARS)
2022	Arch, J. J., Crespi, C. M., Levin, M. E., Genung, S. R., Nealis, M., Mitchell, J. L., Bright, E. E., Albright, K., Magidson, J. F., & Stanton, A. L. (2022). Randomized Controlled Pilot Trial of a Low-	• Adherence: Smart pillbox

	Touch Remotely-Delivered Values Intervention to Promote Adherence to Adjuvant Endocrine Therapy Among Breast Cancer Survivors. Annals of behavioral medicine : a publication of the Society of Behavioral Medicine, 56(8), 856–871. https://doi-org.proxy3.library.mcgill.ca/10.1093/abm/kaab118	
2022	Billings P., Shaunak N., Oakley C., Coughlan C. & Shah T. (2022). Oral Systemic Anti-Cancer Therapy (SACT) clinic to enhance patients' pathway for cancer patients. Journal of Oncology Pharmacy Practice, 28(2 SUPPL), 51-52. https://doi.org/10.1177/10781552221078082	• Adherence: Self-report via telephone call • Confidence in taking medicine and managing/recognizing side effects • Oncology Services awareness/support • Patients' satisfaction
2022	Bright, E. E., Genung, S. R., Stanton, A. L., & Arch, J. J. (2022). A mixed-methods study of the technical feasibility and patient acceptability of a real-time adherence monitor in breast cancer survivors taking adjuvant endocrine therapy. Breast cancer research and treatment, 195(3), 393–399. https://doi-org.proxy3.library.mcgill.ca/10.1007/s10549-022-06705-1	• Adherence: Smart pillbox
2022	Dennis, M., Haines, A., Johnson, M., Soggee, J., Tong, S., Parsons, R., Sunderland, B., & Czarniak, P. (2022). Cross-sectional Census Survey of Patients With Cancer who Received a Pharmacist Consultation in a Pharmacist Led Anti-cancer Clinic. Journal of cancer education : the official journal of the American Association for Cancer Education, 37(5), 1553–1561. https://doi-org.proxy3.library.mcgill.ca/10.1007/s13187-022-02196-2	• Patient perceptions and satisfaction • Adherence: Self-report via questionnaire
2022	El-Behadli, Ana F, Germann, Julie N, Pratt, Chelsea, Acosta, Dailyn, Montiel-Esparza, Raul, Alvarez, Nancy, et al. (2022). Culturally adapted motivational interviewing for pediatric acute lymphoblastic leukemia adherence: Feasibility and acceptability. Clinical Practice in Pediatric Psychology, No Pagination Specified. https://doi.org/10.1037/cpp0000447	• Feasibility and acceptability • Adherence: Self-report via questionnaire
2022	Feral, A., Boone, M., Lucas, V., Bihan, C., Belhout, M., Chauffert, B., & Lenglet, A. (2022). Influence of the implementation of a multidisciplinary consultation program on adherence to the first ever course of oral antineoplastic treatment in patients with cancer. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 28(7), 1543–1551. https://doi-org.proxy3.library.mcgill.ca/10.1177/10781552211035368	• Adherence: Medication possession ratio (MPR) • Adverse events
2022	Keating, N. L., Brooks, G. A., Landrum, M. B., Liu, P. H., Wolf, R., Riedel, L. E., Kapadia, N. S., Jhatakia, S., Tripp, A., Simon, C., Hsu, V. D., Kummet, C. M., & Hassol, A. (2022). The Oncology Care Model and Adherence to Oral Cancer Drugs: A Difference-in-Differences Analysis. Journal of the National Cancer Institute, 114(6), 871–877. https://doi-org.proxy3.library.mcgill.ca/10.1093/jnci/djac026	• Adherence: Proportion of days covered (PDC) via Medicare data
2022	Lau-Min K.S., Marini J., Shah N., Pucci D., Blauch A., Cambareri C., et al (2022). An augmented intelligence mobile phone chatbot for medication adherence and toxicity management among patients with gastrointestinal cancers on capecitabine. Journal of	• Primary: Feasibility: Completion of cohort without safety events • Secondary:

	Clinical Oncology, 40(28 Supplement), 424. https://doi.org/10.1200/JCO.2022.40.28_suppl.424	• Adherence: Self-report via questionnaire • Engagement
2022	Lichtenstein M.R.L., Patel K., Campbell P., Nguyen M.K., Harden E., Spivack J., et al (2022). Evaluation of a pharmacist-led video consultation to identify drug interactions among patients initiating oral anticancer drugs. Journal of Clinical Oncology, 40(16 Supplement 1), no pagination. https://doi.org/10.1200/JCO.2022.40.16_suppl.1592	• Drug–drug interactions • Polypharmacy • Patient satisfaction
2022	Lory, P., Perche, L., Blanc, J., Fouquier, B., Giroux, A., Thomassin, A., Devaux, M., Renaudin, A., Di Martino, C., Quipourt, V., Bengrine-Lefèvre, L., & Schmitt, A. (2022). Adherence to oral anti-cancer therapies in older patients is similar to that of younger patients. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 10781552221103547. Advance online publication. https://doi-org.proxy3.library.mcgill.ca/10.1177/10781552221103547	• Medication adherence: Patient diary • Medication adherence: Pill count
2022	McAuliff K., Rutter W., Cavers W., Shah D., Pittos E., Feczko L., et al (2022). Impact of the COVID-19 pandemic on oral oncolytic adherence. Journal of Clinical Oncology, 40(28 Supplement), 395. https://doi.org/10.1200/JCO.2022.40.28_suppl.395	Primary: • Adherence: MPR Secondary: • Digital engagement: Number of times interacted with platform
2022	Mathur, A. D., Maiers, T. A., & Andrick, B. J. (2022). Impact of a pharmacist-led telehealth oral chemotherapy clinic. American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists, 79(11), 896–903. https://doi.org/10.1093/ajhp/zxac038	Number of: • Patients seen • Referrals made • Times education sessions were conducted
2022	Park, D., Patel, S., Yum, K., Smith, C. B., Tsao, C. K., & Kim, S. (2022). Impact of Pharmacist-Led Patient Education in an Ambulatory Cancer Center: A Pilot Quality Improvement Project. Journal of pharmacy practice, 35(2), 268–273. https://doi-org.proxy3.library.mcgill.ca/10.1177/0897190020970770	• Anxiety • Patient understanding and knowledge
2022	Patel, J. V., Hughes, D. M., & Ko, N. Y. (2022). OPTIMAL Breast Cancer Care: Effect of an Outpatient Pharmacy Team to Improve Management and Adherence to Oral Cancer Treatment. JCO oncology practice, OP2200135. Advance online publication. https://doi-org.proxy3.library.mcgill.ca/10.1200/OP.22.00135	• Adherence to lab parameter monitoring • Number of interventions per patient • Overall time on therapy
2022	Porcher, L., Perron, V., Blanc, J., Kaderbhai, C. G., Tharin, Z., Schmitt, A., & Gallet, M. (2022). Smartphone-based application and nurses' interventions for symptoms monitoring in patients treated with oral anticancer agents: A 1-year follow-up in a tertiary cancer center. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 10781552221117731. Advance online publication. https://doi-org.proxy3.library.mcgill.ca/10.1177/10781552221117731	• Adherence: Self-report via questionnaire • Alerts and nursing intervention type • Symptoms: Grade and type

2022	Sargent, W., & Whalley, A. (2022). Implementation and outcomes of a pharmacist-led oral chemotherapy clinic at VA Maine Healthcare System. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 28(8), 1704–1708. https://doi-org.proxy3.library.mcgill.ca/10.1177/10781552211039501	• Adherence: MPR • Intervention type
2022	Signorelli, J., Bell, C., & Monaco, S. (2022). Oral oncolytic monitoring pilot with patient-reported outcomes and adherence assessments. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 10781552221112603. Advance online publication. https://doi-org.proxy3.library.mcgill.ca/10.1177/10781552221112603	• Adherence: Self-report via MMAS-8 • PROs: ESAS-r
2022	Skrabal Ross, X., Gunn, K. M., Suppiah, V., Patterson, P., Boyle, T., Carrington, C., Tan, S. L., Ryan, M., Joshi, R., & Olver, I. (2022). A smartphone program to support adherence to oral chemotherapy in people with cancer: Proof-of-concept trial. Asia-Pacific journal of clinical oncology, 18(5), e378–e387. https://doi-org.proxy3.library.mcgill.ca/10.1111/ajco.13656	• Acceptability and satisfaction with the intervention • Adherence: Self-report via MARS-5 • Adherence: Electronic smart pillbox • Knowledge • Side effects' presence and severity
2022	Zhang, Y., Zou, W., Wu, X., Wang, X., Zhang, M., Wu, X., Qin, H., & Zhang, M. (2022). Effect of hospital-based case management on psychosocial wellbeing and treatment outcomes in colorectal cancer patients: A quasi-experimental study. International journal of nursing practice, 28(6), e13104. https://doi-org.proxy3.library.mcgill.ca/10.1111/ijn.13104	• Adherence: Self-reported via the Morisky Adherence Questionnaire (MAQ) • Anxiety and depression • Quality of life • Symptom distress: MD-ADI • Unplanned readmission
2021	Bana M. & Szuts N. (2021). Evaluation and experience with nurse-led follow-up phone calls for oral tumor therapies. Oncology Research and Treatment, 44(SUPPL 2), 306. https://doi.org/10.1159/000518417	• Number of nurse consults and phone calls
2021	Bouleftour, W., Muron, T., Guillot, A., Tinquaut, F., Rivoirard, R., Jacquin, J. P., Saban-Roche, L., Boussoualim, K., Tavernier, E., Augeul-Meunier, K., Collard, O., Mery, B., Pupier, S., Oriol, M., Bourmaud, A., Fournel, P., & Vassal, C. (2021). Effectiveness of a nurse-led telephone follow-up in the therapeutic management of patients receiving oral antineoplastic agents: a randomized, multicenter controlled trial (ETICCO study). Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer, 29(8), 4257–4267. https://doi-org.proxy3.library.mcgill.ca/10.1007/s00520-020-05955-3	• Adherence: Self-report via the Morisky Medication Adherence Scale (MMAS-8) • Quality of Life (QoL): Eq-5D • Toxicity
2021	Brice, K.Y. (2021) Development and Evaluation of a Nurse Practioner-Directed Telephone Follow-Up Initiative to Improve Oral Chemotherapy Compliance in an Outpatient Oncology Practice. [Doctoral dissertation, Wilmington University]. ProQuest Dissertations Publishing.	• Adherence: Chart review
2021	Doolin, J. W., Berry, J. L., Forbath, N. S., Tocci, N. X., Dechen, T., Li, S., Hartwell, R. A., Espiritu, J. K., Roberts, D. A., Zerillo, J. A., & Shea, M. (2021). Implementing Electronic Patient-Reported Outcomes for Patients With New Oral Chemotherapy	• Time to first symptom assessment

	Prescriptions at an Academic Site and a Community Site. JCO clinical cancer informatics, 5, 631–640. https://doi-org.proxy3.library.mcgill.ca/10.1200/CCI.20.00191	
2021	Gallagher, Emily Elizabeth. (2021). Oral chemotherapy patient education using the multinational association of supportive care in cancer oral agent teaching tool. Dissertation Abstracts International: Section B: The Sciences and Engineering, 82(12-B), No Pagination Specified. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=psyc18&NEWS=N&AN=2021-65615-039.	• Adherence: Self-report via Adherence Starts with Knowledge scale (ASK-12)
2021	Ghiggia, A., Bianco, A., Castelli, L., Baratta, F., Birocco, N., Scaldaferri, M., Milla, P., Tesio, V., Rosso, S., Torta, R., Brusa, P., & Cattel, F. (2021). Adherence to oral chemotherapy: Evidence from a randomised clinical trial. European journal of cancer care, 30(1), e13336. https://doi-org.proxy3.library.mcgill.ca/10.1111/ecc.13336	• Adherence: Plasma drug concentration • Adherence: Self-report via questionnaire • Psychological assessment: Coping strategies, distress, personality traits
2021	Gönderen Çakmak, H. S., & Kapucu, S. (2021). The Effect of Educational Follow-Up with the Motivational Interview Technique on Self-Efficacy and Drug Adherence in Cancer Patients Using Oral Chemotherapy Treatment: A Randomized Controlled Trial. Seminars in oncology nursing, 37(2), 151140. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.soncn.2021.151140	• Adherence: Self-report via Oral Chemotherapy Adherence Scale (OCAS) • Medication adherence self-efficacy: Medication Adherence Self-Efficacy Scale (MASES)
2021	Healy R., Passey D., Pinnell D., Qualls J., Hamilton C., Burningham Z., et al (2021). Veterans on anticancer medications in rural and community environment support (VA CARES) program: A pharmacist-led telemedicine medication management program for veterans receiving oral antineoplastic therapies through the MISSION Act. Journal of Clinical Oncology, 39(15 SUPPL), no pagination. https://doi.org/10.1200/JCO.2021.39.15_suppl.1545	• Economic benefits: Cost savings or cost avoidance • Patient satisfaction • Safety: Number and type of pharmacist interventions
2021	Johengen E., Davidson A., Beekman K.W., Hecht K. & MacKler E.R. (2021). Improvement in time to oral anticancer agent follow-up. Journal of Clinical Oncology, 39(28 SUPPL), no pagination. https://doi.org/10.1200/JCO.2020.39.28_suppl.235	Time to follow-up
2021	Karaaslan-Eşer, A., & Ayaz-Alkaya, S. (2021). The effect of a mobile application on treatment adherence and symptom management in patients using oral anticancer agents: A randomized controlled trial. European journal of oncology nursing : the official journal of European Oncology Nursing Society, 52, 101969. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.ejon.2021.101969	• Adherence: Self-report via Oral Chemotherapy Adherence Scale (OCAS), • Symptoms: Memorial Symptom Assessment Scale (MSAS)
2021	Kongshaug, N., Skolbekken, J. A., Faxvaag, A., & Hofsli, E. (2021). Cancer Patients' Perceived Value of a Smartphone App to Enhance the Safety of Home-Based Chemotherapy: Feasibility Study. JMIR formative research, 5(1), e20636. https://doi-org.proxy3.library.mcgill.ca/10.2196/20636	• Patients perceptions: Focus groups/interviews (qualitative)

2021	Lin, M., Hackenyos, D., Savidge, N., Weidner, R. A., Murphy-Banks, R., Fleckner, T., Parsons, S. K., & Rodday, A. M. (2021). Enhancing patients' understanding of and adherence to oral anticancer medication: Results of a longitudinal pilot intervention. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 27(6), 1409–1421. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155220960800	• Adherence: Self-report via questionnaire • Understanding
2021	Nhean, S., Kostoff, D., Yang, J. J., Vogel, V., & Rybkin, I. I. (2021). Impact of Oral Chemotherapy Management Program on Capecitabine Toxicity Management. JCO oncology practice, 17(7), e1021–e1029. https://doi-org.proxy3.library.mcgill.ca/10.1200/OP.20.00947	Primary: • Adverse events Secondary: • Adherence: medication possession ratio (MPR) • ER visits/hospitalizations due to toxicity
2021	Psihogios, A. M., Li, Y., Ahmed, A., Huang, J., Kersun, L. S., Schwartz, L. A., & Barakat, L. P. (2021). Daily text message assessments of 6-mercaptopurine adherence and its proximal contexts in adolescents and young adults with leukemia: A pilot study. Pediatric blood & cancer, 68(2), e28767. https://doi-org.proxy3.library.mcgill.ca/10.1002/pbc.28767	• Adherence: Smart pillbox • Feasibility and acceptability: Recruitment/retention rates, cost, and technical issues
2021	Rasschaert, M., Vulsteke, C., De Keersmaeker, S., Vandenborne, K., Dias, S., Verschaeve, V., Vuylsteke, P., Brussel, I. V., Ravelingien, J., Dam, P. V., Segelov, E., & Peeters, M. (2021). AMTRA: a multicentered experience of a web-based monitoring and tailored toxicity management system for cancer patients. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer, 29(2), 859–867. https://doi-org.proxy3.library.mcgill.ca/10.1007/s00520-020-05550-6	• Compliance: Self-report via app • Toxicity
2021	Rubira, L., Leenhardt, F., Perrier, C., & Pinguet, F. (2021). Sécurisation du parcours de soins du patient sous thérapie orale en oncologie : expérimentation autour d'un lien pharmaceutique hôpital–ville [Securing the patient's care path receiving oral anticancer therapy: Experimentation around a pharmaceutical hospital-to-community liaison]. Annales pharmaceutiques francaises, 79(5), 558–565. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.pharma.2021.01.009	• Use of tools over one year: Number of pharmacists contacted and follow-ups
2021	Sun, W., Reeve, R., Ouellette, T., Stutsky, M., De Jesus, R., Huffer, M. J., & Mougalian, S. S. (2021). Novel Tool to Monitor Adherence to Oral Oncolytics: A Pilot Study. JCO clinical cancer informatics, 5, 701–708. https://doi-org.proxy3.library.mcgill.ca/10.1200/CCI.20.00151	• Adherence: Self-report via questionnaire
2020	Bowles, H., Tawfik, B., Abernathy, J., Lauer, R., Hashemi, N., & Dayao, Z. (2020). Pharmacist-Driven Oral Oncolytic Medication Education and Consent. JCO oncology practice, 16(10), e1209–e1215. https://doi-org.proxy3.library.mcgill.ca/10.1200/JOP.19.00418	• Education • Consent rate
2020	Chouinard, A., Charpentier, D., Doucet, S., Messier, C., & Vachon, M. F. (2020). From theory to practice: implementing aregimen	• Patients' level of confidence related to

	standardized, interactive education session on oral anticancer medication (OAM) for patients and their caregivers. Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer, 28(8), 3897–3904. https://doi-org.proxy3.library.mcgill.ca/10.1007/s00520-019-05236-8		
2020	Collado-Borrell, R., Escudero-Vilaplana, V., Ribed, A., Gonzalez-Anleo, C., Martin-Conde, M., Romero-Jimenez, R., Iglesias-Peinado, I., Herranz-Alonso, A., & Sanjurjo-Saez, M. (2020). Effect of a Mobile App for the Pharmacotherapeutic Follow-Up of Patients With Cancer on Their Health Outcomes: Quasi-Experimental Study. JMIR mHealth and uHealth, 8(10), e20480. https://doi-org.proxy3.library.mcgill.ca/10.2196/20480	• (MPR) • • •	Adherence: Medication possession ratio Drug-related problems and side effects Quality of life: EQ-5D Side effects
2020	Curry, M. A., Chineke, I., Redelico, T., Terrell, C., Bell, W., Flood, D., Mishra, P., LaFollette, J., Power, S., & Bernal-Mizrachi, L. (2020). Adherence to Oral Anticancer Medications After Implementation of an Ambulatory Adherence Program at a Large Urban Academic Hospital. JCO oncology practice, 16(4), e350–e356. https://doi-org.proxy3.library.mcgill.ca/10.1200/JOP.19.00167	• (MPR), ER visits, and hospitalization •	Adherence: Medication possession ratio Pharmacist interventions
2020	Deluche, E., Darbas, T., Bourcier, K., Montangon, L., Bayard, G., Caille, E., Querrioux, J., Suchaud, C., Zabaleta, S., Chaput, S., Le Brun-Ly, V., Pestre, J., Venat, L., Thuillier, F., Nevado, E., Maillan, G., Jost, J., Leobon, S., Tubiana-Mathieu, N., & Lavau-Denes, S. (2020). Prospective evaluation of an anti-cancer drugs management programme in a dedicated oral therapy center (DICTO programme). Medical oncology (Northwood, London, England), 37(8), 69. https://doi-org.proxy3.library.mcgill.ca/10.1007/s12032-020-01393-7	• up care	Nurse consults: Time to consult and follow-
2020	Greer, J. A., Jacobs, J. M., Pensak, N., Nisotel, L. E., Fishbein, J. N., MacDonald, J. J., Ream, M. E., Walsh, E. A., Buzaglo, J., Muzikansky, A., Lennes, I. T., Safren, S. A., Pirl, W. F., & Temel, J. S. (2020). Randomized Trial of a Smartphone Mobile App to Improve Symptoms and Adherence to Oral Therapy for Cancer. Journal of the National Comprehensive Cancer Network : JNCCN, 18(2), 133–141. https://doi-org.proxy3.library.mcgill.ca/10.6004/jnccn.2019.7354	• • •	Adherence: Electronic pill caps QoL: FACT-G Symptoms: MDSI
2020	Junior M.M., Pegnolato S., Lodi L.A., Marcolino M. & Fonseca R.P. (2020). Pharmacist assistance for patients on oral oncologic therapy: Impact on adherence and costs. Journal of Clinical Oncology, 38(15), no pagination. https://doi.org/10.1200/JCO.2020.38.15_suppl.e19198	•	Adherence: PDC
2020	Komatsu, H., Yagasaki, K., Yamaguchi, T., Mori, A., Kawano, H., Minamoto, N., Honma, O., & Tamura, K. (2020). Effects of a nurse-led medication self-management programme in women with oral treatments for metastatic breast cancer: A mixed-method randomised controlled trial. European journal of oncology nursing : the official journal of European Oncology	• Primary: Secondary: • • •	Adherence: MPR HRQoL: fact-b Self-efficacy: General self-efficacy scale Symptoms: Mdasi

	Nursing Society, 47, 101780. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.ejon.2020.101780	
2020	McCabe, C. C., Barbee, M. S., Watson, M. L., Billmeyer, A., Lee, C. E., Rupji, M., Chen, Z., Haumschild, R., & El-Rayes, B. (2020). Comparison of rates of adherence to oral chemotherapy medications filled through an internal health-system specialty pharmacy vs external specialty pharmacies. American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists, 77(14), 1118–1127. https://doi-org.proxy3.library.mcgill.ca/10.1093/ajhp/zxaa135	• Adherence: MPR • Adherence: PDC • Adherence: TTT
2020	Marmorat, T., Rioufol, C., Ranchon, F., & Préau, M. (2020). Encounters between medical and lay knowledge in therapeutic patient education. A qualitative study based on an oral chemotherapy program. Patient education and counseling, 103(3), 537–543. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.pec.2019.10.012	• Knowledge sharing • Self-care and psychosocial skills
2020	Menhorn T., Zarick-Jones A., Turquie M.H., Sasankan S., Hashemi-Sadraei N., Dayao Z.R., Lauer, R.C., Tawfik, B., Bowles, H., Crozier, N. (2020). Oral oncolytic education and adherence monitoring in poor, rural and minority patients. Journal of Clinical Oncology, 38(15), no pagination. https://doi.org/10.1200/JCO.2020.38.15_suppl.e19212	• Timing of education
2020	Mir O., Ferrua M., Fourcade A., Mathivon D., Duflot-Boukobza A., Dumont S.N., et al (2020). Intervention combining nurse navigators (NNs) and a mobile application versus standard of care (SOC) in cancer patients (pts) treated with oral anticancer agents (OAA): Results of CapRI, a single-center, randomized phase III trial. Journal of Clinical Oncology, 38(15), no pagination. https://doi.org/10.1200/JCO.2020.38.15_suppl.2000	Primary: • Adherence: Relative dose intensity (RDI) Secondary: • Toxicity • Response and survival • Quality of life • Pts experience (PACIC Score) • End-of-life support • Economic estimation of the use of healthcare resources
2020	Sohal M., McLarty S., Friend K.E., Johnson K.D., Johlie M., Sawicki C., et al (2020). Using digital engagement to proactively manage symptoms in patients on capecitabine. Journal of Clinical Oncology, 38(15), no pagination. https://doi.org/10.1200/JCO.2020.38.15-suppl.12079	• Adherence: PDC
2019	Babin, M., Folliard, C., Robert, J., Sorrieul, J., Kieffer, H., Augereau, P., & Devys, C. (2019). Consultations pharmaceutiques en oncologie : mise en place, bilan à un an et perspectives [Pharmaceutical consultations in oncology: Implementation, one-year review and outlooks]. Annales pharmaceutiques francaises, 77(5), 426–434. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.pharma.2019.05.001	• Number of consults and number of pharmaceutical interventions
2019	Baron J., Lombardi C.L., Yu H., Przespolewski A., Griffiths E.A., Thompson J.E., et al (2019). Benefits of a Pharmacist Led Oral Chemotherapy Monitoring Program for Patients with Chronic	• HRQoL: FACT-Leu • Perceptions/usefulness of program

	Myeloid Malignancies: A Patient Reported Outcome (PRO) Study. Blood, 134(Supplement 1), 3501. https://doi.org/10.1182/blood-2019-131629	
2019	Conliffe, B., Figg, L., Moffett, P., Lauterwasser, L., & Parsons, L. B. (2019). Impact of a formal pharmacist-run oral antineoplastic monitoring program: A pilot study in an adult genitourinary oncology clinic. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 25(4), 777–786. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155217753889	• Adherence/persistence: Chart review • Meeting recommendations: Chart review • Seeking medical care and interventions: Chart review
2019	Corbett M., Arcieri C., Dann E., Durney J., Fuller F., Leonard F., et al (2019). Oral anti-cancer therapy initiation: A standardized approach for patient care and education. JNCCN Journal of the National Comprehensive Cancer Network, 17(3-5), no pagination. https://doi.org/10.6004/jnccn.2018.7113	• Acceptability/satisfaction
2019	Durr P., Schlichtig K., Dorje F. & Fromm M.F. (2019). Medication safety in patients treated with new oral antitumor agents: A prospective, randomized investigation on the impact of intensified clinical pharmaceutical/clinical pharmacological care on patient safety and well-being (AMBORA-Study-supported by the German Cancer Aid (70112447)). Naunyn-Schmiedeberg's Archives of Pharmacology, 392(Supplement 1), S14. https://doi.org/10.1007/s00210-01-0121-6	• Number of drug-related problems • Patient satisfaction
2019	Eldeib, H. K., Abbassi, M. M., Hussein, M. M., Salem, S. E., & Sabry, N. A. (2019). The Effect of Telephone-Based Follow-Up on Adherence, Efficacy, and Toxicity of Oral Capecitabine-Based Chemotherapy. Telemedicine journal and e-health : the official journal of the American Telemedicine Association, 25(6), 462–470. https://doi-org.proxy3.library.mcgill.ca/10.1089/tmj.2018.0077	• Adherence: Pill count • Toxicity: CTCAE
2019	Gerardin E., Protesti E., Cohen-Valensi R., Martinez S. & Berod T. (2019). Chemotherapy pharmaceutical consultation: Pharmaceutical interventions after 18 months of implementation. European Journal of Hospital Pharmacy, 26(Supplement 1), A140. https://doi.org/10.1136/ejhpharm-2019-eahpconf.301	• Medication-related problems • Pharmaceutical consultations
2019	Hartwell R., Cibotti C., Roberts D., Doolin J., Yenulevich M., Trillo K., et al (2019). Impact of pharmacist-led oral antineoplastic patient education on compliance with quality oncology practice initiative (QOPI) measures. Journal of Oncology Pharmacy Practice, 25(3 Supplement), 16. https://doi.org/10.1177/1078155218823168	• Compliance with ACSO standards • Number of interventions
2019	Linder, L. A., Wu, Y. P., Macpherson, C. F., Fowler, B., Wilson, A., Jo, Y., Jung, S. H., Parsons, B., & Johnson, R. (2019). Oral Medication Adherence Among Adolescents and Young Adults with Cancer Before and Following Use of a Smartphone-Based Medication Reminder App. Journal of adolescent and young adult oncology, 8(2), 122–130. https://doi-org.proxy3.library.mcgill.ca/10.1089/jayao.2018.0072	• Adherence: Patterns via electronic pill caps

2019	Maritaz, C., Gault, N., Roy, C., Tubach, F., Burnel, S., Lotz, J. P., & CHIMORAL (2019). Impact d'une organisation régionale coordonnée pour sécuriser la prise en charge des patients sous anticancéreux oraux : CHIMORAL, une étude comparative [Impact of a coordinated regional organization to secure the management of patients on oral anticancer drugs: CHIMORAL, a comparative trial]. Bulletin du cancer, 106(9), 734–746. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.bulcan.2019.03.019	• Use of hospital for adverse events within 6 months of treatment
2019	McLarty S., Friend K.E., Chadha N., Verma S.K., Sawicki C. & Johnson K.A. (2019). Effect of secure clinical messaging on chemotherapy adherence. Journal of Clinical Oncology, 37(Supplement 15), no pagination. https://doi.org/10.1200/JCO.2019.37.15_suppl.e18542	• Adherence: MPR
2019	Montiel-Esparza R., El-Behadli A., Pratt C., Alvarez N., Saenz M.G., Germann J., et al (2019). Improving adherence to oral chemotherapy in all with motivational interviewing: A feasibility pilot. Pediatric Blood and Cancer, 66(Supplement 2), S188-S189. https://doi.org/10.1002/pbc.2771	• Knowledge • Patient ratings
2019	Moreira G., Ferreira C.G., Montella T., Vasconcellos J. & Goncalves I. (2019). P1.26 Pharmaceutical Follow-up Program for Patients with Oral Drug Treatment in Non-small Cell Lung Cancer in a Heterogeneous Health Care System. Journal of Thoracic Oncology, 14(11 Supplement 2), S1184. https://doi.org/10.1016/j.jtho.2019.09.161	• Hospitalizations • Toxicities
2019	Zukin M., Simoes Travassos Soares M.C., Gamboa N.F., Pombo F.H. & Carvalho L. (2019). Oral chemotherapy follow up on a Brazilian private health care unit. Journal of Clinical Oncology, 37(Supplement 15), no pagination. https://doi.org/10.1200/JCO.2019.37.15_suppl.e18311	• Adherence: Self-report via the Morisky Medication Adherence Scale (MMAS-8)
2018	Do L., Hiroo K. & White J. (2018). A pharmacist-monitored oral chemotherapy program at a community hospital. JACCP Journal of the American College of Clinical Pharmacy, 1(2), 314-315. https://doi.org/10.1002/jac5.1059	• Acceptability • Patients and oncologist
2018	Duffy A. & Gilmore S.A. (2018). Evaluating the inpatient of an oral chemotherapy standardized process improvement tool on patient-perceived ability to adhere to oral chemotherapy treatment plans. Journal of Oncology Pharmacy Practice, 24(2 Supplement 1), 6-7. https://doi.org/10.1177/1078155217751308	• Patient perspective: • Patient perceived ability to adhere to and handle medication safely (not explicitly stated: self-efficacy) • Barriers/facilitators to adherence
2018	Fischer N., Agboola S., Palacholla R., Atif M., Jethwani K. & Kvedar J. (2018). A 2-arm randomized pilot study to evaluate the impact of a mobile health application on medication adherence in patients on oral anti-cancer medications. Value in Health, 21(Supplement 1), S35. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed19&NEWS=N&AN=623583696.	• Adherence: Electronic pill bottle • Adherence: Self-report via the Morisky Medication Adherence Scale (MMAS)
2018	Middendorff G., Elsey R., Lounsbery B. & Chadwell R. (2018). Impact of a specialty pharmacy case management service on adherence in patients receiving oral antineoplastic agents. Journal	• Adherence: MPR

	of Oncology Pharmacy Practice, 24(5), 371-378. https://doi.org/10.1177/1078155217708022	
2018	Morgan, K. P., Muluneh, B., Deal, A. M., & Amerine, L. B. (2018). Impact of an integrated oral chemotherapy program on patient adherence. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 24(5), 332–336. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155217703792	• Adherence: MPR
2018	Muluneh B., Schneider M., Faso A., Amerine L., Daniels R., Crisp B., et al (2018). Improved Adherence Rates and Clinical Outcomes of an Integrated, Closed-Loop, Pharmacist-Led Oral Chemotherapy Management Program. Journal of Oncology Practice, 14(6), e324-e334. https://doi.org/10.1200/JOP.17.00039	• Molecular response rates • Pharmacist intervention • Patient and provider satisfaction • Patient understanding of treatment
2018	Newman V. (2018). Structured patient education utilizing the medication oral agent teaching tool for oncology patients prescribed oral chemotherapy in the outpatient setting. Supportive Care in Cancer, 26(Supplement 3), S393. https://doi.org/10.1007/s00520-018-4356-1	• Adherence: Patient diary • Knowledge: Adherence Starts with Knowledge-12 survey (ASK-12)
2018	Pavese I., Collon T., Chait Y., Cherait A., Bisseux L., MBarek B., et al (2018). Impact on treatment adherence, side effects control, patients QoL, and rehospitalization rate through new management of oral chemotherapy. Journal of Clinical Oncology, 36(15 Supplement 1), no pagination. https://doi.org/10.1200/JCO.2018.36.15-suppl.e18533	• Adherence • QoL • Toxicity • Hospitalization rates
2018	Riu, G., Gaba, L., Victoria, I., Molas, G., do Pazo, F., Gómez, B., Creus, N., & Vidal, L. (2018). Implementation of a pharmaceutical care programme for patients receiving new molecular-targeted agents in a clinical trial unit. European journal of cancer care, 27(1), 10.1111/ecc.12447. https://doi-org.proxy3.library.mcgill.ca/10.1111/ecc.12447	• Adherence: MPR • Pharmaceutical interventions
2018	Sikorskii, A., Given, C. W., Given, B. A., Vachon, E., Krauss, J. C., Rosenzweig, M., McCorkle, R., Champion, V. L., Banik, A., & Majumder, A. (2018). An Automated Intervention Did Not Improve Adherence to Oral Oncolytic Agents While Managing Symptoms: Results From a Two-Arm Randomized Controlled Trial. Journal of pain and symptom management, 56(5), 727–735. https://doi-org.proxy3.library.mcgill.ca/10.1016/j.jpainsymman.2018.07.021	• Adherence: Pill counts • Adherence: RDI • Symptoms
2017	Battis, B., Clifford, L., Huq, M., Pejoro, E., & Mambourg, S. (2017). The impacts of a pharmacist-managed outpatient clinic and chemotherapy-directed electronic order sets for monitoring oral chemotherapy. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 23(8), 582–590. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155216672314	• Adherence: Refill history • Cognitive impairment • Complexity of regimen • Depression • Missed appointments • Social support • Side effects
2017	Dolezal M.V., Leong V. & Behl R. (2017). Monitoring oral anti-cancer therapy adherence in cancer patients using web based application guided communication compared with nurse	• Quality of Life: RAND-36

	counseling in a community cancer center. Journal of Clinical Oncology, 35(5 Supplement 1), no pagination. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed18&NEWS=N&AN=618046957	
2017	Kimura, M., Go, M., Iwai, M., Usami, E., Teramachi, H., & Yoshimura, T. (2017). Evaluation of the role and usefulness of a pharmacist outpatient service for patients undergoing monotherapy with oral anti-cancer agents. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 23(6), 413–421. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155216655473	• Adherence to prescription recommendations: Self-report via questionnaire
2017	Mackler E.R., Beekman K.W., Bushey L., Gentz A., Davis K., Yarrington C., et al (2017). Utilizing patient reported outcomes for patients recieving oral chemotherapy. Journal of Clinical Oncology, 35(8 Supplement 1), no pagination. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed18&NEWS=N&AN=618100222.	% PROS complete Side effects Adherence • Self-report
2017	Northcutt L., Drenning J., Ping C.B. & Milks K. (2017). Evaluation of a customized compliance program for oral oncolytic therapy for leukemia. Value in Health, 20(5), A311. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed18&NEWS=N&AN=617599882	Adherence • MPR
2017	Pereira-Salgado, A., Westwood, J. A., Russell, L., Ugalde, A., Ortlepp, B., Seymour, J. F., Butow, P., Cavedon, L., Ong, K., Aranda, S., Breen, S., Kirsa, S., Dunlevie, A., & Schofield, P. (2017). Mobile Health Intervention to Increase Oral Cancer Therapy Adherence in Patients With Chronic Myeloid Leukemia (The REMIND System): Clinical Feasibility and Acceptability Assessment. JMIR mHealth and uHealth, 5(12), e184. https://doi-org.proxy3.library.mcgill.ca/10.2196/mhealth.8349	• Clinical feasibility and acceptability
2017	Rodriguez, G., Utate, M. A., Joseph, G., & St Victor, T. (2017). Oral Chemotherapy Adherence: A Novel Nursing Intervention Using an Electronic Health Record Workflow. Clinical journal of oncology nursing, 21(2), 165–167. https://doi-org.proxy3.library.mcgill.ca/10.1188/17.CJON.165-167	• Adherence: Self-report asked by nurse and documented in system
2017	Tokdemir, G., & Kav, S. (2017). The Effect of Structured Education to Patients Receiving Oral Agents for Cancer Treatment on Medication Adherence and Self-efficacy. Asia-Pacific journal of oncology nursing, 4(4), 290–298. https://doi-org.proxy3.library.mcgill.ca/10.4103/apjon.apjon_35_17	• Medication Adherence Self-Efficacy Scale (MASES) • Symptoms: MSAS
2017	Vella J., Wirth F., Anastasi A., Azzopardi L.M. & Serracino-Inglott A. (2017). Pharmacist-led adherence clinics for Hodgkin's and non-Hodgkin's lymphoma. International Journal of Clinical Pharmacy, 39(1), 307. https://doi.org/10.1007/s11096-016-0404-4	• Adherence: Self-report via the Morisky 8-item Medication Adherence Scale (MMAS-8)
2016	Bellomo, C. (2016). Oral Chemotherapy: Patient Education and Nursing Intervention. Journal of Oncology Navigation & Survivorship . Jul2016, Vol. 7 Issue 6, p20-27. 8p.	• Adherence knowledge: Self-report via Adherence knowledge (ASL-12)

2016	Bourmaud, A., Rousset, V., Regnier-Denois, V., Collard, O., Jacquin, J. P., Merrouche, Y., Lapoirie, J., Tinquaut, F., Lataillade, L., & Chauvin, F. (2016). Improving Adherence to Adjuvant Endocrine Therapy in Breast Cancer Through a Therapeutic Educational Approach: A Feasibility Study. Oncology nursing forum, 43(3), E94–E103. https://doi-org.proxy3.library.mcgill.ca/10.1188/16.ONF.E94-E103	• Anxiety • Knowledge • Trust in the treatment
2016	Degui E., Vinson C., Pelagatti V.C., Canonge J.-M. & Puisset F. (2016). Pharmacist counselling for outpatient treated by oral chemotherapy. International Journal of Clinical Pharmacy, 38(5), 1338. https://doi.org/10.1007/s11096-016-0347-9.	• Number of HCP communicated with
2016	Deutsch, S., Koerner, P., Miller, R. T., Craft, Z., & Fancher, K. (2016). Utilization patterns for oral oncology medications in a specialty pharmacy cycle management program. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 22(1), 68–75. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155214547664	• Adverse events • Medication discontinuations
2016	Griffiths T. & Pascoe E. (2016). Evaluation of an education program to facilitate patient adherence, toxicity monitoring and promote safety and well-being in the self administration of oral chemotherapy. Supportive Care in Cancer, 24(1 Supplement 1), S78. https://doi.org/10.1007/s00520-016-3209-z	• Patient knowledge and understanding
2016	Jean E.P., Selloum N.E., Regnier O., Poirot B., Abdelghani M.B. & Prebay D. (2016). Pharmaceutical care consultations and multidisciplinary educational program for improving adherence in oncology. International Journal of Clinical Pharmacy, 38(5), 1343. https://doi.org/10.1007/s11096-016-0347-	• Adherence: Self-report via Morisky Green scoring
2016	Lam, M. S., & Cheung, N. (2016). Impact of oncology pharmacist-managed oral anticancer therapy in patients with chronic myelogenous leukemia. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 22(6), 741–748. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155215608523	Primary: • Adherence: MPR Secondary: • Adverse event • Drug interactions • Dose adjustment • Other drugs taken • Laboratory follow-up
2016	McNamara, E., Redoutey, L., Mackler, E., Severson, J. A., Petersen, L., & Mahmood, T. (2016). Improving Oral Oncolytic Patient Self-Management. Journal of oncology practice, 12(9), e864–e869. https://doi-org.proxy3.library.mcgill.ca/10.1200/JOP.2016.011304	• Documentation in chart
2016	Murugan K., Ostwal V., Carvalho M.D., D'souza A., Achrekar M.S., Govindarajan S., et al (2016). Self-identification and management of hand-foot syndrome (HFS): effect of a structured teaching program on patients receiving capecitabine-based chemotherapy for colon cancer. Supportive Care in Cancer, 24(6), 2575-2581. https://doi.org/10.1007/s00520-015-3061-6	• Patient knowledge

2016	Page R.D., Conerly N., Ward L. & Hodges A. (2016). Novel management of oral chemotherapy adherence using Navigating Cancer's patient-reported outcomes mobile application. Journal of Clinical Oncology, 34(Supplement 15), no pagination. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed17&NEWS=N&AN=611756150.	• Adherence: Self-report via app • Symptoms and adverse events
2016	Patel, J. M., Holle, L. M., Clement, J. M., Bunz, T., Niemann, C., & Chamberlin, K. W. (2016). Impact of a pharmacist-led oral chemotherapy-monitoring program in patients with metastatic castrate-resistant prostate cancer. Journal of oncology pharmacy practice : official publication of the International Society of Oncology Pharmacy Practitioners, 22(6), 777–783. https://doi-org.proxy3.library.mcgill.ca/10.1177/1078155215612541	• Number of interventions • Overall time on therapy
2016	Rasschaert M., Helsen S., Rolfo C., Van Brussel I., Ravelingien J. & Peeters M. (2016). Feasibility of an interactive electronic self-report tool for oral cancer therapy in an outpatient setting. Supportive Care in Cancer, 24(8), 3567-3571. https://doi.org/10.1007/s00520-016-3186-2	• Adherence: Self-report via app • Toxicity
2016	Ribed, A., Romero-Jiménez, R. M., Escudero-Vilaplana, V., Iglesias-Peinado, I., Herranz-Alonso, A., Codina, C., & Sanjurjo-Sáez, M. (2016). Pharmaceutical care program for onco-hematologic outpatients: safety, efficiency and patient satisfaction. International journal of clinical pharmacy, 38(2), 280–288. https://doi-org.proxy3.library.mcgill.ca/10.1007/s11096-015-0235-8	Primary: • Adverse events • Drug-related problems • Drug interactions Secondary: • Adherence (MPR) • Patient satisfaction • Permanence
2016	Todo M., Arakawa I., Ueda S., Osaki A. & Saeki T. (2016). Collaborative pharmacotherapy involving physicians and pharmacists aimed at improving adherence in everolimus therapy for advanced/recurrent breast cancer and its outcomes. Supportive Care in Cancer, 24(1 Supplement 1), S108. https://doi.org/10.1007/s00520-016-3209-z	• QoL • Medical costs
2016	Todo M., Arakawa I., Ueda S., Osaki A. & Saeki T. (2016). Collaborative pharmacotherapy involving physicians and pharmacists aimed at improving adherence in everolimus therapy for advanced/recurrent breast cancer and its outcomes. Supportive Care in Cancer, 24(1 Supplement 1), S108. https://doi.org/10.1007/s00520-016-3209-z	Primary: • Medication persistence: Medical record • Interventions Secondary: • Adverse events • Cost • Drug interactions
2016	Wong, S. F., Bounthavong, M., Nguyen, C. P., & Chen, T. (2016). Outcome Assessments and Cost Avoidance of an Oral Chemotherapy Management Clinic. Journal of the National Comprehensive Cancer Network : JNCCN, 14(3), 279–285. https://doi-org.proxy3.library.mcgill.ca/10.6004/jnccn.2016.0033	• Medication persistence: Medical record • Types and outcomes of interventions
2016	Zhao I., Lai J., Seike B., Wilson M., Brennan L., Li T., et al (2016). Evaluation of a pharmacist-driven oral chemotherapy adherence	Adherence: MPR

	program. Journal of Oncology Pharmacy Practice, 22(2 Supplement 1), 3. https://doi.org/10.1177/1078155215624650	
2015	Boucher, J., Lucca, J., Hooper, C., Pedulla, L., & Berry, D. L. (2015). A Structured Nursing Intervention to Address Oral Chemotherapy Adherence in Patients With Non-Small Cell Lung Cancer. Oncology nursing forum, 42(4), 383–389. https://doi-org.proxy3.library.mcgill.ca/10.1188/15.ONF.383-389	• Adherence: Self-report via the Morisky Medication Adherence Scale–8 (MMAS-8) • Knowledge: Knowledge Rating Scale (KRS)
2015	Hendricks C. B. (2015). Improving adherence with oral antiemetic agents in patients with breast cancer receiving chemotherapy. Journal of oncology practice, 11(3), 216–218. https://doi-org.proxy3.library.mcgill.ca/10.1200/JOP.2015.004234	• Adherence: Medical record
2015	Ramesh A., Rajanandh M.G., Thanmayee S., Merin G.S., Suresh S. & Srinivas K.S. (2015). Impact of patient counseling on medication adherence, beliefs and satisfaction about oral chemotherapies in patients with metastatic cancer at a super specialty hospital. International Journal of Cancer Research, 11(3), 128-135. https://doi.org/10.3923/ijcr.2015.128.135	• Adherence: Self-report via MARS • Belief about Medication Questionnaire (BMQ)
2015	Sheridan B., Larmour I., Manser A., Sturm S., Allan B., Fazli O., et al (2015). Compliance enhancing patient information leaflets-a strategy to decrease patient misadventure with oral chemotherapies. Pharmacotherapy, 35(11), e250-e251. https://doi.org/10.1002/phar.1659	• Patient perceived usefulness
2015	Spoelstra, S. L., Given, C. W., Sikorskii, A., Coursaris, C. K., Majumder, A., DeKoekkoek, T., Schueller, M., & Given, B. A. (2015). Feasibility of a Text Messaging Intervention to Promote Self-Management for Patients Prescribed Oral Anticancer Agents. Oncology nursing forum, 42(6), 647–657. https://doi-org.proxy3.library.mcgill.ca/10.1188/15.ONF.647-657	• Adherence: RDI • Symptoms: Symptom Experience Inventor
2014	Bordonaro, S., Romano, F., Lanteri, E., Cappuccio, F., Indorato, R., Butera, A., D'Angelo, A., Ferraù, F., & Tralongo, P. (2014). Effect of a structured, active, home-based cancer-treatment program for the management of patients on oral chemotherapy. Patient preference and adherence, 8, 917–923. https://doi-org.proxy3.library.mcgill.ca/10.2147/PPA.S62666	• Adherence: Self-report via questionnaire • Quality of Life: EORTC QLQ-C30
2014	Campbell, C. (2014). Nursing intervention to improve adherence and safety with oral cancer therapy. Canadian Oncology Nursing Journal, 24(4), 302-309.	• Patient knowledge • Chart review: Adverse events, number of cycles, and dose reductions
2014	Clottens N. (2014). Integration of a clinical pharmacist in a multidisciplinary team for renal cell carcinoma patients treated with oral chemotherapy: Impact on adherence and financial aspects. Journal of Oncology Pharmacy Practice, 20(3 SUPPL. 1), 23-24. https://doi.org/10.1177/1078155214523700	• Adherence: Refills • Financial cost
2014	Schneider, S. M., Adams, D. B., & Gosselin, T. (2014). A tailored nurse coaching intervention for oral chemotherapy adherence. Journal of the advanced practitioner in oncology, 5(3), 163–172.	• Adherence: Pharmacy refill rates • Adherence: Self-report via questionnaire
2014	Wong, S. F., Bounthavong, M., Nguyen, C., Bechtoldt, K., & Hernandez, E. (2014). Implementation and preliminary outcomes of a comprehensive oral chemotherapy management clinic.	• Adherence: Self-report by patient, assessed on phone • Adverse events

	American journal of health-system pharmacy : AJHP : official journal of the American Society of Health-System Pharmacists, 71(11), 960–965. https://doi-org.proxy3.library.mcgill.ca/10.2146/ajhp130278	• Drug interactions • Medication errors • Symptom management
2013	Gebbia V., Bellavia M., Banna G.L., Russo P., Ferrau F., Tralongo P., et al (2013). Treatment monitoring program for implementation of adherence to second-line erlotinib for advanced non-small-cell lung cancer. Clinical Lung Cancer, 14(4), 390-398. https://doi.org/10.1016/j.cllc.2012.11.007	• Adherence: Pill count • Adherence: Self-report via Basel Assessment of Adherence Scale (BAAS)
2013	Spoelstra, S. L., Given, B. A., Given, C. W., Grant, M., Sikorskii, A., You, M., & Decker, V. (2013). An intervention to improve adherence and management of symptoms for patients prescribed oral chemotherapy agents: an exploratory study. Cancer nursing, 36(1), 18–28. https://doi-org.proxy3.library.mcgill.ca/10.1097/NCC.0b013e3182551587	• Adherence: Pharmacy refill • Adherence: Self-report • Symptom: Symptom Experience Inventory
2012	Bordonaro, S., Raiti, F., Di Mari, A., Lopiano, C., Romano, F., Pumo, V., Giuliano, S. R., Iacono, M., Lanteri, E., Puzzo, E., Spada, S., & Tralongo, P. (2012). Active home-based cancer treatment. Journal of multidisciplinary healthcare, 5, 137–143. https://doi-org.proxy3.library.mcgill.ca/10.2147/JMDH.S31494	• Adherence: Self-report via questionnaire • Healthcare utilization • QoL: EORTC QLQ-C30
2012	Khandelwal, N., Duncan, I., Ahmed, T., Rubinstein, E., & Pegus, C. (2012). Oral chemotherapy program improves adherence and reduces medication wastage and hospital admissions. Journal of the National Comprehensive Cancer Network : JNCCN, 10(5), 618–625. https://doi-org.proxy3.library.mcgill.ca/10.6004/jnccn.2012.0063	• Adherence: MPE • Side effects and adverse events
2012	Smith K. (2012). The development and evaluation of an oncology patient compliance tool. Journal of Oncology Pharmacy Practice, 18(SUPPL. 2), 11. https://doi.org/10.1177/1078155212439813	• Patient satisfaction and perceptions of program
2012	Sommers R.M., Miller K. & Berry D.L. (2012). Feasibility pilot on medication adherence and knowledge in ambulatory patients with gastrointestinal cancer. Oncology Nursing Forum, 39(4), E373-E379. https://doi.org/10.1188/12.ONF.E373-E379	• Adherence: Self-report via MMAS-8
2012	Wang Y. (2012). An analysis of using pamphlets of oral chemotherapy guidelines and calendars for patients less educated. Supportive Care in Cancer, 20(SUPPL. 1), S81. https://doi.org/10.1007/s00520-012-1479-7	• Adherence: Self-report via MMAS-8
2012	Welslau M., Haase S., Jakob A. & Marschner N. (2012). Quality assurance of oral Xeloda chemotherapy by a mobile phone application. Journal of Cancer Research and Clinical Oncology, 138(SUPPL. 1), 33. https://doi.org/10.1007/s00432-011-1144-4	• Adherence/compliance: Self-report on App
2011	Samuel L.M., Lynch D., Christie G., Collie J., McLachlan N., Jordan J., et al (2011). Nurse-lead clinics for capecitabine: A prospective audit evaluating changes in toxicity profile and efficacy. Journal of Clinical Oncology, 29(4 SUPPL. 1), no pagination. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=emed12&NEWS=N&AN=70679774.	• Adverse events • Dose reductions
2011	Simons S., Ringsdorf S., Braun M., Mey U.J., Schwindt P.F., Ko Y.D., et al (2011). Enhancing adherence to capecitabine chemotherapy by means of multidisciplinary pharmaceutical	• Adherence: Electronic pill cap (MEMS)

	care. Supportive Care in Cancer, 19(7), 1009-1018. https://doi.org/10.1007/s00520-010-0927-5	
2010	Oakley, C. Johnson & Ream, E.. (2010). Developing an intervention for cancer patients prescribed oral chemotherapy: a generic patient diary. European Journal of Cancer Care19, 21–28	• Adherence self-efficacy: Cancer Behavior Inventory Brief Form (CBI-B) • Patient perceptions • Symptom management: Memorial Symptom Assessment Scale Short Form (MSAS-SF)

Summary

Findings from this mapping review highlight the current state of knowledge regarding OAA supportive interventions and underscore the need for more rigorous studies of theoretically based interventions. Few experimental studies have been conducted to date (i.e., only 16.7% or 20 out of 120 publications were RCTs). Furthermore, as medication adherence is a learned behavior, interventions should be guided by theoretical underpinnings, yet only 17.5% reported using theory. Self-efficacy (SE) appeared to be the most promising due to its significant positive associations with medication adherence (Náfrádi, Nakamoto, & Schulz, 2017). This theory was referred to in three publications and was included as an outcome in six. When study interventions were broken down into modes/domains of focus (behavioral, educational, medical, and technological) only 3% contained all four approaches, despite promising benefits of multimodal/multidomain interventions (Dang et al., 2022; Ngandu et al., 2015; Lee et al., 2021, Izmailova et al., 2023; Rosenberg et al., 2020; Spoelstra & Sansoucie, 2015).

The mapping review also emphasized the disparity in the operationalization of medication adherence, as there exist many outcome measures, each with their own strengths and limitations. It is difficult to compare and determine how conclusive results may be, as most studies utilized either subjective (e.g., self-report questionnaires) or objective (e.g., pharmacy refills, electronic pill bottles) measures. Only 7 publications (out of 120) relied on a combination of both objective and subjective measures of medication adherence.

A limitation of this mapping review is that it was conducted by one person, the doctoral candidate. This raises the potential for interpretation bias, which may impact the reliability of the findings. However, considering that the review is central to the dissertation work, the candidate

possesses an in-depth understanding of the subject matter. This expertise may have allowed for a more discerning selection of relevant publications based on titles and abstract content than might be expected from less informed and involved reviewers.

CHAPTER 3

Preface

Chapter 3 presents the second manuscript of the dissertation, describing the research protocol with aims and measures, the intervention, as well as the methodology. The manuscript is titled **"Feasibility, acceptability, and potential effects of a digital oral anticancer agent intervention: A pilot randomized controlled trial protocol"** (Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2024), submitted to the *Journal of Medical Internet Research Protocols*.

Pilot randomized controlled trials (RCTs) are critically important as a first step in the evaluation process, helping identify and address any practical, logistical and/or methodological issues that may arise, as well as providing preliminary insights that may contribute to the potential clinical success of an intervention. Well-designed RCTs are the gold standard in the evaluation of the true efficacy and safety of an intervention (Sibbald & Roland, 1998). Key features of this study included blinded randomization – all participants being equally likely to receive the intervention (experimental group) or usual care (control group) and unaware to which group they belong to, and pre-established study aims and measures of success. The three aims include study feasibility, acceptability of the intervention, and potential effects of the intervention, each with specific objectives. In addition, the use of a mixed-method approach yielded a complementary understanding of the unfolding of the study and potential effects of the intervention.

Self-efficacy (SE) is an important concept in medication adherence (Lawrence & McLeroy, 1986; Okuboyejo et al., 2018). SE, defined as individuals' beliefs in their own ability to successfully perform a specific task related to a specific behavior, has been found to have

significant and strong relationships with health behavior change and maintenance (Bandura, 1977; Lorig, 1996, Strecher, 1986). In addition, significant relationships between SE and medication adherence have been established in several chronic conditions including HIV (Johnson et al., 2006; Simoni et al., 2006; Roura et al., 2009; Langebeek et al., 2014), hypertension (Warren-Findlow et al., 2012), and type 2 diabetes (Liu et al., 2023). Furthermore, a systematic review found positive links between SE and medication adherence in 89% (59 out of 66) studies reviewed, validating SE as a strong predictor of medication adherence (Nafradi et al., 2017). In a study among participants taking OAAs (Tokdemir & Kav, 2017), a structured patient education and follow-up intervention successfully increased medication adherence SE post intervention (66.39 vs. 71.04, $P < 0.05$).

Behavior is influenced by interactions between perceived SE and expectations surrounding behavioral outcomes; thus, medication adherence is affected by a person's belief in their capacity to consistently remember to take the medication and the belief that consistently taking the medication as prescribed will be an effective treatment to kill cancer cells. SE serves as an appropriate measure of behavior change that may occur from a particular intervention (Lawrence & McLeroy, 1986). There exist four main sources of SE: 1) mastery experiences, past positive experiences that stem from performing a task reinforcing an individual's belief in their ability to perform that task again; 2) vicarious experiences, observing or modeling others performing a task will reinforce one's belief that they can perform the task as well; 3) social persuasion, verbal encouragement and feedback from others, 4) affective states, the physiological effects combined with emotional states felt when performing a task (Bandura, 1977). The intervention designed and evaluated in this dissertation integrated these four sources into its various components. The supportive intervention included: 1) OAA informational multilingual

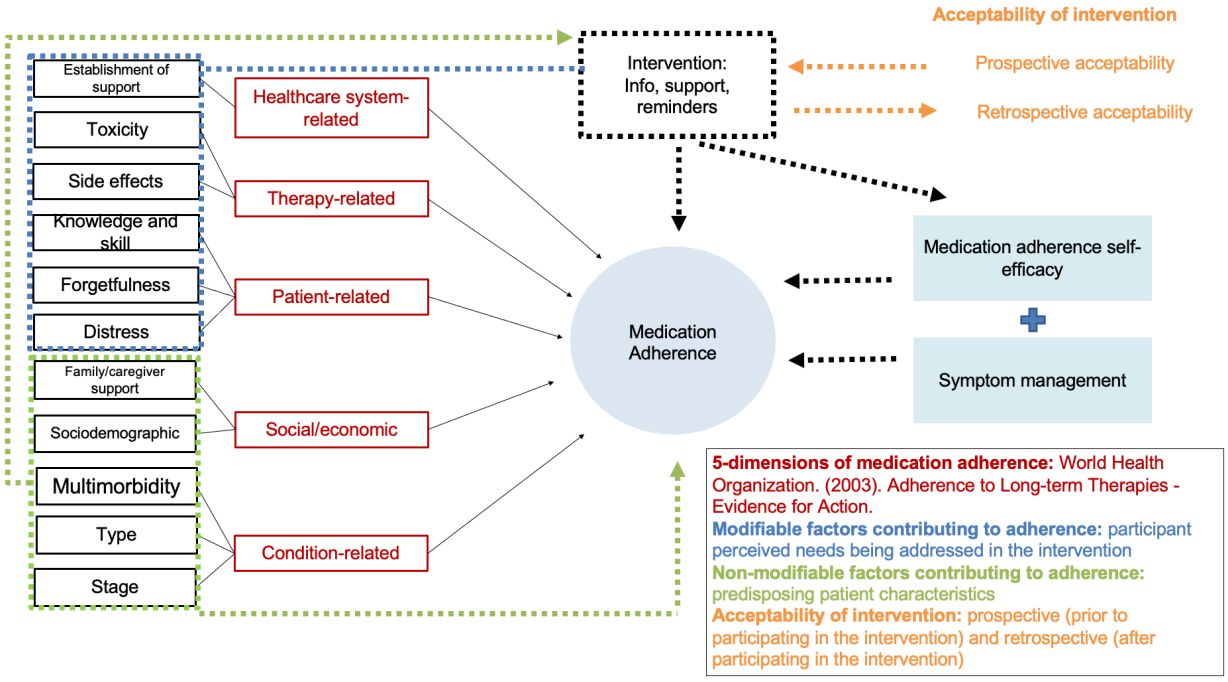
videos, 2) symptom-related e-handouts and reputable web links, 3) follow-up phone calls from a nurse, and 4) e-reminders to take OAAs. Designed to increase SE for medication adherence to OAA through direct mastery experiences (taking medication over time and e-reminders), vicarious experiences (video), verbal persuasion (phone calls), and feedback (feelings in response to management of physical and psychosocial symptoms), increasing OAA knowledge and symptom management, altogether combining to influence adherence behavior and performance. In addition, the intervention also contains four intervention modes/domains: behavioral, educational, medical, and technological.

In accordance with Sekhon et al.'s (2017) theoretical framework of intervention acceptability, this dissertation assessed two temporal perspectives of acceptability, prospective and retrospective. The prospective (pre-intervention) acceptability, anticipated by participants prior to beginning the study, influenced how they intended to interact with the intervention (Sekhon et al., 2017). The retrospective (post-intervention) acceptability demonstrated how they actually experienced it (Sekhon et al., 2017). Patient-related (e.g., forgetfulness), therapy-related (e.g., side effects), and healthcare system-related (e.g., changing the environment by providing additional resources and time) are modifiable factors targeted by the intervention, whereas social/economic and condition-related factors were non-modifiable and unique to each patient. Altogether, combined within the theoretical framework guiding the intervention (Figure 3-1).

Medication adherence was measured in two ways, self-report via Medication Adherence Report Scale (MARS-5), and pharmacy refill using the Proportion of Days Covered (PDC). To ensure optimal measurement of medication adherence, exchanges with pharmacists, nurses, and oncologists helped provide guidance. Utilizing both subjective and objective measures of medication adherence provides complementary perspectives, reduces bias, and further enhances

the breadth of understanding of medication adherence to OAAs regarding the effects of the intervention. PDC was chosen over Medication Possession Ratio (MPR) as MPR may overestimate adherence if participants refill their prescription early. In a systematic review conducted by Forbes et al. (2018), after examining 16 observational studies, 5 systematic reviews and 7 guidelines comparing various methods of calculating medication adherence and persistence, PDC was recommended as the gold standard for adherence calculation.

Figure 3-1. Theoretical Framework of study.



Manuscript #2

Feasibility, acceptability, and potential effects of a digital oral anticancer agent intervention: A pilot randomized controlled trial protocol

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Abstract

Introduction: Individuals on oral anticancer agents (OAAs) often face important challenges requiring timely informational support, monitoring, and medication management. **Objective:** This study aims to assess the feasibility, acceptability and potential effects of a comprehensive digital OAA intervention. **Methods:** A 2-arm, mixed-method pilot randomized controlled trial (RCT) is taking place at a large university-affiliated cancer centre in Montreal, Quebec, Canada. Participants (N=52) complete baseline online self-report e-questionnaires, then are randomized to the experimental group (intervention plus usual care, n = 26) or control group (usual care only, n = 26). The study intervention includes: 1) OAA informational videos, 2) OAA-related e-handouts and other supportive resources, 3) nurse-led phone call follow-ups, and 4) e-reminders to take OAAs. Study e-questionnaires are completed once a week for the first month, and every two weeks for subsequent four months, or until OAA treatment is completed. A subset (n = 20) will participate in semi-structured interviews once they complete the study requirements. Study feasibility is assessed using recruitment, retention, and response rates, as well as intervention uptake. Through e-questionnaires and exit interviews, intervention acceptability is assessed prospectively at baseline and retrospectively upon study completion. Potential effects will be assessed via medication adherence self-efficacy, medication adherence self-report, and symptom distress. **Results:** Data collection will be complete December 2023. Results are expected in early 2024. **Conclusions:** This study relies on a theory-based multimodal OAA digital intervention that is tailored to the needs of participants. Using both quantitative and qualitative data collection approaches enhances insights into study purpose. Following participants over the course of

treatment captures potential changes in processes and outcomes. **Trial registration number:** NCT04984850.

Introduction

It is estimated that 18.1 million new cancer cases are diagnosed globally every year (Sung et al, 2020; World Cancer Research Fund, 2020). Whereas survival rates vary among cancer diagnoses and countries, mortality rates for the most prevalent cancers in the developed world continue to decrease (American Cancer Society, 2022; World Cancer Research Fund, 2020). Individuals with cancer are living longer and with higher quality of life due to improvements in prevention, detection, and advancements in treatment (Brenner et al., 2020). Driven by cost-effectiveness, patient convenience, and the potential for improved patient outcomes, the use of orally administered anti-cancer drugs continues to grow, it is estimated that 60% of all new cancer medications currently in the development pipeline are oral (Iqvia Institute, 2022).

Oral anticancer agents (OAAs), having grown in popularity in the past few years, demonstrate equivalent efficacy, safety, and outcomes as IV chemotherapy, while being less invasive and easier to administer (Moreira et al., 2022). As OAAs are taken at home rather than in cancer centers or hospitals, medication management resides with patients- requiring them to be active participants in their care (Neuss et al., 2016). For OAAs to be as effective as possible and demonstrate outcomes equivalent to those seen in clinical trials, patients must follow best practices for their treatment, resulting in added responsibilities for medication management (Arber et al., 2017). These include attention to treatment adherence, as well as monitoring and management of side effects and adverse events, especially at OAA treatment onset when side

effects/toxicity may be high (Gustafson & Kettle, 2015; Jacobs et al., 2019). However, the literature to date suggests that patients often report unmet OAA-related needs, feeling helpless at home, with insufficient knowledge and support to manage their treatment, and suboptimal medication adherence (Jacobs et al., 2019; Murphy et al., 2019; Talens et al., 2021; Wei et al., 2017).

A Canadian survey conducted among individuals treated for cancer in the last 6 months (N = 3300), for instance, found that 62% of individuals on OAAs reported receiving information and guidance on potential side effects and how to manage them, compared to 74% for radiation and 76% for IV chemotherapy. In the same sample, 67% of individuals on OAAs felt their care provider did everything they could to help with side effects, compared to 73% for radiation and 76% for IV – OAAs ranking lowest for both (Rossy Cancer Network, 2018). Elsewhere, lack of OAA information and monitoring for side effects was found to be significantly related to fatigue, nausea/vomiting, change of taste, and poorly managed mouth sores (Kutlutürkan, Yurtal & Kirca, 2018).

Medication adherence, the extent to which patients "behaviour corresponds with agreed upon recommendations from their healthcare provider" (World Health Organization, 2003), denotes a collaborative relationship between the healthcare provider and patient where the patient plays an active role in taking their prescribed treatment (Mir, 2023). Medication adherence is construed as one of the primary determinants of treatment success, as unwanted alterations in dose and timing affect treatment-related outcomes (C. St-Pierre, personal communication, March 1, 2020; Early Breast Cancer Trialists' Collaborative Group, 2019; Lenhart, 2005). However, medication adherence rates for OAAs are not optimal, a systematic review of adherence to OAAs across 63 studies found rates ranging from 46 to 100% (Greer et

al., 2016). Lower OAA adherence is found to be related to decreased treatment effectiveness, increased healthcare utilization, and increased costs due to more physician visits, higher hospitalization rates, longer hospital stays, and in some cases, decreased survival (Cutler et al., 2018; DiMatteo et al., 2002; Ganesan et al., 2011; Wu et al., 2010).

As OAA development and use expand, medication adherence issues related to OAAs are increasingly of interest to multiple stakeholders, including policymakers, insurance companies, drug makers, healthcare providers, and researchers (Rosenberg et al., 2020). A systematic review of factors influencing adherence to oral anti-cancer drugs identifies three potentially modifiable factors that interventions should address: 1) side effects/toxicities, 2) forgetfulness, and 3) lack of timely information (Skrabal Ross et al., 2020). The American Society of Clinical Oncology (ASCO) and the Oncology Nursing Society (ONS) jointly released evidence-based guidelines and OAA management standards. These emphasize patient education at OAA initiation and ongoing monitoring throughout treatment to enable early identification of side effects and toxicities, thus preventing complications (Howell, 2016; Neuss et al., 2016). Consequently, there is a need for timely and accessible patient support for individuals receiving OAAs (Belcher et al., 2022).

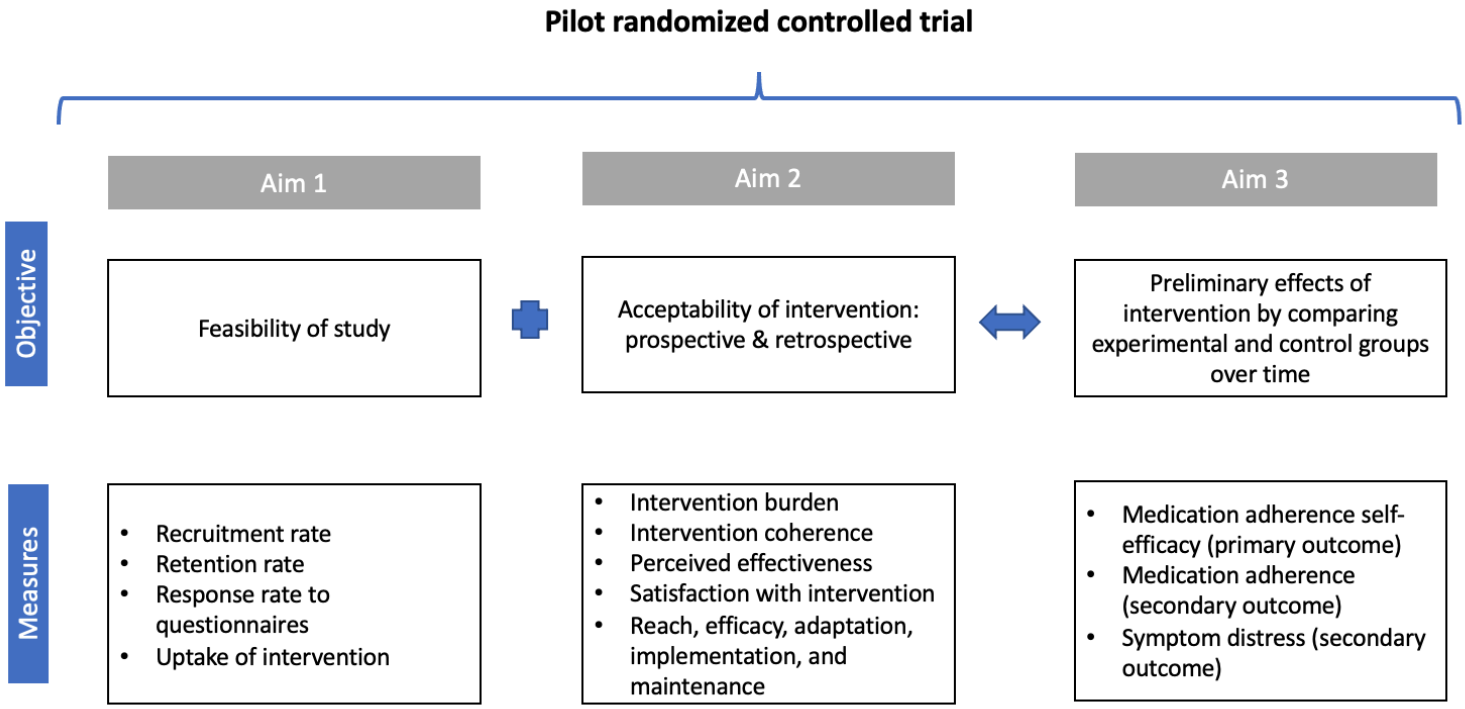
A comprehensive, personalized digital OAA intervention was developed based on Bandura's Self-Efficacy Theory (1977). Self-efficacy (SE) is identified as individuals' beliefs in their own ability to successfully perform a specific task related to a specific behaviour, for instance, remembering to take medication on time to adhere to treatment, or effectively self-managing fatigue experienced from treatment (Bandura, 1977; Lorig, 1996). A systematic review of the relationship between SE and medication adherence found a positive link between these two variables in 59 out of 66 studies reviewed (Nafradi et al., 2017). Behaviour is influenced by

the interaction between perceived SE and expectations surrounding the outcome of the particular behaviour; thus, medication adherence is affected by a patient's belief in their capacity to consistently remember to take medication and the belief that consistently taking the medication as prescribed will be an effective treatment to kill cancer cells in their body. Knowledge and self-management skills of disease care can enhance SE through expectations (Hoffman, 2013). A structured patient education and follow-up intervention for oral chemotherapy by Tokdemir & Kav (2017) successfully increased medication adherence SE after the intervention (66.39 vs. 71.04, $P < 0.05$).

Purpose of study

The aim of this pilot randomized controlled trial (RCT) is to document the feasibility and acceptability of the proposed intervention. In addition, preliminary evidence will also be provided to assess trends and potential intervention effects on medication adherence self-efficacy, medication adherence, and symptom distress. More specifically, this pilot RCT seeks to determine whether study components can be executed and delivered to the participants as planned and the intervention's potential impact on participants on OAAs. Each study aim is reviewed in turn, Figure 3-*2* provides an overview.

Figure 3-2. Aims, objectives, and measures.



Aim 1 – Feasibility of study

Feasibility is defined as "whether the intervention, study design, and procedures can be successfully executed by the researcher and delivered to the participants as planned" (Feeley et al., 2009). The constructs of feasibility to be assessed in the present study are the processes of the main study; this includes participant recruitment, retention, self-report questionnaire response, and uptake of the intervention.

Recruitment rate: Calculated by dividing the total number of participants recruited throughout the study by the number of months recruitment occurred.

- Objective: based on clinical estimates of eligible individuals, approximately 3 to 4 participants are being recruited each month.

Retention rate: Calculated by comparing the number of participants who complete baseline e-questionnaires to the number of participants who complete study exit e-questionnaires.

- Objective: Of participants who begin the study, ≥45% complete the study, reasons for drop-out will be documented, if participants wish to share (Perez-Cruz et al., 2018; Hui et al., 2013)

Response rate to study e-questionnaires: Determined by the number of completed follow-up e-questionnaire assessments for participants who complete the study.

- Objective: Of participants who complete the study, ≥ 70% complete outcome measures across all timepoints **Slightly higher than the 60% minimum required by biomedical journals (Livingston & Wislar, 2012), typical for email/online based questionnaires and patient acceptability/satisfaction research (Sitzia & Wood, 1998; Wilson et al., 2024; Yun & Trumbo, 2000)*

***Uptake of intervention*:** Nature of intervention access (modality, topics, timepoints).

- Objective: Of participants in the experimental group, ≥ 85% access at least one intervention modality (Kekale et al. 2016; Spoelstra et al. 2016).

Aim 2 – Acceptability of the intervention

The definition and measures of acceptability are based upon Sekhon et al.'s (2017) theoretical framework of the acceptability of healthcare interventions, which defines acceptability as a multi-faceted construct reflecting the appropriateness of the intervention. A key feature of this framework is the distinction between prospective, concurrent, and retrospective acceptability, emphasizing that acceptability can be assessed pre-, during, and post- intervention as all three can have an impact on participant use and access of the intervention. Although Sekhon et al.

(2017) propose seven concepts of intervention acceptability, only the three most relevant are included herein, namely intervention burden, coherence, and perceived effectiveness (Table 3-1). The other constructs, affective attitude, ethicality, opportunity costs, and self-efficacy (related to intervention) are explored indirectly in exit interviews.

Table 3-1. Constructs and definitions of acceptability (Sekhon et al., 2017).

Construct of acceptability	**Definition**
Intervention burden	Perceived amount of effort required to participate in the intervention
Intervention coherence	Extent to which participant understands the intervention and how it works
Perceived effectiveness	Extent to which the participants perceive the intervention as likely to achieve its purpose

- ***Intervention burden, intervention coherence, and perceived effectiveness*** are assessed prospectively and retrospectively using the Tariman et al. (2011) *Acceptability e-scale for web-based patient-reported outcomes in cancer care,* a mean score of 80% or higher is the objective. It evaluates the acceptability and usability of computerized health-related programs in oncology. The scale has a reliability of 0.757. It contains 6 items that are rated from 1 (very difficult) to 5 (easy to understand), with total scores ranging from 6 to 30.
- ***Post-intervention acceptability*** is assessed in exit interviews with a subsample of participants (n = 20, 10 per group) using questions based on the Glasgow et al. (1999, 2019) RE-AIM framework of Reach, Efficacy, Adoption, Implementation and Maintenance to evaluate health behavior interventions.

Aim 3 – Potential effects of the intervention

As stated in the CONSORT statement extension to randomized pilot and feasibility trials (Eldridge, 2010), pilot trials may assess potential effectiveness using surrogate outcomes. Potential effects are assessed by comparing experimental and control groups over time, from baseline, every two weeks (depending on the outcome), and post-intervention in terms of the following outcomes: medication adherence self-efficacy, medication adherence (self-report and pharmacy records), and symptom distress. It is hypothesized that over time, compared to the control group, the experimental group reports:

- Higher medication adherence self-efficacy
- Higher medication adherence
- Lower overall symptom distress

Methods and analysis

Design

A prospective, mixed-method, 2-arm pilot randomized controlled trial (RCT) is being conducted to address study aims and hypotheses.

Setting

The study takes place at a large cancer centre in a McGill University-affiliated hospital in Montreal, Quebec, Canada.

Sample

A sample of 52 participants (26 per arm) are recruited and randomized, at any moment from the decision to start OAA therapy to the completion of their first cycle.

Sample Size. Sample size calculation was undertaken using procedures provided by the software program G*Power 3 (Faul et al., 2007) upon consultation with a statistical consultant using a repeated measures ANOVA, within-between interaction with an effect size of 0.25 (standard medium effect size for ANOVA; Cohen, 1998), alpha of 0.01 and a power of 0.95. These parameters allow for adequate power in determination of potential effects of the intervention (aim 3). The sample size will test a 0.25 SD change between the experimental and control groups. The sample size accounts for a 30% attrition rate over the study duration, which was determined to be appropriate given a review of attrition rates in supportive oncology trials found a mean of 26% across 18 trials (i.e. original sample size was 36, total with added 30% attrition is 52) (Hui et al., 2013).

Inclusion criteria*:* Being 18 years or older, seen at the affiliated hospital centre**,** diagnosis of cancer, any stage, about to start or within the first cycle of oral anticancer treatment (traditional cytotoxic, targeted therapy, hormonal therapy as adjuvant treatment)**,** access to a computer/tablet/smartphone device with internet**,** ability to communicate, read, and write in English and/or French.

Exclusion criteria*:* Receiving IV chemotherapy, immunotherapy, and/or oral hormonal therapy as long-term maintenance treatment, assisting in prolonged remission, significant physical or cognitive limitations that would prevent ability to participate in study (such as the completion of e-questionnaires or uptake of the intervention) as reported by patient, primary healthcare provider, or research staff, being at imminent “end-of-life”: defined as a condition in rapid decline whereby active treatment is stopped and considered in the actual process of dying (Jerofke et al., 2014), participating in an ongoing clinical trial.

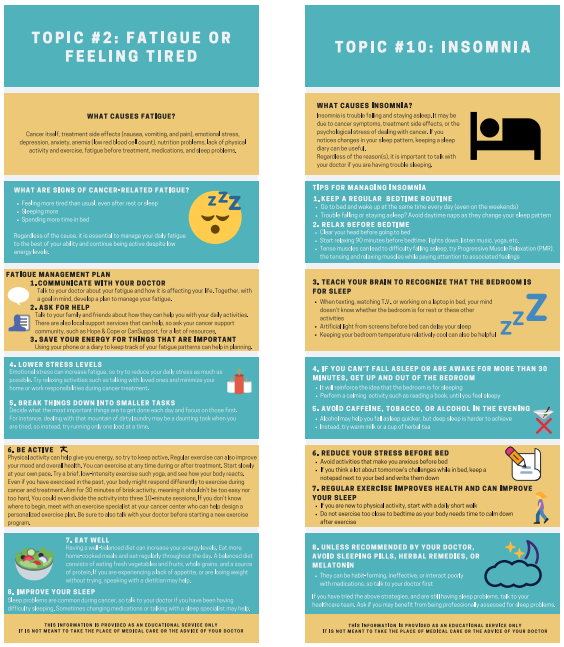
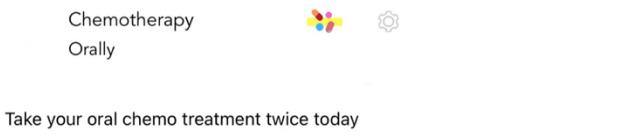
OAA intervention

All intervention components are available remotely and online on BELONG – Beating Cancer Together (https://cancer.belong.life/), a supportive digital platform with a closed community for patients, caregivers and healthcare providers at the institution to create networks and connect with other patients (Ahmed et al., 2022). Participants will be able to access the platform on their smartphone or tablet by entering an access code for the study as a closed community in the platform. As opposed to a "one-size-fits-all" approach, the study intervention accords the choice to select specific supportive means (Figure 3-3*).* The intervention was developed through rigorous multi-stakeholder consultation processes, beginning with a comprehensive review of existing OAA-related interventions and evidence by the senior author (CGL). Noting no published OAA-specific supportive interventions at the time, the senior author secured funding from the Rossy Cancer Network to design and test a OAA intervention, including videos and e-handouts addressing potential side effects and complications related to OAA intake. After meeting with Precare, a company providing educational video resources to patients (https://precare.ca/), the first and senior authors met with pivot oncology nurses, oncologists, researchers, cancer community organizations, patient partners and informal caregivers/family member representatives to get their feedback on the initial intervention. More specifically, these stakeholders provided insights on the content, duration, and overall aspects of the videos and e-Handouts, contributing to the refinement of the intervention. The final version was thoroughly reviewed by the first and senior author and subsequently integrated into an App (Belong – Beating Cancer Together platform – https://cancer.belong.life/).

1) OAA informational video. In the context of this study, an evidence-based animated video was developed. The content of the video has been reviewed by multiple stakeholders, including

healthcare providers, patients, and caregivers. The video is available to be watched in English or French, with sub-titles available in 16 languages. The video contains four parts: general information on OAAs, side effects, support, fertility & work, and symptoms. **2) Symptom management tip sheets and additional web-based resources for common physical and psychosocial concerns of oral anticancer therapy.** These e-handouts provide knowledge, facts, tips, and additional online or telephone resources. The content has been reviewed by multiple stakeholders, including healthcare providers, patients, and caregivers. E-handouts are available in French and English on the following 12 topics: pain, fatigue, drowsiness, nausea, lack of appetite, shortness of breath, depression, anxiety, sleep, fear of cancer recurrence, and work. The handouts will be available for download in PDF format**. 3) Follow up calls from oncology nurse.** Participants in the experimental group can receive a call from the oncology nurse specific to their tumor site. A participant may request a phone call at each follow-up e-questionnaire by selecting "I would like to receive a phone call from a nurse" and identifying the topics(s) they would like to discuss. The study coordinator forwards the participant's name and contact number to the nurse. The participant's symptom scores from the e-questionnaire is shared with their nurse at this time. The nurse calls the participant, speaks to them on the topic of their choice, and the interaction is documented in the patient chart as a virtual encounter. **4) Medication reminders.** Participants can receive daily e-reminder notifications on their smartphone to take their OAA medication. The e-reminders utilize pre-configured templates tailored to a 21-day cycle (14 days on/7 days off) or a 28-day cycle (21 days on/7 days off) that must users select, with options for once or twice daily reminders. Upon the conclusion of each cycle, users receive a notification prompting them to refill their prescription and reload the 21-day or 28-day cycle template.

Figure 3-3. Multimodal OAA intervention.

1	**OAA informational video** General information, side effects, support, fertility & work, and symptoms	
2	**Symptom management tip sheets and additional web-based resources** Pain, fatigue, drowsiness, nausea and vomiting, lack of appetite, shortness of breath, depression, anxiety, wellbeing, insomnia, fear of cancer recurrence, and work	
3	**Call(s) with a nurse navigator/pivot nurse** Support and dispatch	
4	**Medication reminders** Reminder notification pop-ups	
	Any combination of services above	

The study intervention has been designed to increase SE for OAA adherence through direct mastery experiences (self-management and reminders), vicarious experiences (video), verbal persuasion (phone calls), and feedback (self-management and reminders).

Participants in the control group continue to receive care as usual. This includes follow-up care with their oncologist, contact with their pharmacist and nurse, as well as access to any internal and/or external supportive services from other healthcare professionals.

Recruitment, consent, and randomization

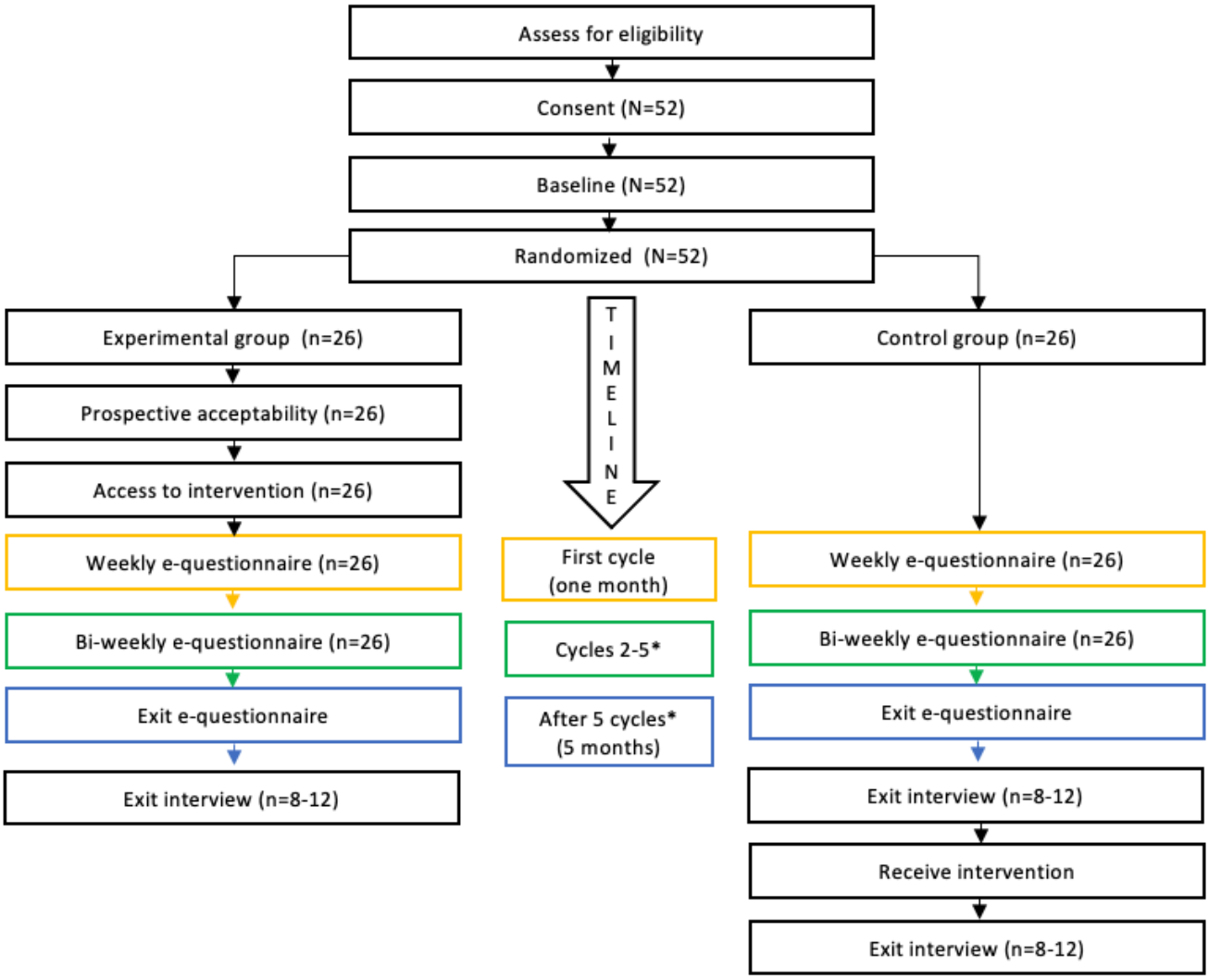
Participant recruitment occurs at the cancer centre in two ways:

1) A member of the oncology clinical care team (oncologist, radiation oncologist, nurse, and/or administrative staff) briefly explains the study and asks patients if they are interested in hearing more about the study. If yes, a member of the study team is informed (in-person, email, or telephone) and contacts the patient.

2) A study poster/postcard placed at relevant locations within the cancer centre contains the contact information (QR code, email and telephone number) of the study team. Patients contact the team directly.

Interested individuals meet with a member of the research team in-person or communicate over email/telephone. Study details are provided, and eligibility is verified. If still interested and eligible, a secure link to an electronic consent form is emailed, followed immediately by the baseline questionnaire. Participants are randomized to intervention plus usual care (experimental group, n = 26) or usual care only (control group, n = 26). Participants in the control are blinded to group assignment (Article 3.7A of TPS2; Panel on Research Ethics, 2018). Randomization sequence is determined using R, a software program, using the randomizeR package for clinical trials (https://cran.r-project.org/web/packages/randomizeR/index.html).

Figure 3-4. Diagram of study design, measurement points, and timeline.



In both groups, follow-up e-questionnaires are completed every week for the first month and two weeks for the following four months, or until treatment is completed (if less than five months). Given the considerable variability in the duration of time patients may remain on

OAAs, the study duration of five months was established as a long enough period in consultation with medical oncologists and pharmacists and was deemed appropriate for assessing the primary outcomes of feasibility and acceptability. Participants are monitored more closely during the first treatment cycle, as this period is critical for identifying potential toxicities and making necessary dosage adjustments. Furthermore, it is crucial to establish positive medication adherence behaviors early in the treatment process (Alloway, 2020). After five months or until OAA treatment is completed (if less than five months), participants complete the exit questionnaire, and a subset of participants in the experimental group (n = 10) and control group (n = 10) who have completed the study are invited to participate in a semi-structured interview. Details of each measure and timepoint are provided in Table 3-2.

All e-questionnaires are completed on Qualtrics, a secure web-based electronic data capture system licensed through McGill University (https://www.qualtrics.com/research-core/). A data management plan between the university and the affiliated hospital has been established for the study.

Medication Adherence Self-Efficacy. The Medication Adherence Self-Efficacy Scale (MASES) (Ogedegbe et al., 2003) asks about participants' level of confidence in taking their medication. The original scale contains 25 items, each rated from 1 (not at all sure) to 3 (extremely sure), with a total score calculated by summing the responses. Initially developed within the context of anti-hypertensive medication, the scale has been modified and adapted into 24-items for oncology oral agents (Tokdemir & Kav, 2017). For the current study, 4 items were removed, and 20 items are used. The four items removed were not deemed suitable for the study as they pertain to taking the medication for the rest of their life, coming home late from work, being in a public area, and being afraid of becoming dependent on the medication.

Medication adherence via Proportion of Days Covered (PDC): Participants are asked to provide the name and telephone number of their pharmacy, as well as consent for the research team to contact the pharmacy for records to calculate *Proportion of Days Covered (PDC),* the average adherence of each participant over five cycles of OAAs. PDC is defined as the "sum of the days' supply for all fills of a given drug in a particular time period, divided by the number of days in the time period" (Crowe, 2015). PDC is preferred over Medication Possession Ratio (MPR) as MPR can over-estimate adherence for participants who refill their prescription early (Crowe, 2015). PDC will be assessed as the mean PDC for each group.

Medication adherence via MARS-5. The Medication Adherence Report Scale (MARS-5 © Professor Rob Horne; Chan et al., 2020), is a validated measure of medication adherence, with a Cronbach alpha of 0.67 (Chan et al., 2020; Mahler et al., 2010). It is the shorter version of the MARS-10. MARS-5 contains five items, each rated from 1 (always) to 5 (never). Total scores range from 5 to 25. In addition, participants are asked specifics about their OAA regimen such as timing, dose delays, interruptions, and stoppages (Wyatt et al., 2015).

Symptom distress. Physical and psychosocial distress is measured using the Edmonton Symptom Assessment Scale Revised (ESAS-r). The current version, ESAS-r, has been revised to include psychosocial needs; depression, anxiety and wellbeing (Watanabe et al., 2009; Watanabe et al., 2010). Each item is rated from 0 (none) to 10 (worst possible). The scale has been tested in cancer populations (Cronbach alpha = 0.71).

Sociodemographic and medical characteristics. At baseline, participants are asked to complete a sociodemographic questionnaire identifying their sex, gender, age, work status, country of birth, languages spoken, and education. They are also asked to complete a medical questionnaire identifying their current diagnosis, cancer stage, and OAA medication.

Cancer Information-Seeking Preferences (CISP) scale. This brief self-report questionnaire based on Self-Evaluation Theory (SET) (Loiselle, 2023) contains 5 statements related to distinct preferences for cancer information. Respondents select the one that best describes how they go about getting information about their cancer: 1. Intense – I seek as much information as possible about my cancer, 2. Complementary - I seek information about my cancer that adds to what I was told, 3. Peer-focused – I seek cancer information from others diagnosed with the same cancer, 4. Minimal – I do not seek information about my cancer, 5. Guarded – Cancer is stressful enough; I only seek information about my cancer that is hopeful. In a large sample (N = 2,142), participants treated for cancer within the past six months responded to the CISP scale and patient satisfaction survey (AOPPS). 50.2% identified as complementary, 25.2% minimal, 14.4% guarded, 6.4% peer-focused, and 3.8% intense. With intense seekers rreporting lower satisfaction with cancer care (Loiselle 2019, 2023).

Knowledge. The 7-item OAA knowledge questionnaire was developed by Ahmed and Loiselle (2019) for the purpose of this study. The scale contains 7 true/false items pertaining to OAA knowledge and self-management (e.g. If I forget to take my oral chemo, I should not double the next dose).

Data Analysis

Statistical analyses will be performed using the excel, Statistical Package for the Social Sciences (SPSS) version 25 (IBM Corp, 2021) and the R Project for Statistical Computing (R project, 2023). Changes over time in MARS-5, MASES, and ESAS-r will be assessed using repeated-measures ANOVA. Between analyses will be conducted to examine differences between the two groups, within analyses will be conducted to examine how participants changed over time, and

within-between analyses will be conducted to examine how each group changed over time. OAA knowledge at baseline and study exit will be compared using paired sample t-tests. Interview data will be analyzed using thematic analysis as outlined by Braun and Clarke (2006).

Results

The study has an anticipated final sample of 41, considering 11 dropouts after consent.

Table 3-2. Study data collection.

Objective	Measure	Instrument	Number of items	Baseline	Weekly for first cycle	Every 2weeks cycles 2 - 5	Final questionnaire	Study completion
	Sociodemographic		12	x				
	Medical characteristics		7	x				
	Knowledge		9	x			x	
Feasibility of study	Recruitment rate							x
Feasibility of study	Retention rate							x
Feasibility of study	Response to online questionnaire							x
Feasibility of study	Intervention uptake							x
Prospective acceptability of intervention	Intervention burden, perceived effectiveness	Acceptability e-scale for web-based patient-reported outcomes in cancer care	3	x				
Retrospective acceptability of intervention	Intervention burden, perceived effectiveness, and intervention coherence		5				x	
Retrospective acceptability of intervention	Exit interview							x
Preliminary effects of the intervention	Medication adherence	Proportion of Days Covered (PDC)	Chart review					x
Preliminary effects of the intervention	Medication adherence	Medication Adherence Rating Scale (MARS-5 © Professor Rob Horne)	5		x	x		
Preliminary effects of the intervention	Medication adherence self-efficacy	Medication Adherence Self-Efficacy Scale (MASES)	20	x	x	x		
Preliminary effects of the intervention	Symptom distress	Edmonton Assessment Scale revised (ESAS-r)	12	x	x	x		

Discussion

Individuals receiving OAAs face many challenges, ultimately impacting medication adherence. While studies have begun to test supportive interventions, there remains a lack of theory-based interventions supported by high quality studies that follow explicit reporting guidelines (Ahmed & Loiselle, 2023). This pilot RCT seeks to inform study and intervention feasibility and acceptability from the perspective of patients. In addition, the study results will provide preliminary evidence to assess trends using potential effects of the comprehensive theory-based intervention, when compared to usual care. The use of qualitative interviews will add further insight to study findings, providing context for significance or non-significance of primary and secondary outcomes. As OAA use continues to grow in upcoming years, the study design and reporting of theory-based intervention will contribute much needed insights towards how patients on these drugs can best be supported.

The pilot RCT is only the first step of understanding, results will inform what adaptations may be needed for the intervention. Following participants over time provides an opportunity to perform finer-grain analyses to identify who may benefit most from the intervention and its specific components. If deemed acceptable and feasible, this will inform larger scale implementation and future studies focussed on efficacy.

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Competing interests

None declared.

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Summary

Conducting an RCT is challenging under the best circumstances. The COVID-19 pandemic posed an additional obstacle as it delayed study approval from the research ethics board (REB) and restricted in-person access, increased clinician workloads, and led to breaks in patient contact. Consequently, participant recruitment was slower than anticipated. To optimize participant recruitment, early ethics amendments (e.g., implementing a virtual recruitment strategy, utilizing email correspondence, and expanding inclusion criteria) were carried out. First, a virtual/online recruitment strategy was adopted, which involved distributing study recruitment postcards with QR codes, utilizing online recruitment, and digital consent forms. In addition, communication with healthcare team members– including doctors, residents, nurses, and administrative staff – was primarily conducted via email to identify eligible individuals who gave verbal consent to be contacted for the study. The protocol included distress assessment, wherein participants who reported high ratings on acute symptoms received a follow-up phone call from a nurse. This approach was expanded to include email correspondence of symptom ratings to the nurse. Last, upon consultation with healthcare team members to boost recruitment, inclusion criteria were expanded from solely systemic OAAs to include targeted and hormonal OAAs as active treatment. Ultimately, a virtual and broadened approach led to a timelier participant recruitment process.

CHAPTER 4

Preface

Chapter 4 presents the third and final manuscript of the dissertation with results from the pilot randomized controlled trial (RCT). Titled **"Acceptability, feasibility and potential effects of a multimodal remote oral anticancer agent supportive intervention: A pilot randomized controlled trial**" (Ahmed & Loiselle, 2024), this manuscript has been submitted to *the Journal of Psychosocial Oncology Research and Practice*.

The RCT had three aims. Aim 1 was to conduct study feasibility assessments, "whether the intervention, study design, and procedures can be successfully executed by the researcher and delivered to the participants as planned" (Feeley et al., 2009). These included: 1) recruitment rates – with an objective of 3 to 4 participants recruited per month, 2) retention rates - with an objective of 45% or more of participants recruited completing the study, 3) response rates – with an objective of 70% or more e-questionnaires completed throughout the study, and 4) uptake of intervention – with an objective of 85% or more of participants in the experimental group accessing at least one intervention modality.

Aim 2 involved the acceptability of the intervention, assessed prospectively (pre-intervention) and retrospectively (post-intervention), with an expected average rating of 4 (on a scale from 1 to 5, corresponding to 80%). In addition, acceptability was explored in exit interviews with participants (n = 20, 10 per group) to learn more about participant experiences with the study, intervention, and OAAs.

Aim 3 sought to document the potential effects of the study intervention, by comparing experimental and control groups over time, from baseline, every 1 to 2 weeks, and post-

intervention. The outcomes included medication adherence self-efficacy, medication adherence through self-report and pharmacy records, symptom distress for anxiety, depression, drowsiness, fatigue, fear of cancer recurrence, lack of appetite, nausea, shortness of breath, sleep, wellbeing, and work. In addition, participant OAA knowledge and Cancer Information Seeking Preferences (CISP) were captured as exploratory variables.

Manuscript #3

Acceptability, feasibility and potential effects of a multimodal remote oral anticancer agent supportive intervention: A pilot randomized controlled trial

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Abstract

Background: Guided by Self-Efficacy Theory, a multimodal remote intervention was developed to provide information and support to patients on oral anticancer agents (OAAs). The overall goal of the pilot randomized controlled trial (RCT) was to test feasibility and acceptability of study procedures and intervention, as well as potential effects of the latter. **Methods:** Participants (N = 52) were randomized to the intervention plus usual care (experimental group, n = 26) or usual care only (control group, n = 26). Participants completed e-questionnaires initially weekly (i.e., every week for first month), then bi-weekly until completing OAA treatment (up to five months). Prospective acceptability was assessed quantitatively via self-report questionnaires at baseline (prior to the intervention) and retrospectively at study completion. Feasibility assessment included participant recruitment, retention, and response rates, as well as intervention uptake. Potential intervention effects were compared between experimental and control groups over time for medication adherence self-efficacy, medication adherence, symptom distress, and OAA knowledge. A subset (n = 20, 10 per group) participated in semi-structured exit interviews further exploring study/intervention acceptability. **Results:** Participants were recruited over 17 months with an average of 3 per month. Forty-one completed the entire study (experimental group, n = 23; control group, n = 18), with 78.8% retention, and mean response rate to questionnaires of 88.4%. The mean rating for retrospective acceptability was 4.13 out of 5. Medication adherence was 97.78% for the experimental and 92.92% for the control group. Although medication adherence self-efficacy scores increased over time for the experimental group when compared to the controls, the trend did not reach statistical significance. Similarly, there were trends over time towards lower anxiety, depression, and fatigue in the experimental

when compared to the control group. Three themes emerged from exit interviews: (1) Timeliness of support across key points in the treatment trajectory and immediacy of response, (2) OAA hands-on knowledge as empowering, and (3) Connecting and feeling less alone in treatment. **Conclusion:** This promising OAA multimodal remote intervention was well received by users and initial testing supports its acceptability and feasibility. The study intervention has the potential to meet the unique informational and supportive needs of individuals on OAAs.

Introduction

Driven by cost-effectiveness, convenience, and potential to enhance health-related outcomes, the development of oral anticancer agents (OAAs), as opposed to intravenous ones, is growing rapidly (Schlichtig et al., 2019; van Dyk et al., 2021). OAAs now represent half of all cancer drugs sold in Canada (Government of Canada, 2020) and 50-60% of oncology drugs in the global development pipeline (Iqvia Institute, 2022). The management of OAAs resides mostly with the patient – who is no longer seen as a passive recipient of medical care but instead actively involved (Neuss et al., 2016). For OAAs to be as effective as possible and demonstrate outcomes equivalent to those seen in clinical trials, patients must follow best treatment practices which increases their responsibility for medication management (Bhattacharyya, 2010; Arber et al., 2017).

Medication adherence, a behavior defined as the extent to which patients "correspond with agreed upon recommendations from their healthcare provider" is the primary determinant of treatment success (World Health Organization, 2003). Non-prescribed alterations in dose and timing affect treatment-related outcomes (C. St-Pierre, personal communication, March 1, 2020; Early Breast Cancer Trialists' Collaborative Group, 2019). However, medication adherence has emerged as a central challenge for OAAs. In a systematic review of OAA adherence, 63 studies were included that assessed adherence to OAAs across various cancer diagnoses, adherence on average varied from 46 to 100% (Greer et al., 2016). Lower adherence may lead to decreased effectiveness of treatment, increased healthcare utilization, and increased costs due to more physician visits, higher hospitalization rates, longer hospital stays, and in some cases, decreased survival (Cutler et al., 2018; DiMatteo et al., 2002; Ganesan et al., 2011; Wu et al., 2010).

Despite the importance of patient adherence in OAAs, there is a lack of high-quality evidence on what interventions may be beneficial to patients, rigorous studies of theory-guided interventions are needed (Ahmed & Loiselle, 2023).

Models of adherence across various chronic conditions refer to self-efficacy as a central factor influencing adherence (Lawrence & McLeroy, 1986; Okuboyejo et al., 2018; Warren-Findlow et al., 2012). Defined as one's belief in their ability to do a specific behavior, self-efficacy, developed and described in Bandura's (1977) Self-Efficacy Theory, can be influenced by internal and social factors such as past experiences, feelings, modeling, and feedback from others. High levels of self-efficacy have been consistently linked to high medication adherence to treatment (Martos-Méndez, 2015; Nafradi et al., 2017). However, a literature review of self-efficacy in patients with chronic disease found a lack of active self-efficacy interventions in the current day, and identified patient-facing programs, and remote-delivery methods (e.g. telehealth, mobile applications, and social media) as promising strategies with the potential to promote self-efficacy (Farley, 2020).

Intervention

A comprehensive remote OAA intervention was developed for this study based on Bandura's Self-Efficacy Theory (1977). The intervention components were available remotely on BELONG – Beating Cancer Together (https://cancer.belong.life), a person-centered cancer navigation and support remote health platform available at the institution (Ahmed et al., 2022). The intervention includes: (1) OAA informational videos, (2) Symptom-related handouts and other supportive resources, (3) nurse-led phone call follow-ups, and (4) e-reminders to take OAAs. As opposed to a "one-size-fits-all" approach, it accords patients the choice to select the

information and support they receive (none, certain components, all). As medication adherence performance is influenced by the interaction between perceived self-efficacy and expectations surrounding the outcome of the behavior, medication adherence to OAAs is affected by a patient's belief in their capacity to consistently take medication as prescribed and the belief that it is an effective and manageable treatment for their cancer. The intervention, providing OAA information and support based on their preferences is expected to increase knowledge as well as physical and psychosocial symptom management. It was designed to increase self-efficacy for medication adherence to OAAs through internal factors such as direct mastery experiences (taking the medication over time and e-reminders) and feedback (feelings in response to management of physical and psychosocial symptoms), as well as social factors such as vicarious experiences (video) and verbal persuasion (phone calls). Altogether combining to influence adherence behavior and performance.

As interventions require the best current evidence to support informed decisions about patient care, the feasibility and acceptability are the first step in the process. Feasibility determines "whether something can be done, should we proceed with it, and if so, how" (Eldridge, 2016). It aids in determining how to best allocate limited available resources and effective implementation strategies for the larger scale (Pearson et al., 2020). Sekhon et al.'s (2017) theoretical framework on the acceptability of healthcare interventions, defines acceptability as a multi-faceted construct reflecting the appropriateness of the intervention (Sekhon et al., 2017). The framework distinguishes between prospective acceptability (i.e., prior to intervention access) regarding what is anticipated by participants, and retrospective acceptability (i.e., post-intervention), pertaining to what is actually experienced. The successful implementation of an intervention is dependent on both its acceptability and feasibility, which

provide valuable insights to clinicians and researchers as well as increase its likelihood of success (Sekhon et al., 2017). Pilot trials may assess potential effectiveness using surrogate outcomes, helping determine which outcomes are most sensitive to the effects of the intervention (Eldrige, 2010). To study these issues, the ON-BOARD - *Oncology Bolstering Oral Agent Reporting related to Distress*, study (Trial registration number: NCT04984850) sought to develop and test a remote multimodal OAA intervention.

Purpose of study

A pilot randomized control trial (RCT) was conducted to document feasibility and acceptability of the study and proposed intervention, as well as provide preliminary evidence of potential intervention effects.

Feasibility of the study (Aim 1) was assessed by the recruitment rate, retention rate, response rate to study e-questionnaires, and uptake of the intervention.

Acceptability of intervention (Aim 2) was assessed prospectively (pre-intervention) by anticipated intervention burden, coherence, and satisfaction, and retrospectively (post-intervention) by intervention burden, coherence, and satisfaction, as well as exit semi-structured interviews in a subset of participants.

Potential effects of the intervention (Aim 3) were assessed comparing trends between experimental and control groups over time, in terms of medication adherence self-efficacy, medication adherence, symptom distress, and OAA knowledge.

Method

Design

A prospective, mixed-method, 2-group pilot randomized controlled trial (RCT) was conducted.

Setting

The study took place at a large university-affiliated outpatient cancer centre in Montreal, Quebec, Canada.

Sample

A sample of 52 participants was recruited and randomized to the experimental group (OAA intervention plus usual care, n = 26) or control group (usual care only, n = 26), at any moment from the decision to start OAA therapy to the completion of their first cycle. A final sample of 41 completed all study requirements (experimental group n = 23, control group n = 18). A subsample (n = 20; 10 from each group) was subsequently randomly selected for exit interviews to assess acceptability (aim 2). Details on sample size calculations can be found in the study protocol (Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2023).

Inclusion criteria for study participation included being 18 years or older, being treated at the study cancer centre, having a diagnosis of cancer at any stage, about to start or within the first cycle of OAA treatment (traditional cytotoxic, targeted therapy, hormonal therapy as adjuvant treatment), having unrestricted access to a computer/tablet/smartphone device with internet, and able to understand, read and communicate in English or French. Exclusion criteria included receiving IV chemotherapy, immunotherapy, and/or hormonal therapy as long-term maintenance treatment, significant physical or cognitive limitations that would prevent ability to participate in the study (such as the completion of e-questionnaires or uptake of the intervention) as reported

by patient, primary healthcare provider, or research staff, being at imminent end-of-life - defined as a condition in rapid decline whereby active treatment is stopped and considered in the actual process of dying (Jerofke et al., 2014), and/or participating in an ongoing clinical trial.

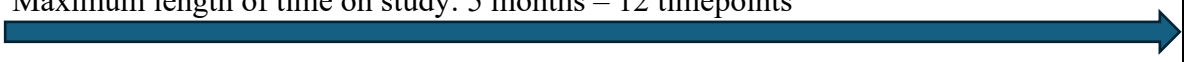
Procedures

Oncologists, nurses, and/or administrative staff briefly explained the study and ask patients starting OAAs if they were interested in hearing more about the study. If yes, the staff informed a member of the study team who contacted the patient by phone or in-person after a medical appointment to provide further details. In addition, a poster containing a brief description of the study, its requirements, contact information of the study team and a QR code to the *Remote Recruitment Tool and Form* was placed at relevant locations within the cancer centre. Interested individuals contacted the team by email or by phone and screened for eligibility. If interested and eligible, they were emailed a secure link to an electronic consent form. Once remote consent was obtained, each participant was redirected to complete baseline e-questionnaires. Participants were then randomized to either the experimental or control group. The randomization sequence was determined using R, a software program, using the randomizeR package for clinical trials (https://cran.r-project.org/web/packages/randomizeR/index.html). Every week for the first month and every two weeks for the following four months, participants received an email reminder at each timepoint and were asked to complete follow-up e-questionnaires* remotely. After five months or until OAA treatment was completed (if less than five months), participants completed the exit e-questionnaire (different from follow-ups). A subset of participants in the experimental group (n = 10) and control group (n = 10) who completed the study were invited to participate in a semi-structured interview. For those in the

experimental group, questions explored acceptability. For those in the control group, questions explored the support and care they received. The control group received a debrief form to sign and were given access to the intervention. After having access to the intervention, if interested/still relevant, participants in the control group were asked to participate once again in an-in-depth semi-structured interview, this time, questions were similar to those of the experimental group and explored acceptability of the intervention (n = 5). Data collection timepoints and corresponding questionnaires are explained in Table 4-1.

*At the end of each e-questionnaire, the contact information of the psychological oncology support program was provided along with community-based resources.

Table 4-1. Data collection timepoints and corresponding questionnaires explained.

Maximum length of time on study: 5 months – 12 timepoints 				
Timepoint	0	1-4	5-12	Study completion
Questionnaire	Baseline	Weekly follow-up for first month	Bi-weekly follow-up (every 2 weeks) for following four months, or until OAA treatment was completed (if less than five months)	Exit

Measures

Study feasibility

Recruitment rate. Calculated by dividing the total number of participants recruited throughout the study by the number of months recruitment occurred. Prior to beginning the study, based on clinical estimates of eligible individuals, approximately three to four participants recruited per month was determined to be the goal.

Retention rate. Calculated by comparing the number of participants who complete baseline questionnaires to the number of participants who complete study exit questionnaires. Prior to the beginning of the study, ≥45% of individuals completing the study was determined to be the goal (Perez-Cruz et al., 2018; Hui et al., 2013).

Response rate to e-questionnaires. Determined by the number of completed follow-up e-questionnaires for each participant who completes the study divided by the number of e-questionnaire assessments for the length of time they participated in the study (maximum length of study participation is five months – 12 timepoints, Table 4-1). 70% or more completing outcome measures across all timepoints was the goal for response rate prior to the beginning of the study. This is slightly higher than the 60% minimum required by biomedical journals (Livingston & Wislar, 2012), and more typical for email/online based questionnaires and patient acceptability/satisfaction research (Yun & Trumbo, 2000; Sitzia & Wood, 1998).

Uptake of intervention. Nature of intervention access (modality and topics) by participants in the experimental group. Of participants in the experimental group, 85% or more accessing at least one intervention modality was the goal for uptake (Kekale et al. 2016; Spoelstra et al. 2016).

Intervention acceptability

Acceptability e-scale for web-based patient-reported outcomes in cancer care. Intervention burden (perceived amount of effort required to participate in the intervention), coherence (extent to which participants understand the intervention and how it works), and perceived effectiveness (extent to which the participants perceive the intervention as likely to achieve its purpose) were explored using the Tariman et al. (2011) Acceptability e-scale for web-based patient-reported outcomes in cancer care, evaluating the acceptability and usability of computerized health-related programs in oncology (Sekhon et al., 2017). Items are rated from 1 (very difficult) to 5 (very easy), ratings for each item are summated and divided by the number of questions to calculate the overall score for acceptability ($\alpha = 0.76$). A mean rating of 4 out of 5 or higher, corresponding to 80% or higher, was the acceptability objective set for the intervention.

Qualitative semi-structured interviews. An author-generated semi-structured interview guide was developed based on the Glasgow et al. (1999, 2019) framework of Reach, Efficacy, Adoption, Implementation and Maintenance to evaluate health behavior interventions. Questions explored participants' perceptions of OAA information and support, such as "what are your general impressions of the information and support you received during your OAA treatment?". Interviews were conducted by the first author, a female doctoral candidate with previous experience conducting qualitative interviews. Participants were aware that these interviews were part of the dissertation work of the doctoral candidate. A convenience sample was used for this purpose and potential interviewees were approached in-person or over the telephone and interviews took place in-person or over the telephone. Only the researcher and the participant were present for the interview, except for one who required their sister to translate from Chinese.

Potential Effects

Medication adherence self-efficacy. The Medication Adherence Self-Efficacy Scale (MASES) developed by Ogedge et al. (2003) evaluates patient confidence in taking their medication. The original scale contains 25 items, each are rated from 1 (not at all sure) to 3 (extremely sure), a total score is calculated by summing the response. The Cronbach alpha is 0.95 for the entire scale (Ogedge et al.,2003). Initially developed within the context of anti-hypertensive medication, it has been modified for oral cancer agents (24 items) (Tokdemir & Kav, 2017). For the current study, MASES was further modified with the removal of four items deemed not suitable for OAAs. Total scores range from 20 to 60, with higher scores indicating higher medication adherence self-efficacy.

Medication Adherence. Participant self-report medication adherence was collected via the Medication Adherence Report Scale (MARS-5, Professor Rob Horne; Chan et al., 2020), a validated 5-item scale. Each item is rated from 1 to 5 with total scores ranging from 5 to 25, higher scores indicating higher medication adherence. The scale was developed and tested in various chronic populations, with Cronbach alphas of 0.67 for hypertension and 0.89 for diabetes and asthma (Chan et al., 2020).

Medication Adherence via Proportion of Days Covered (PDC). Participants were asked to provide the name and telephone number of their pharmacy, as well as consent for the research team to contact them. The pharmacy of each participant was contacted for pharmacy records to calculate PDC, the “sum of the days' supply for all fills of a given drug in a particular time period, divided by the number of days in the time period”, multiplied by 100 to give a percentage (Crowe, 2015).

Symptom Distress. Physical and psychosocial distress was measured using the Edmonton Symptom Assessment Scale Revised (ESAS-r) (Watanabe et al., 2011). ESAS, initially developed as a simple method of physical symptom assessment for pain, tiredness, drowsiness, nausea, lack of appetite, and shortness of breath for use in the cancer population (Bruera et al., 1991). The current version, ESAS-r, has been revised to include psychosocial needs; depression, anxiety, and wellbeing (Watanabe et al., 2011). ESAS has been tested in the general cancer population, with a Cronbach's alpha of 0.79 (Chang et al., 2000), and a modified version with sleep and constipation in the advanced cancer population with a Cronbach's alpha of 0.69 (Hannon et al., 2015) . Each item is rated from 0 to 10, with 0 being none and 10 being the worst possible.

Knowledge. The OAA knowledge questionnaire was developed by Ahmed and Loiselle (2019) for the purpose of this study. Questions were based on the content of the video developed for the intervention. The scale contains 7 true/false items pertaining to OAA knowledge and self-management (e.g. True or false, if I forget to take my oral chemo, I should not double the next dose – correct answer is true). Each correct response is worth 1 point, the number of correct responses are summated for a total score ranging from 0 to 7.

Additional measures

Cancer Information-Seeking Preferences (CISP) scale. The CISP scale is a brief self-report questionnaire based on Self-Evaluation Theory (SET) (Loiselle, 2023) and contains five statements related to distinct preferences for cancer information. Respondents select the statement that best describes how they go about getting information about their cancer: 1. Intense - I seek as much information as possible about my cancer, 2. Complementary - I seek

information about my cancer that adds to what I was told, 3. Peer-focused - I seek cancer information from others diagnosed with the same cancer, 4. Minimal - I do not seek information about my cancer, 5. Guarded - Cancer is stressful enough; I only seek information about my cancer that is hopeful. A large sample (N = 2,142) of individuals treated for cancer within the past six months completed the CISP scale, 50.2% identified as complementary, 25.2% minimal, 14.4% guarded, 6.4% peer-focused, and 3.8% intense (Loiselle 2019, 2023). Herein, we will compare the CISP of study participants to those of the larger sample, as CISP may influence how they interact with the intervention, given that certain of its components (e-handouts and videos) provide information.

Data analysis

Quantitative data. All descriptive statistical analyses for feasibility were performed on excel (Microsoft Corporation, 2018). Analyses for potential effects were performed using the Statistical Package for the Social Sciences (SPSS) version 25 (IBM, 2021) and the R Project for Statistical Computing (R project, 2023). For data collected at multiple timepoints through weekly/biweekly questionnaires (medication adherence self-efficacy, medication adherence, and symptom distress), between, within, and within-between analyses were conducted. Between analyses determined differences between experimental and control groups (group/intervention effect), within analyses to examine differences in how participants overall changed across time regardless of study group (time effect), and a within-between interaction of group*time to explore how each group changed over time (interaction between group/intervention and time). As this data was not normally distributed, a nonparametric method of longitudinal data analysis was utilized. Rank-based methods generated ANOVA-type statistics to determine significant

effects (Noguchi et al., 2012). Post-hoc analyses of multiple comparisons were performed if significant effects were found, and p-values were multiplied by the number of comparisons for Bonferroni-adjustment. As data for OAA knowledge was normally distributed, changes in knowledge at baseline (pre) and study completion (post) for each study group were assessed using paired samples t-test (one-sided). The differences in scores between study groups were compared using independent t-test for differences.

Qualitative data. Interviews were conducted individually, audio-recorded, and transcribed verbatim. Interview data were analyzed using thematic analysis as described by Braun & Clarke (2006), beginning with several thorough readings of participant verbatim content to familiarise the researcher with the data and the identification of significant statements relating to the phenomenon under investigation (Morrow et al., 2015). Next, significant statements were placed into initial categories and organized into broader themes and sub-themes. Themes and sub-themes were reviewed, redefined, renamed, and explored as needed until no new themes emerged from the data.

Results

Herein, we will first provide details on participant characteristics and then present findings for each aim, starting with the feasibility of the study and intervention, followed by acceptability of the intervention, and last potential effects of the intervention.

Participant characteristics

Table 4-2 presents an overview of sociodemographic and medical characteristics. The mean age of participants in the experimental and control groups respectively were 61.7 [29-85], and 64.3 [31-88]. In both groups, the majority were female, Caucasian, English-speaking, had an

undergraduate education, and are currently retired. Most participants in both groups were taking Capecitabine.

Table 4-2. Baseline sociodemographic and medical characteristics of participants (N = 41).

Participant characteristics	**Experimental (n = 23)**	**Control (n = 18)**
Age in Years, mean [range]	61.7 [29-85]	64.3 [31-88]
Gender/Sex, n (%)		
Table 4-2 (continued).		
Female	15 (65.2)	12 (66.7)
Male	8 (34.8)	6 (33.3)
Ethnicity, n (%)		
Aboriginal	0 (0)	1 (5.6)
Caribbean	2 (8.7)	0 (0)
East Asian	5 (21.8)	1 (5.6)
North African	1 (4.4)	1 (5.6)
Middle Eastern	1 (4.4)	1 (5.6)
White (Caucasian)	13 (56.5)	14 (77.8)
South Asian	1 (4.4)	0 (0)
Language, n (%)		
English	7 (30.4)	9 (50.0)
French	6 (26.1)	5 (27.8)
Other	10 (43.5)	4 (22.2)
Education, n (%)		
Elementary	1 (4.4)	1 (5.6)
High School	5 (21.7)	4 (22.2)
Technical / Vocational	3 (13)	4 (22.2)
University: Undergraduate	11 (47.8)	6 (33.3)
University: Graduate or Post-Doc	3 (13.0)	3 (16.7)
Work status, n (%)		
Caregiver	1 (4.4)	1 (5.6)

Disability	5 (21.7)	3 (16.7)
Full-Time	5 (21.7)	4 (22.2)
Part-Time	1 (4.4)	0 (0)
Retired	8 (34.8)	8 (44.4)
Self-Employed	1 (4.4)	1 (5.6)
Unemployed	2 (8.7)	1 (5.6)
Cancer Diagnosis, n (%)		
Bladder	1 (4.3)	0 (0)
Breast	8 (24.8)	5 (27.8)
Table 4-2 (continued).		
Breast + Second Primary	2 (4.3)	4 (22.2)
Colorectal	8 (24.8)	5 (27.8)
Duodenum	1 (4.3)	0 (0)
Hematological	1 (4.3)	2 (11.1)
Liver	0 (0)	1 (5.6)
Prostate	2 (8.7)	0 (0)
Thyroid	0 (0)	1 (5.6)
Cancer Stage, n (%)		
Stage 0	1 (4.3)	0 (0)
Stage 1	2 (8.7)	0 (0)
Stage 2	3 (13.0)	1 (5.6)
Stage 3	11 (44.0)	0 (0)
Stage 4	4 (17.4)	4 (22.2)
Participant doesn't know	11 (47.8)	13
OAA type, n (%)		
Abemaciclib	1 (4.3)	1 (5.6)
Apalutamide	1 (4.3)	0 (0)
Capecitabine	17 (73.9)	10 (55.6)
Cyclophosphamide	0 (0)	2 (11.1)
Dasatinib	1 (4.3)	0 (0)
Enzalutamide	1 (4.3)	0 (0)
Lenvatinib	0 (0)	1 (5.6)

Nilotinib	0 (0)	1 (5.6)
Palbociclib	1 (4.3)	0 (0)
Ribociclib	1 (4.3)	2 (11.1)
Zanubrutinib	0 (0)	1 (5.6)

Feasibility

One hundred and forty individuals were assessed for eligibility, 51 did not meet eligibility criteria, 37 were eligible but no longer interested. 52 were consented and randomized. 11 individuals dropped out, leading to a final sample size of 41. Details of recruitment are presented in a CONSORT (Moher et al., 2010) flowchart in Figure 4-1.

Recruitment rate. Study recruitment began in January 2022 and ended May 2023, lasting 17 months. Based on enrollment numbers (as seen in Figure 4-1), each month, 8.2 individuals were assessed for eligibility, and 3 were recruited and randomized.

Retention rate. Based on participant flow as presented in Figure 4-1, 52 participants were recruited and 41 completed the study, this presents an overall 78.8% retention rate. The retention rate for the experimental group is higher at 88.5% and the control group is 69.2%. Reasons for drop-out were documented: change of treatment (n = 4), feeling overwhelmed (n = 3), too busy (n = 2), feeling too sick (n = 2).

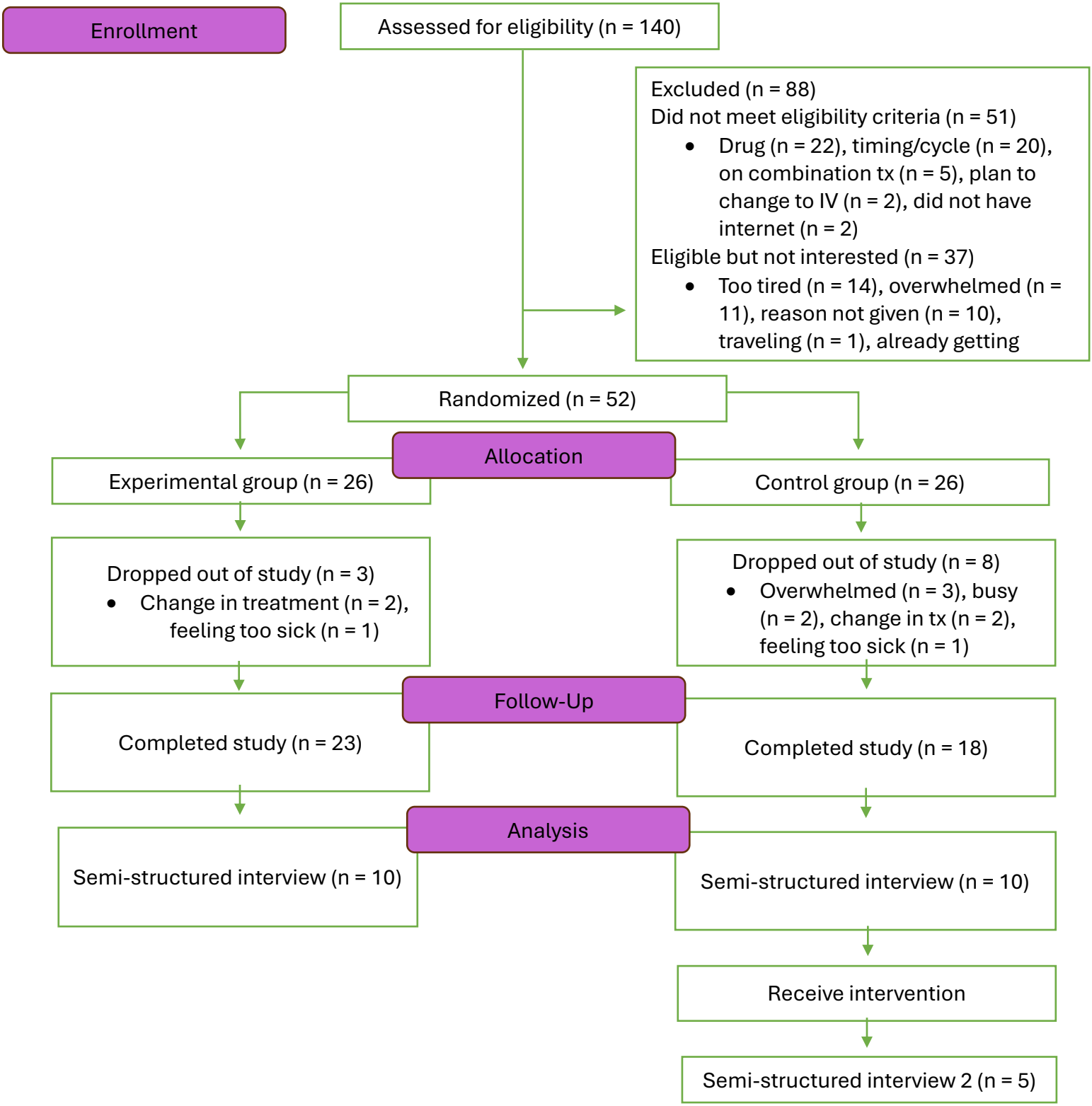
Response rate to e-questionnaires. Of the 41 participants who completed the study, the mean length of time to study completion was three months and two weeks (out of potential five months), corresponding to 9 out of 12 follow-up e-questionnaire timepoints. The mean response rate for all participants was 88.4%.

For the 23 participants in the experimental group, the mean length of time to study completion was three months and two weeks, corresponding to 9 out of 12 follow-up e-

questionnaire timepoints. The mean number of questionnaires completed was 8 (out of 9). The mean response rate for experimental participants was 90.6%.

For the 18 participants in the control group, the mean length of time to study completion was four months, corresponding to 10 out of 12 follow-up e-questionnaire timepoints. The mean number of questionnaires completed was 8 (out of 10). The mean response rate for control participants was 86.9%.

Figure 4-1. CONSORT (Moher at al., 2010) Flow Diagram.



Uptake of intervention. Of the 23 participants in the experimental group, the BELONG platform was accessed by 20 participants (87%) in the experimental group. The videos in the platform were accessed a total of 46 times (34 English, 12 French). The e-handouts were accessed 96 times (55 English, 41 French), the most frequently accessed content determined by the total number of views in the platform were (1) Fatigue, (2) Wellbeing, (3) Anxiety, (4) Fear That Cancer Will Return, and (5) Work. The e-reminders were used 2 times, and 3 participants requested a phone call from the nurse.

Table 4-3. Summary of feasibility objectives and results for study.

Feasibility measure	**Objective**	**Result**
Recruitment rate	3 to 4 participants recruited per month	3 participants recruited per month
Retention rate	≥45% will complete study	Overall: 78.8% Experimental: 88.5% Control: 69.2%
Response rate to questionnaires	≥ 70% complete outcome measures across all timepoints	Overall: 88.4% Experimental: 90.6% Control: 86.9%
Uptake of intervention (Experimental group only, n = 23)	≥ 85% access at least one intervention modality	87% accessed platform o Number of times video accessed: 46 o Number of times e-handouts accessed: 96 o Most frequently accessed e-handouts: Fatigue, wellbeing, anxiety, fear that cancer will return, and work. o Number of e-reminders used: 2 o Number of phone calls requested: 3

Acceptability

The mean rating for prospective (pre-intervention, anticipated) acceptability was 3.71 out of 5. The anticipated perceived effectiveness of the information and support offered by the intervention and its burden both rated 4.13 out of 5, and the anticipated perceived effectiveness of reminders rated lowest at 2.87. Table 4-4 presents details for each prospective acceptability construct, question, and rating. The mean rating for retrospective (post-intervention, experienced) acceptability was 4.13 out of 5. The highest rated constructs were the experienced intervention burden of e-handouts, video(s), and intervention burden overall at 4.48, 4.25 and 4.48, respectively, out of 5. Table 4-5 presents details for each retrospective acceptability construct, question, and rating.

Table 4-4. Prospective (pre-intervention, anticipated) acceptability collected at baseline (n = 23).

Construct of acceptability	**Question**	**Min**	**Max**	**Mean (SD)**
Perceived effectiveness: treatment management	How helpful do you anticipate the information and support offered in this study will be in helping you manage your treatment?	1	5	4.13 (1.25)
Perceived effectiveness: reminders	How helpful do you anticipate the information and support offered in this study will be in reminding you to take your medication?	1	5	2.87 (1.18)
Intervention burden	Do you anticipate the amount of time you will spend reading and watching video(s) in this study will be acceptable?	3	5	4.13 (0.63)
	Mean score			3.71 (0.73)

Table 4-5. Retrospective (post-intervention, experienced) acceptability collected at study completion (n = 23).

Construct of acceptability	**Question**	**Min**	**Max**	**Mean (SD)**
Intervention burden: overall	How easy was it for you to access and use the information and support offered in the study?	2	5	4.48 (0.78)
Intervention coherence	How understandable was the information in the e-handouts?	3	5	4.13 (0.54)
Intervention coherence	How understandable was the information in the videos?	3	5	4.13 (0.74)
Perceived effectiveness: treatment management	How helpful was the information and support offered in this study in helping you manage your treatment?	2	5	3.88 (0.94)
Perceived effectiveness: reminding	How helpful was the information and support offered in this study in reminding you to take your medication?	2	5	3.75 (1.03)
Intervention burden: e-handouts	Was the amount of time you spent reading the information on the e-handouts acceptable?	3	5	4.48 (0.90)
Intervention burden: Video(s)	Was the amount of time you spent watching the video(s) acceptable?	3	5	4.25 (0.72)
Overall satisfaction	How would you rate your overall satisfaction with the information and support offered in this study?	1	5	4.13 (0.98)
	Mean score			4.13 (0.22)

Semi-structured interviews. 20 participants, 10 per group took part in semi-structured exit interviews. Three main themes along with several sub-themes emerged from the data: (1) Timeliness - of experimental support across key points in the treatment trajectory and the immediacy of response, (2) OAA hands-on knowledge as empowering – for patients, family members, and caregivers, and (3) Connecting and feeling less alone in treatment. All resulting themes were present among both experimental and control groups although varying in content of the quotes. Each theme is reviewed in turn.

Theme 1: Timeliness

Sub-theme 1.1 Support offered at different points in the treatment trajectory.

Many participants in the experimental group discussed the timing of the intervention. They described accessing the intervention prior to starting OAA treatment and the reassurance it provided. One participant stated “Starting a new treatment, you've got this fear - it (video) takes it away. It gave me lots of info. Every little thing that bothered me, I was able to see it was normal. It reassured me." (P7, female, 72 years old, experimental). In contrast, many participants in the control group expressed wishing they had access to more information when starting treatment, the difficulties and fears they faced because of it. “Had I known more about them (side effects), maybe I would have been more accepting. It was very scary in the beginning.” (P13, female, 72 years old, control). Once they were given access to the intervention, those in the control group wished they had received it earlier. In her first semi-structured interview, one participant in the control group had expressed being content with usual care and not needing anything additional. However, once she was given access to the intervention, in her second semi-structured interview she stated “I think the video is very important for people starting treatment. I

would have liked to have had it at the beginning." (P6, female, 59 years old, control, translated from French).

At the same time, some participants talked about the usefulness of accessing the intervention at later times. For a few, the beginning of a new treatment was an overwhelming time, and some topics were not completely relevant to them. "The first month and a half, we were completely absorbed in processing the news. There are topics that at the beginning, there is no point in reading about." (P10, male, 57 years old, experimental, translated from French). While others knew that their information needs may change over time and anticipated the intervention being there for them, "I still don't know what the long-term effects will be. So, I will be going back to this if I need to." (p49, female, 52 years old, experimental).

Sub-theme 1.2: Immediacy of response.

Participants in the experimental group where pleased by how they were able to request a call from a nurse, the immediacy of the response, and the void it filled in the healthcare system. "In my experience, it is very difficult to reach the doctor or nurse if you are not dying. I had a diarrhea problem and the nurse contacted me in less than 48 hours. This addresses a major communication problem between the patient and the care provider." (P9, male, 68 years old, experimental, translated from French). The calls were especially timely considering the rapid onset of side effects and symptoms and the home-based nature of treatment. "When you take oral chemo, you're home alone, and you're in charge. It's really serious because at any time you can have side effects. If I hadn't gotten a call from (the nurse), I don't know what I would have done. We only see the doctor every 4 weeks, but the rest of the time, we are on our own. I started having serious side effects. Thanks to the study, the nurse contacted me. I wasn't all alone. It was quick." (P1, male, 85 years old, experimental, translated from French). Those who did not

request calls, noted that being able to access the information online at any time, provided immediate answers to questions as they arose. “When I had questions, the answers were there, and the information was good.” (P12, female, 61 years old, experimental, translated from French).

In contrast, in the control group, despite being provided with the telephone number of a nurse as part of usual care, many expressed not wanting to bother calling or asking too much of the healthcare system due to its perceived shortcomings. “Well to be perfectly honest, I depend a lot on my own. Because it's hard to get people. They are not on the phone, and they say they will call you back, but they don’t. You know, the hospitals are short staffed, and there's a lot of pressure on everybody. So, you know what? I don't want to be that individual who is needy.” (P36, female, 57 years old, control). Some in the control group described starting to experience side effects at home but waiting until the appointment with their oncologist to discuss it. One participant described having diarrhea but not informing anyone. “At the beginning, I did very well. I felt no symptoms. Then I started having diarrhea. I only told my doctor later…” (P3, female, 67 years old, control). Another participant described questions arising at home, and how not having an immediate or timely response was anxiety provoking. “You take it (OAA pill) within 30 minutes after eating. So, you're on a full stomach. But then I get anxious, I only had a bowl of soup. Those days when you're nauseous, that's all you have, a bowl of chicken soup. Is that enough to make the pill work? Some days for lunch I have yogurt. Is that enough? There is no one to ask in that moment.” (P13, female, 72 years old, control).

Theme 2: OAA hands-on knowledge as empowering.

Sub-theme 2.1: Patient empowerment

In the experimental group, participants noted how information was practical and provided to them in an easy to access manner. “It covers quite a lot of varied, practical, and important subjects. It shows how to approach all this.” (P10, male, 57 years old, experimental, translated from French). While they acknowledged that their healthcare team could be a source of information, participants noted the complementary nature of this intervention. They liked how the information was separated into folders by topic and preferred having only the relevant information distilled for them, rather than having to seek it out on their own online. “I'm not going to say that it's necessarily new, because it's similar information from the doctor and nurse. But it's information to help situate yourself. It's a very, very good tool. It was really easy to navigate and fast. Compared to going on the internet, I preferred this.” (P12, female, 61 years old, experimental, translated from French). Many participants referred to the intervention as a “tool” and appreciated the videos being accessible in multiple languages.

Participants in the control group relied primarily on their doctor and healthcare team to meet their information needs but admitted to having to go online to fill in the gaps. “The information my doctor gave me was minimal. I went to look on the internet. I’m usually totally against it, but I had nothing else, so I did it anyway. I read about the side effects and it’s a good thing I did.” (P19, female, 77 years old, control, translated from French). Most in the control group spoke of feeling overwhelmed or having negative thoughts because of information found online. One participant noted how online searches made them anxious “Like when I go on Google and start reading about different things about cancer and treatment, I always feel bad. I start thinking am I going to live?” (P3, female, 67 years old, control).

When those in the experimental group were asked what part of the intervention was most essential, 40% stated that videos and e-handouts were both useful and complementary and they

could not pick one, 30% responded videos, 20% e-handouts, and 10% nurse call. No one chose the e-reminders.

Sub-theme 2.2: Family and informal caregiver empowerment

Sharing the intervention with their family and/or caregiver(s) was important to some participants. One spoke of her husband taking care of her and the video being useful to him as well, "When I was running into an issue, I sat down with my husband and we went over it (the video) together." (P7, female, 72 years old, experimental). Another participant mentioned how her husband was not able to make it to her appointments because of work commitments, and how sharing the video with him was easier than having to re-state everything the doctor had said (P49, female, 52 years old, experimental). In the control group, when offered the intervention, a few participants were not interested but asked to share it with family members. One spoke of sharing it with her daughter "My daughter kept saying how she really liked the information." (P6, female, 59 years old, control).

Theme 3: Connecting and feeling less alone in treatment.

Participants in both groups acknowledged that taking OAAs made them feel isolated. One spoke of loneliness because her family and friends perceived her illness to be less serious as she was on oral rather than IV treatment "It can be overwhelming because they don't understand how serious it is. I have metastatic breast cancer. If I stop taking these medications, I'll die. They don't get it. It's very hard because it's a very lonely path." (P40, female, 41 years old, control). The support provided by the intervention was noted by many as being helpful in feeling less alone. "It really gave me support. I got so much from it. I feel so alone and just reading and seeing other people like me. It was an amazing feeling." (P11, female, 51 years old, experimental).

Completing follow-up questionnaires served as a reminder to take medication, symptoms to be alert for, and additional resources (contact information of the psychological oncology support program and telephone numbers of community-based resources) offered at the end of each questionnaire were appreciated. Those in the control group said simply participating in the study provided the additional support they felt they needed. “And it was so nice to get the little email reminder. I felt supported through the questionnaire because it gave me numbers to contact.” (P40, female, 41 years old, control). For some in the control group, completing the questionnaires gave them the feeling of being followed more closely “I found that being part of your study, I felt well supported. With each questionnaire, I felt less alone. I knew you were there to follow me.” (P21, female, 88 years old, control, translated from French).

Potential effects

As the mean number of study questionnaires completed in both study groups was 8 timepoints, corresponding to 3 months of study participation, this was chosen as the length of time for between, within, and interaction effects analyses. Timepoint 0 corresponds to baseline, timepoints 1 to 4 are weekly questionnaires, and 5 to 8 are bi-weekly. 15 participants from the experimental group and 12 from the control group (n = 27) were included in these analyses as their length of time in the study corresponded to 8 timepoints or more, the others were excluded from these analyses as their length of participation in the study was shorter (1-7 timepoints). Table 4-6 represents a summary of group effects, time effects, the interaction between group and time for each dependent variable considered in the study.

Table 4-6. Summary of between, within, and interaction effects for medication adherence self-efficacy, medication adherence (self-report), anxiety, depression, drowsiness, fatigue, fear of cancer recurrence, lack of appetite, nausea, shortness of breath, sleep, wellbeing, and work (n = 27).

Dependent Variable	**Effects p-values**			**Pairwise Significant Differences**
	Group	**Time**	**Interaction (Group:Time)**	**Adjusted p-values among timepoints** *p < 05, **p < .01, ***p < .001
Medication Adherence Self-Efficacy	0.78	<.001 ***	0.20	Time 0 (Baseline) < Time 4 ** Time 0 (Baseline) < Time 7 ***
Medication adherence (self-report)	0.74	0.18	0.84	N/A
Anxiety	0.73	<.001 ***	0.19	Time 2 < Time 5 * Time 2 < Time 6 *** Time 2 < Time 7 *** Time 2 < Time 8*** Time 3 < Time 6 ** Time 3 < Time 7 * Time 3 < Time 8 *** Time 4 < Time 6 *
Depression	0.56	<.001 ***	0.140	Time 0 < Time 6 ** Time 0 < Time 7 *** Time 0 < Time 8 *** Time 1 < Time 5 * Time 1 < Time 6 *** Time 1 < Time 7 ***

Table 4-6 (continued).

				Time 1 < Time 8 *** Time 2 < Time 5 *** Time 2 < Time 6 *** Time 2 < Time 7 *** Time 3 < Time 5 ** Time 3 < Time 6 *** Time 3 < Time 7 *** Time 3 < Time 8 *** Time 4 < Time 5 ** Time 4 < Time 7 *** Time 4 < Time 8 **
Drowsiness	0.46	<.001 ***	0.89	Time 2 < Time 8 ** Time 4 < Time 8 *
Fatigue	0.78	<.001 ***	0.20	No significant pairwise differences
Fear of Cancer Recurrence	0.59	0.70	0.48	N/A
Lack of Appetite	0.86	<.01 **	0.80	Time 1 > Time 3 * Time 1 > Time 4 * Time 3 < Time 7 * Time 3 < Time 8 * Time 4 < Time 5* Time 4 < Time 6 * Time 4 < Time 7 *** Time 4 < Time 8 ***

Table 4-6 (continued).

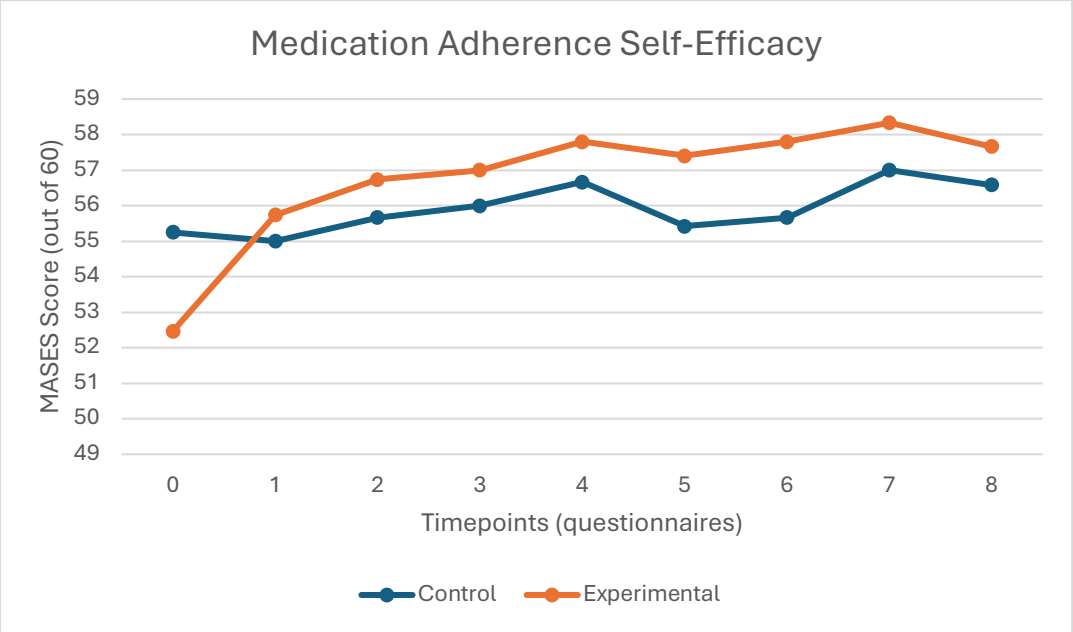
Nausea	0.95	<.001 ***	0.16	Time 0 < Time 5 * Time 0 < Time 6 *** Time 0 < Time 8*** Time 1 < Time 7 ** Time 1 < Time 8 *** Time 2 < Time 5 *** Time 2 < Time 6 *** Time 2 < Time 7 *** Time 2 < Time 8 *** Time 3 < Time 6 *** Time 3 < Time 7 *** Time 4 < Time 7 * Time 4 < Time 8 ***
Shortness of Breath	0.90	<.001 ***	0.33	Time 0 < Time 6 * Time 0 < Time 7 *** Time 0 < Time 8 *** Time 1 < Time 7 ** Time 1 < Time 8 ** Time 2 < Time 7 ** Time 2 < Time 8 ** Time 3 < Time 6 * Time 3 < Time 8***

Table 4-6 (continued).

				Time 4 < Time 6 ** Time 4 < Time 7 *** Time 4 < Time 8 ***
Sleep	0.78	<.05 *	0.97	Time 4 < Time 7 *
Wellbeing	0.89	0.09	0.16	N/A
Work	0.77	<0.001 ***	0.35	Time 0 > Time 7 ** Time 0 < Time 8 ** Time 1 < Time 5 ** Time 1 < Time 6 ** Time 1 < Time 7 *** Time 1 < Time 8 *** Time 2 < Time 5 *** Time 2 < Time 6 *** Time 2 < Time 7 *** Time 2 < Time 8 *** Time 3 < Time 5 *** Time 3 < Time 6 *** Time 3 < Time 7 *** Time 4 < Time 5 *** Time 4 < Time 6 *** Time 4 < Time 7 *** Time 4 < Time 8 ***

Medication Adherence Self Efficacy. The graph in Figure 4-*2* illustrates medication adherence self-efficacy by mean MASES scores (out of 60) from timepoint 0 (baseline) to timepoint 8 (three months). As seen in Table 4-6, there was a time effect as MASES scores significantly increased over time within both groups, across all participants. There were significant differences between the distributions at timepoint 0 (baseline) and 4 (four weeks), and timepoint 0 (baseline) and 7 (ten weeks), respectively, indicating that MASES scores increased over time. Although there were no statistically significant changes in MASES score between groups or interaction between groups and time, there is a nonsignificant trend that can be observed of mean MASES scores in the experimental group being higher than the control.

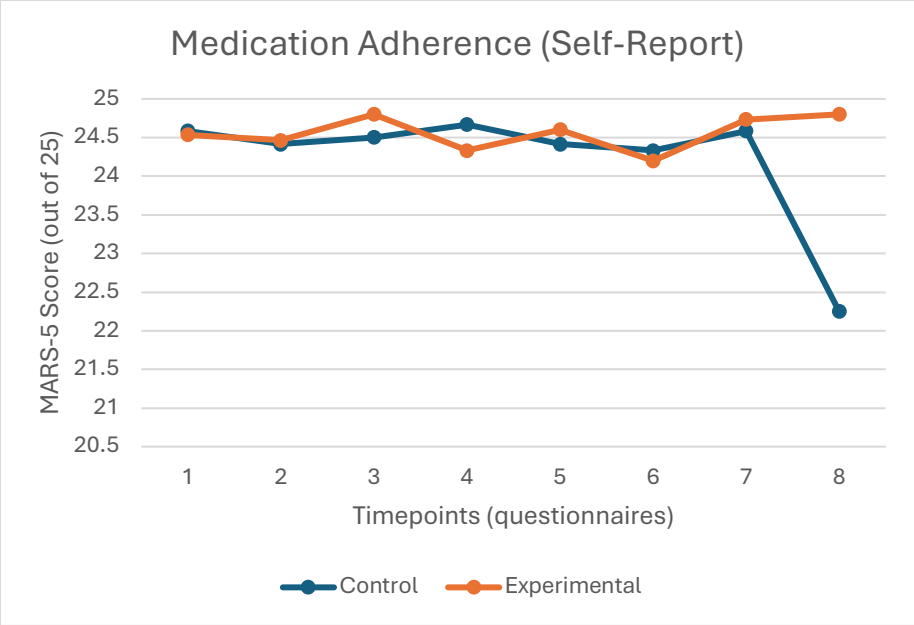
Figure 4-2. Medication adherence self-efficacy score, out of 60, over timepoints 0-8 (n = 27).



Medication Adherence (Self-Report). The graph in Figure 4-3 illustrates medication adherence by mean MARS-5 scores (out of 25) from timepoint 1 (week 1) to timepoint 8 (three months). As seen in Table 4-6, there were no statistically significant changes in MARS-5 scores

between or within groups or interaction between groups and time. In addition, there is no trend that can be observed as mean MARS-5 scores are consistent between both study groups.

Figure 4-3. Medication adherence, out of 25, over timepoints 1-8 (n = 27).



Medication Adherence (Proportion of Days Covered). Table 4-7 illustrates medication adherence by Proportion of Days Covered (PDC), a value out of 100% for the duration of study participation. The mean PDC value for the experimental group was slightly higher at 97.78% compared to 92.92% for the control group.

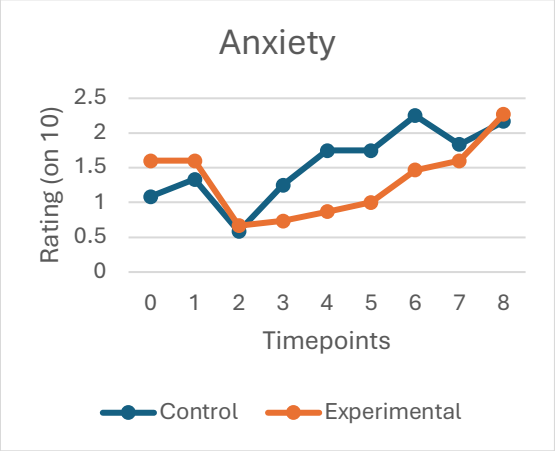
Table 4-7. Medication Adherence via Proportion of Days Covered, out of 100 (n = 32).

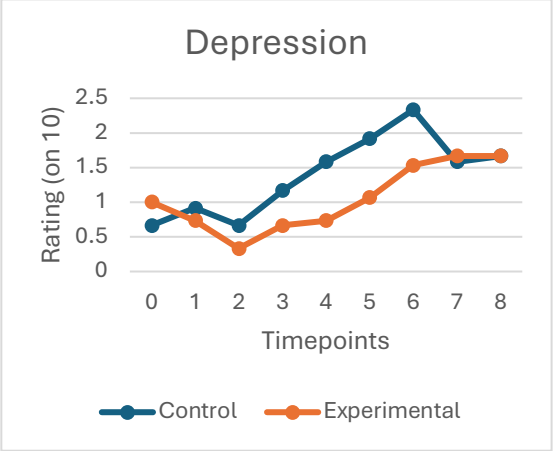
Group	**PDC, % [min – max]**
Experimental (n = 18)	97.78 [85.37-100]
Control (n = 14)	92.92 [64.62 – 100]

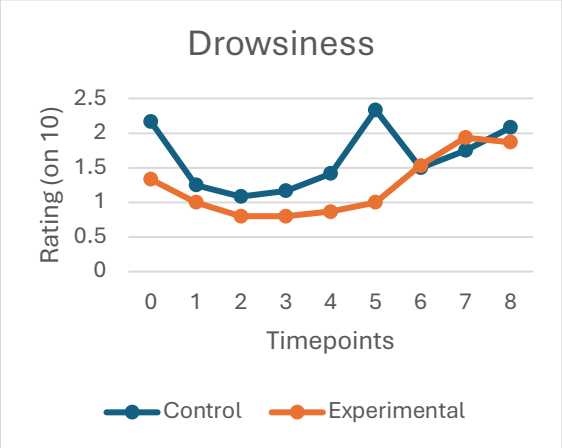
Symptom Distress. As seen in Table 4-6, anxiety, depression, drowsiness, lack of appetite, nausea, shortness of breath, sleep, and work all significantly increased over time across

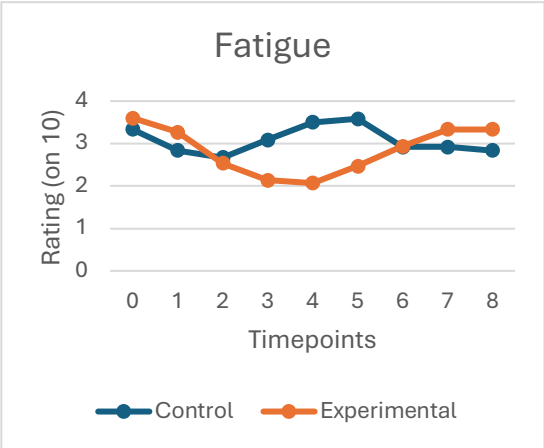
all participants, within both study groups. There were no statistically significant differences between or group and time interactions, the graphs in Figure 4-4 illustrate trends. Trends in differences between control and experimental groups in symptom distress for anxiety, depression, and fatigue, reveal experimental mean ratings for those symptoms being lower.

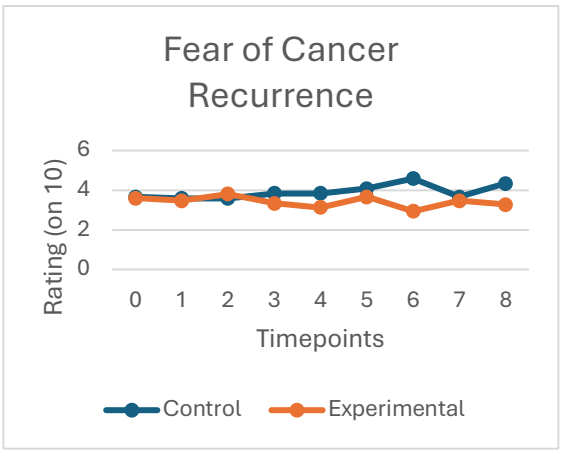
Figure 4-4. Graphs of symptom distress, rated 0 to 10, over timepoints 0-8, for anxiety, depression, drowsiness, fatigue, fear of cancer recurrence, lack of appetite, nausea, shortness of breath, sleep, wellbeing, and work-related problems (n = 27).

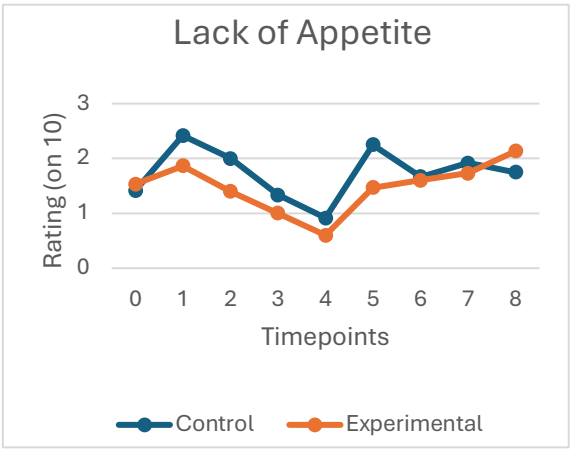


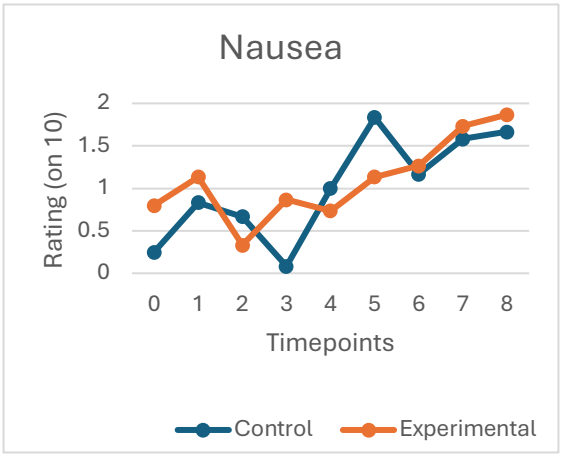


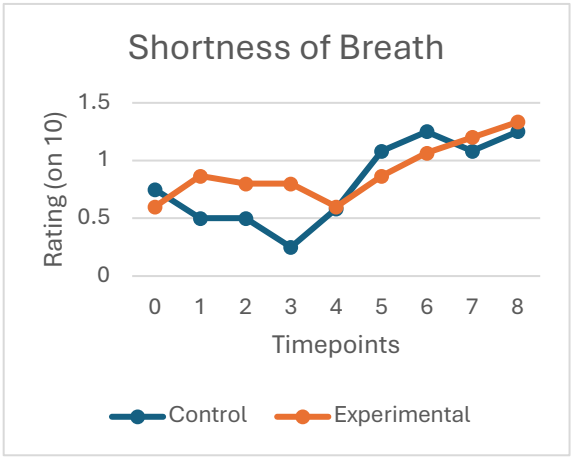


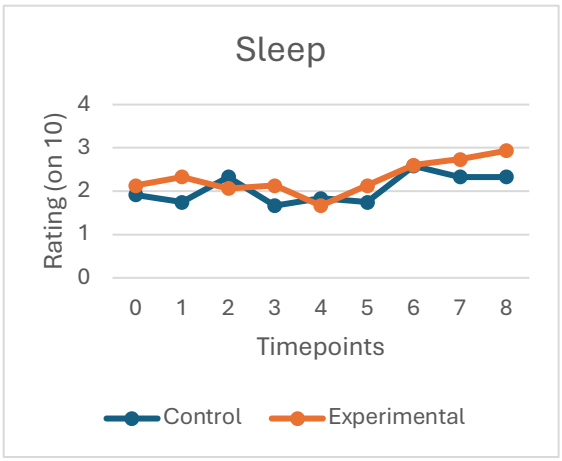


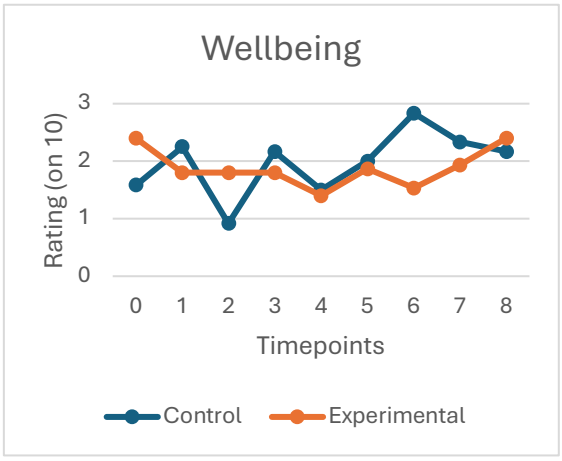

Fear of Cancer Recurrence
Rating (on 10)
0
2
4
6
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental

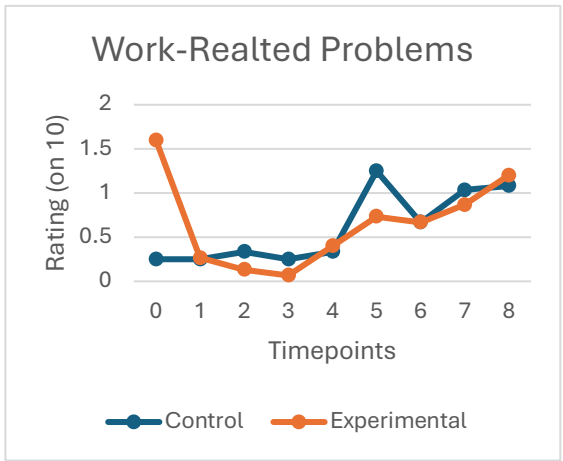

Lack of Appetite
Rating (on 10)
0
1
2
3
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental


Nausea
Rating (on 10)
0
0.5
1
1.5
2
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental


Shortness of Breath
Rating (on 10)
0
0.5
1
1.5
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental


Sleep
Rating (on 10)
0
1
2
3
4
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental


Wellbeing
Rating (on 10)
0
1
2
3
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental


Work-Realted Problems
Rating (on 10)
0
0.5
1
1.5
2
0 1 2 3 4 5 6 7 8
Timepoints
Control
Experimental

Knowledge. All participants who completed the study were included in this analysis (N = 41). Overall, both experimental and control groups significantly increased treatment knowledge from baseline to study completion (Table 4-8).

Table 4-8. Participant knowledge on OAA treatment, scores from 0-7, at baseline (pre) and study completion (post) (N = 41).

Group	**Correct Pre-Intervention, Mean (SD)**	**Correct Post-Intervention, Mean (SD)**	**Pre-Post Difference, Mean (SD)**	**Paired sample t-test** **p < 05, **p < .01, ***p < .001*	**Independent samples t-test**
Experimental (n = 23)	4.65 (2.50)	6.04 (0.95)	1.39 (2.25)	p < .01 **	0.343
Control (n = 18)	3.78 (2.82)	4.89 (1.97)	1.11 (2.08)	p < .05 *	

Cancer Information-Seeking Preferences. At baseline, 56.5% of participants in the experimental group self-identified as intense information seekers and 21.7% as complementary. At study completion, fewer participants self-identified as intense (39.1%), with more as guarded (30.4%) or complementary (26.1%). In the control group, 50% self-identified as intense information seekers and 33.3.% as complementary at baseline. At study completion, less self-identified as intense (33.3%), and more as complementary (44.4%). When participants were asked "Over the past x weeks, have you sought or received cancer information from…" in weekly and bi-weekly e-questionnaires, 66.7% in the control group responded "Yes" to various

sources across study participation, compared to 47.8% in the experimental group at timepoints 1 to 4 and 30.4% after timepoint 5. When asked what sources they turned to for information, participants in the control group responded books, magazines, newspapers, radio, scientific journals, social media, YouTube, websites. For those in the experimental group it was books, scientific journals, social media, websites.

Discussion

This pilot randomized controlled trial reported on the feasibility, acceptability, and potential effects of a remote OAA intervention. Our findings suggest that the study and intervention are feasible and acceptable as the recruitment rate, retention rate, response rate, and uptake of the intervention, as well as the retrospective post-intervention acceptability, all met the pre-determined study objectives. As this study is a pilot, knowledge generated from feasibility and acceptability will be especially important in informing a larger scale implementation of the remote OAA intervention across our cancer center.

The videos and e-handouts were the most utilized components of the intervention by participants. Qualitative interviews reveal they were particularly easy to access, understandable, and worthwhile for participants to engage with. Both experimental and control participants disclosed that the intervention serves as an important complement to services offered by the current system. To be successful in responding to patient needs, remote interventions require the provision of information and support tailored to meet them, available in real-time (Smith, Loscalzo, Mayer & Rosenstein, 2018). Key qualitative themes pointed to the intervention being helpful in easing worries by providing practical and emotional support when patients need it. The responsiveness of the intervention may in turn alleviate concerns that increase over time when

delay in communication occurs. The integration of intervention components within a platform makes the information and support available easily, participants can watch and/or read at their own leisure. They can learn more about their treatment and find answers to new or forgotten questions, this is especially pertinent given the home-based nature of OAAs. Patients on OAAs often lack reliable information and would appreciate information on issues specific to their treatment (Boons et al., 2017; Wei et al., 2016).

The primary outcome of interest with regards to potential intervention effects was medication adherence self-efficacy, with a time effect revealing that MASES scores increased over time across all participants. The statistically nonsignificant trend demonstrated MASES scores of the participants in the experimental group were higher than the control. In comparison to medication adherence, which did not differ between groups, MASES is a more feasible primary outcome as it may be more sensitive to the intervention effects.

There were no significant differences nor nonsignificant trends in medication adherence self-report. This may be due to the extremely strong positive skew of MARS-5 scores. From timepoint 0 (baseline) to timepoint 7, the mean score across both study groups ranged steadily between 24 and 25, out of 25. It is difficult to interpret the decrease in MARS-5 scores for the control group at timepoint 8 as there is no further information or context collected. Medication adherence calculated by proportion of days covered was only slightly more sensitive with the experimental group at 97.78% compared to 92.92% for the control group. E-reminders were the least popular aspect of the OAA intervention as they were seldom used. This is likely due to participants perceiving e-questionnaires as actual reminders, as revealed in exit interviews. This was also the lowest rated aspect of pre-intervention acceptability. Participant interviews revealed that study questionnaires may have served as reminders to take medication and they felt cared for

by simply participating in the study. Suggesting that study participation in and of itself can be construed as an intervention. This phenomenon has been seen in other clinical trials where controls received communication and follow up (i.e. study related phone calls and emails) identical to the experimental group (LaFave et al., 2019). These follow-ups being perceived as a benefit to controls (LaFave et al., 2019).

The fact that, on average, e-questionnaires were completed for the first eight evaluation periods in both groups can be attributed to the majority of participants undergoing OAA treatment for a relatively short duration (three months). Many participants may have transitioned to a different treatment following this period.

There was a statistically nonsignificant trend of lower anxiety, depression, and fatigue in the experimental group. Timepoint 2, two weeks into treatment, was a timepoint of interest across these three symptoms. Between both study groups, anxiety and depression increased after timepoint 2 with the mean score for the control group having a nonsignificant trend of being higher than the experimental. Fatigue at baseline was similar across both study groups, and then changed from timepoints 2 to 6. As the cutoff for mild fatigue is 3 on 10 as per remote symptom practice guidelines for adults on cancer treatments (COSTaRS, 2020), the ratings for fatigue being above 3 between timepoints 2 and 6 in the control group may be clinically significant, indicating moderate fatigue. Altogether, these three symptoms should be closely monitored in patients in their first cycle of OAAs.

At baseline, half of the participants in each study group self-identified as intense information seekers from Loiselle's (2023) Cancer Information-Seeking Preferences (CISP) scale (I seek as much information as possible about my cancer). At study completion, this number decreased to 39.1% and 33.3% in the experimental and control groups, respectively.

Thus, our sample overall may have had particularly high knowledge needs and both study groups had significant increases in their OAA knowledge. From qualitative interviews, participants in the experimental group appreciated being provided with quality relevant information rather than having to seek it out themselves. While those in the control admitted to going online and finding worrisome information. A higher percentage of participants in the control group sought information online (66.7%).

A few limitations of the study should be considered. First, acceptability and self-report adherence ratings may be subject to social desirability biases. Recall bias may have been operative for retrospective (post-intervention) ratings. The study may be underpowered as the sample size is small and the true effect size may also be small. It is important to note that the study is a pilot, and its primary focus was not effectiveness or efficacy. The drop-out rate was higher in the control group, this is a well-known phenomenon of RCTs as participants in the control group do not perceive any benefit to study participation (Bell et al., 2013). Reasons for drop-out for were documented as the rentention rate was one of the elements of acceptability examined in the study.

Conclusion

A comprehensive remote OAA intervention is feasible and acceptable. Given the increasing use of OAAs in routine care and widespread digital health modalities, the intervention offers an opportunity to improve care delivery to patients on OAAs who have distinct information and support needs. With a significant time-effect of medication adherence self-efficacy increasing over time within all participants, and a trend of differences in self-efficacy between groups, the study provides insight into the importance of theoretically grounded

intervention and outcome development. This pilot study represents a first phase of rigorous intervention assessment and will inform larger-scale implementation planning.

Trial registration number: NCT04984850.

Ethics

The study has received ethical and institutional approval from the Centre intégré universitaire de santé et de services sociaux (CIUSSS) du Centre Ouest (2021-2861).

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Summary

Findings from this mixed-method pilot RCT indicate the study was feasible as the recruitment rate (3 participants per month), retention rate (78.8% overall, 88.5% experimental, and 69.2% control), response rate (88.4% overall, 90.6% experimental, 86.9% control), and uptake of intervention (87% of experimental group accessed platform) all met study objectives. The intervention was acceptable with a mean rating of 3.71 (on a scale from 1 to 5) pre-intervention and 4.13 (on a scale from 1 to 5) post-intervention. Themes from exit interviews highlighted the potential positive impact of the intervention. These included: (1) Timeliness of support across key points in the treatment trajectory and the immediacy of response, (2) OAA hands-on knowledge as empowering – for patients, family members, and caregivers, and (3) Connecting and feeling less alone in treatment. The findings of this pilot RCT underscore the potentially meaningful impact of the study intervention on patient experiences and outcomes related to OAAs.

CHAPTER 5

Overall Discussion

Supporting individuals on their cancer trajectory includes ensuring they have access to the best-available, evidence-based resources to optimize treatment processes and outcomes. Breakthroughs in cancer, especially with oral anticancer agents (OAAs), can bring about new and, at times, unexpected patient experiences (American Cancer Society, 2023; Bloom, 2023). Therefore, it is crucial to provide timely and high-quality supportive interventions grounded in research.

The series of manuscripts presented in this dissertation offer preliminary evidence into the implementation potential and outcomes of a remote supportive intervention to address the unmet needs of individuals on OAAs. More specifically, this dissertation aims to: 1) provide a comprehensive overview of the current evidence concerning OAA-supportive adherence interventions from the literature, 2) develop and test a promising OAA adherence supportive intervention, and 3) explore the potential influence of the intervention on medication adherence self-efficacy, medication adherence, symptom management, and the experiences of individuals receiving OAA treatment. Herein, the dissertation contributions to theory, research, and clinical practice are discussed.

Aim 1: A comprehensive literature review of OAA-supportive adherence interventions

The first dissertation aim was addressed by conducting a mapping literature review of the current evidence concerning OAA-supportive adherence interventions (Chapter 2, manuscript 1; Ahmed & Loiselle, 2023). The review examined essential components of interventions and identified gaps in the literature emphasizing the need for rigorous evaluation of theory guided

OAA interventions. Self-efficacy was identified as a promising construct to better understand OAA adherence. In addition, it was recognized that interventions should integrate all four modes or domains: behavioral, educational, medical, and technological. Takeaways from the mapping review also highlighted the need for closer links between theory and outcomes, as well as addressing variability in objective and subjective measurement of medication adherence.

Aim 2: The development and testing of a promising OAA adherence supportive intervention

Based on observations from the mapping review, a remote self-efficacy based OAA intervention was developed. Multiple stakeholders, including healthcare providers, patients, and informal caregivers provided insights into an optimal OAA intervention design. The intervention contained: 1) OAA informational multilingual videos, 2) symptom-related e-handouts and reputable web links, 3) follow-up phone calls from a nurse, and 4) e-reminders to take OAAs. To address the challenges of testing an intervention for the first time as well as enhancing the rigor and value of a future full-scale study, a pilot randomized controlled trial (RCT) was conducted. The primary focus of the pilot RCT was to assess the feasibility of the study and acceptability of the intervention (Chapter 3, manuscript 2; Ahmed, Maheu, Gotlieb, Batist, & Loiselle, 2024). Findings revealed all feasibility and acceptability objectives were achieved (Chapter 4, manuscript 3; Ahmed & Loiselle, 2024). As such, the processes of the study and intervention testing were successful and the OAA intervention was well received by participants.

When asked about the most essential intervention components, participants stated videos, e-handouts, or both together were most useful. This suggests there is value in offering digital forms of OAA support. These findings are consistent with the National Cancer Institute's Health Informational National Trends Survey (HINTS, 2022), which gathers representative data on how

the American public utilizes cancer-related information. For instance, when asked *"In the past 12 months, have you used the Internet to look for health or medical information?",* 84.1% (N = 5166) responded *Yes* (HINTS, 2022). In addition, previous studies have shown that informational videos significantly improve cancer knowledge (Bol et al., 2013; Dahodwala, Geransar, Babion, de Grood, & Sargious, 2018; Occa,& Suggs, 2016; Tan, Lee, Yong, & Rodgers, 2018), understanding of cancer treatment (Pentz et al., 2019), and treatment adherence (Adam, Bond, & Murchie, 2015; Yeung et al., 2017). While free-access videos on OAAs are available online (Yang et al., 2022) such as those from the Canadian Cancer Society (2017), the Dana-Farber Cancer Institute (2015) and the Cleveland Clinic (2015), this is the first study to examine the preliminary effects of an OAA informational video within the context of a pilot RCT.

Interestingly, an additional component of the OAA intervention—calls from a trained oncology nurse—was seldom requested by participants. But when requested, they were highly rated. Reasons for not requesting a call included not wanting to place an additional burden on an already overwhelmed healthcare system. This is documented among individuals with cancer as they worry about imposing added burden on carers including their family and loved ones (Liu et al, 2022). Access to supportive health resources is also a significant issue in Quebec, where the study took place (Adam et al., 2023). The situation has been described as "worse than ever" (Bongiorno & Oduro, 2023, Derfel, 2023) and this has had a significant impact for individuals on OAAs. This dissertation work demonstrates how automatic follow ups based on periodic assessments of treatment-related symptoms using Patient Reported Outcomes (PROs), such as ESAS-r is a promising approach to reduce burden on an already stretched health care system.

Aim 3: Preliminary effects of the OAA intervention on outcomes and patient experiences

The intervention's preliminary effects reveal its potential to enhance medication adherence self-efficacy, medication adherence via the proportion of days covered (PDC), and symptom distress related to anxiety, depression, and fatigue (Chapter 4, manuscript 3; Ahmed & Loiselle, 2024). In particular, the use of an objective method of medication adherence assessment, PDC, revealed a trend toward higher medication adherence (although non-significant) in the experimental group. This stands in contrast to the self-report measure, where medication adherence remained similar between both groups.

Exit interviews further explored OAA-related experiences and distinct narratives of how the intervention addressed unique informational and supportive care needs, which quantitative measures did not capture. A scoping review by Thiessen et al. (2022) explored qualitative research conducted alongside RCTs in oncology. In 35 of the 54 studies, both control and experimental arms participated in qualitative data collection during the study/intervention (e.g., interviews, focus groups). Qualitative data collection at study exit/post-intervention occurred in only 18 of the 54 studies (33%). Herein, knowledge gained from qualitative methodologies at study exit is seen as a significant contribution to the findings of this pilot RCT.

In addition, findings from the cancer information-seeking preference measure (Loiselle, 2023) for both experimental and control groups align with prior evidence. Participant preferences for cancer information (Loiselle, 2023) were particularly high at the beginning of the study. The importance of early treatment-related information to help individuals understand and manage the treatment, is well-documented (Alloway, 2020; Holmes, 2019; Yoon & Son, 2022). Their information needs are highest at the beginning of treatment and decrease as treatment progresses (Eheman et al., 2009; Vogel, Bengal, & Helmes, 2008). When not provided with the information they required, the control group actively sought it out on their own. Interestingly, the National

Comprehensive Cancer Network conducted a study reviewing the most popular social media articles on common cancers, they found 32.5% contained misinformation and 30.5% contained harmful information (Johnson et al., 2022). As individuals increasingly use the internet to obtain health-related information, findings underscore the importance of being proactive and forthcoming with reliable cancer treatment information (Loiselle & Ahmed, 2017). This is crucial as research demonstrates that patients who are more engaged/activated tend to experience better health outcomes than those who are not (Greene & Hibbard, 2012; Hibbard & Greene, 2013). The Supportive Care Framework, developed by Fitch (2008), proposes an evidence-based stepped-care model of cancer care which suggests that all patients should have access to information, basic emotional support, ongoing communication, and acute symptom management (Fitch, 2008). Complementary to Fitch's Supportive Care Model, Howell et al.'s (2015) tiered model of psychosocial care identifies that all patients entering the cancer system require relevant information, support, communication, and symptom management. Although essential for every patient, there has been limited work on sustainable means to promptly deliver information and support to those who require these the most. If successfully implemented, this OAA intervention could empower individuals by meeting their basic needs for information, support and access to care (De Santis, Hervas, Weinman, & Bottarelli, 2018; Sindhu, 2020).

The remote intervention was particularly timely amidst the COVID-19 pandemic, as oncology teams increasingly performed remote consultations, and immunocompromised patients were at higher risk for virus-related complications. Social distancing, isolation, and quarantine all further limited the support and resources available to patients. As remote consultations and special attention is still paid to immunocompromised patients in the current period, the study and intervention are both relevant. Whether the COVID-19 pandemic acted as a confounding factor

in testing for changes in potential outcomes remains unclear. In addition, the virtual recruitment strategy implemented due to the COVID-19 pandemic worked well and could be utilized in future work.

Implications for future research

This pilot RCT focused on theoretical underpinnings, components of the OAA intervention, as well as its acceptability and feasibility to better inform future clinical implementation. Preliminary effects and trends, emphasizing clinical significance, helped identify outcomes of interest that may make a difference in patients' OAA treatment trajectory. These outcomes may be further explored in larger scale studies with a primary focus on efficacy. The study and intervention were piloted in a single setting, next steps should include multi-site investigation to determine whether it is scalable and relevant locally, and eventually nationally and internationally. Prior to protocol and intervention implementation within different contexts, it must align with local practices, policies, and resources. Involving key stakeholders, including healthcare providers, and patients in the planning and adaptation process is critical. As e-reminders were seldom used, they may need to be deleted or replaced by text messages, which might be a more direct and effective (Cazeau, 2021). E-handouts were the most popular intervention component, they could be further tailored to directly address distinct symptoms associated with OAAs (e.g., hand and foot syndrome). As some participants appeared reluctant to request nurse calls, possibly to avoid being perceived as burdensome, nurses may conduct systematic outreach calls instead of waiting for participants to initiate the request. In the future, enhanced reliance on pharmacists is promising as they can offer personalized information, address concerns, and potentially reinforce adherence to the prescribed regimen. In fact, the

integration of periodic pharmacist phone calls may be a more cost-effective alternative than relying on nurses' follow ups if they are too busy.

Herein, PDC was chosen as the objective method and surrogate outcome for medication adherence measurement. PDC could be kept for a larger trial as it is simple to obtain and calculate and may even be considered as the primary outcome. The sample size calculation based on medication adherence must be adjusted, given the likely small (0.2) or very small (0.01) effect sizes, indicating that the differences between groups are subtle. Consequently, a larger sample size would be necessary. However, considering that medication adherence was already high in both groups, even a larger sample size may not detect a statistically significant difference. Therefore, it is essential to also consider the context and clinical significance of the findings. The potential role of symptom management merits further exploration. To appropriately analyze this relationship, advanced statistical techniques such as a generalized estimating equation (GEE), generalized linear mixed model (GLMM), or linear mixed model (LMM) would be required. Additionally, assessing the impact of symptom variability on medication adherence would necessitate the application of hierarchical multiple regression. In this approach, symptoms would be entered as Block 1, followed by the inclusion of other covariates in Block 2.

Similar evidence-based videos and e-handouts with tailored content may hold promise for addressing the unique needs of other cancer populations, including those receiving immunotherapy (Kutzleben, Galuska, Hein, Griesinger, & Ansmann, 2022), hematopoietic stem cell transplants (Janicsák, Ungvari, & Gazdag, 2021; Nakajima & Kamibeppu, 2022), and complement emerging treatment advancements such as CART-T cell therapy (National Cancer Institute, 2022) or anti-cancer vaccines (Carvalho, 2023).

Despite the abundance of digital health cancer tools that exist to support patients today, few are guided by solid theorizing, tested for their potential effects, or personalized, in real time, to the patient experience. Further expanding on the responsiveness to patient symptoms and timeliness of support, the intervention could be incorporated into an artificial intelligence (AI) model that may enhance personalized care by relying on algorithms to provide supportive care services. For instance, BELONG – Beating Cancer Together (https://belong.life/), has developed Dave, the world's first AI oncology mentor for individuals coping with cancer (Belong Life, 2024). Similar to ChatGPT, Dave is a conversational AI chatbot. However, Dave has been distinctively trained on "billions of unique data points and anonymized real-world patient journey information accumulated over seven years on BELONG's platform" (Belong Life, 2024).

On the platform, users ask oncology-specific questions (but no medical advice), and Dave gives real-time "precise, comprehensive, and empathetic answers" (Belong Life, 2024). By further training Dave on OAA specific resources such as content from the videos, e-handouts, and reputable web-links of the intervention, combined with pre-determined symptom rating algorithms (similar to the distress protocol of the study; Appendix N), Dave could serve as a virtual patient navigator and provide even more personalized support and dispatch individuals to care resources and interventions. A quality improvement project in colorectal cancer screening, utilized MyEleanor, an AI virtual navigator to assist patients who had previously been nonadherent to their colonoscopy appointments (Moadel et al., 2024). Results were promising, indicating increased patient engagement (Moadel et al., 2024). In addition, a virtual AI navigator has the potential to overcome differences in language and level of education by tailoring of tone

and wording to match that of the user. If successful, the proposed model would enable patients to coordinate in real-time, resources and support tailored to their needs.

Timeliness of the intervention was a central theme to the OAA experience as uncovered in qualitative interviews. Perceived empathy may also play an important role in patient care. The literature supports that recognizing the right moment and right way to respond to patients' needs and preferences can affect outcomes (Butow, 1995; Herrman et al., 2018; Noteboom et al., 2021; Westendorp et al., 2022). A recent study exploring digital empathy in behaviour change interventions in diabetes (Rey Velasco et al., 2024) demonstrates its presence, however further work is needed to explore its impact on patient outcomes and experiences. As healthcare providers are growing more comfortable integrating technology and AI into their practice (Pearl, 2023), and we move toward an era of virtual patient navigation, further qualitative work would be needed to explore the role of an AI patient navigator for OAAs on patient perceptions of empathy and health-related outcomes.

Limitations of the dissertation work

There are several limitations to the findings presented herein. For instance, participant recruitment involved the potential for self-selection bias, given that those interested may already have been sympathetic to the study topic and wanted OAA information and/or support. The generalizability of findings may be constrained by demographics, whereby most reported, at least, a high school education and were predominantly female. Identifying strategies to enroll individuals not initially interested in the study topic should be further explored. These include more proactive recruitment in diverse settings such as community pharmacies, volunteer-based organizations and using stratified sampling for sex/gender, age, education levels. The

retrospective nature of participant interviews and questionnaire completion means that they may have forgotten details of their OAA experiences. Last, the study sample was small with 41 participants completing the study and only a subset (i.e., 27) included in the final analysis for preliminary effects. Despite these limitations, the use of a mixed methods approach relying on quantitative and qualitative methods provided a complementary and rich data collection process.

Conclusion

This dissertation highlights the importance of implementing comprehensive support for individuals on OAAs, emphasizing the need for interventions that address physical, psychosocial, and instrumental aspects of their experiences. The intervention presented a promising tangible approach that can be easily integrated into patient care. Its remote nature means that it is more sustainable, leading to efficient resource use at controlled costs. Numerous opportunities for future research to further integrate and customize intervention components across information technologies and patient groups have been identified (e,g, immunotherapy, hematopoietic stem cell, CART-T cell therapy, anti-cancer vaccines). Altogether, providing individuals on OAAs with timely and accessible information and support extends beyond medical outcomes, encompassing emotional support, guidance, and empowerment throughout treatment and beyond.

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APPENDICES

Appendix A

National Library of Medicine (2024). Oncology - Bolstering Oral Agent Reporting Related to Distress (ON-BOARD) (NCT04984850). Retrieved from https://www.clinicaltrials.gov/study/nct04984850 on April 13, 2024

COMPLETED

Oncology - Bolstering Oral Agent Reporting Related to Distress (ON-BOARD)

ClinicalTrials.gov ID NCT04984850

Sponsor McGill University

Information provided by Carmen G. Loiselle, N., Ph.D., McGill University (Responsible Party)

Last Update Posted 2024-02-29

Study Details Tab

Study Overview

Brief Summary

Individuals on oral chemotherapy (OC) often face many challenges requiring adequate informational support, monitoring, and management. This pilot randomized control trial (RCT) aims to assess the feasibility, acceptability, and preliminary effects of a comprehensive OC intervention on medication adherence self-efficacy, medication adherence, and symptom distress.

Official Title

Feasibility, Acceptability, and Potential Effects of a Comprehensive Oral Chemotherapy Intervention on Medication Adherence Self-efficacy, Medication Adherence, and Symptom Distress: A Pilot Randomized Control Trial

Conditions

Oral Chemotherapy

Intervention / Treatment

- Other: Oral chemotherapy information and support

Other Study ID Numbers

- 2021-2861

Study Start (Actual)

2022-01-07

Primary Completion (Actual)

2023-12-30

Study Completion (Actual)

2024-01-30

Enrollment (Actual)

52

Study Type

Interventional

Phase

Not Applicable

Resource links provided by the National Library of Medicine

FDA Drug and Device Resources (https://www.clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

Canada

Quebec Locations

Montréal, Quebec, Canada, H3A1L4
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal

Click to view interactive map

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://www.clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- 18 years of age or older
- Diagnosis of cancer, any stage
- Being followed by a care team at the affiliated hospital centre
- About to start or within the first cycle of oral anticancer treatment (traditional cytotoxic, targeted therapy, hormonal therapy as active ongoing treatment for cancer with the aim of killing cancer cells/shrinking tumor size)
- Has a computer/tablet/smartphone device with internet
- The ability to communicate, read, and write in English or French

Exclusion Criteria:

- Receiving IV chemotherapy, immunotherapy, and/or oral hormonal therapy as long-term maintenance treatment for prevention of cancer's return/growth of cancer cells after initial treatment
- Significant physical or cognitive limitations that would prevent ability to participate in study as reported by patient, primary healthcare provider, or research staff
- At imminent "end-of-life"
- Participating in an ongoing clinical trial

Ages Eligible for Study

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Feasibility and acceptability	Study feasibility assessed by the recruitment rate (percentage, dividing the total number of participants recruited throughout the study by the number of months recruitment occurred), retention rate (percentage, comparing the number of participants who complete baseline e-questionnaires to the number of participants who complete study exit e-questionnaires), response rate to study e-questionnaires (percentage, the number of completed follow-up e-questionnaire assessments for participants who complete the study), and uptake of intervention (percentage, calculated by comparing by number of participants who actually access the intervention to the total number who are given access). Intervention acceptability assessed by intervention burden, intervention coherence, and perceived effectiveness using the Tariman et al. (2011) Acceptability e-scale for web-based patient-reported outcomes in cancer care. Mean scores range from 1 to 5, higher score indicating higher acceptability.	Five months

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Potential effects of intervention via medication adherence self-efficacy, medication adherence and symptom distress	Medication adherence self-efficacy by the Medication Adherence Self-Efficacy Scale (MASES) (Ogedegbe et al., 2003). Total scores range from 20 to 60, higher scores indicating higher medication adherence self-efficacy. Medication adherence via Proportion of Days Covered (PDC), percentage representing the sum of the days' supply of a given drug divided by the number of days in the time period. Higher percentage indicating higher medication adherence. Medication adherence self-report via the Medication Adherence Report Scale (MARS-5, Professor Rob Horne; Chan et al., 2020). Total scores range from 5 to 25, higher score indicating higher self-reported adherence. Physical and psychosocial symptom distress measured via Edmonton Symptom Assessment Scale Revised (ESAS-r) for anxiety, depression, drowsiness, fatigue, fear of cancer recurrence, lack of appetite, nausea, shortness of breath, sleep, wellbeing, and work. Each is rated from 0 to 10, 0 being none and 10 being the worst possible.	Five months

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

McGill University

Collaborators

- Rossy Cancer Network

Investigators

No information provided

Publications

The person responsible for entering information about the study voluntarily provides these publications. These may be about anything related to the study.

General Publications

No publications available

*** Find Publications about Study Results and related Pubmed Publications in the "Results" section of the study record.**

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2021-06-09

First Submitted that Met QC Criteria

2021-07-28

First Posted

2021-08-02

Study Record Updates

Last Update Submitted that met QC Criteria

2024-02-26

Last Update Posted

2024-02-29

Last Verified

2024-02

More Information

Terms related to this study

Keywords Provided by Carmen G. Loiselle, N., Ph.D., McGill University

Oral chemotherapy
medication adherence
self-efficacy
pilot randomized control trial

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

Study Documents

No study documents available

Appendix B

CIUSSS Centre-Ouest-de-l'Île-de Montréal Research Ethics Board (REB) documents

- Science committee review
- Psychosocial Research Ethics Committee (REC) approval
- Nursing feasibility review
- Final authorization to conduct research

Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal
Québec

2021-08-26

Dr. Carmen Loiselle
c/o: Saima Ahmed
email: saima.ahmed2@mail.mcgill.ca

Re: Project 2021-2861 Feasibility, acceptability, and potential effects of a comprehensive oral chemotherapy intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial - Science committee final approval

---

Dear Dr. Loiselle,

Thank you for submitting the above-mentioned protocol for review by the Science Committee.

The Science Committee reviewed the research project at its meeting of 2021-04-30.

The Science Review Committee rendered a favorable decision in regards to the scientific aspects of the study.

Sincerely,

Dr. Myrna Lashley, PhD.
Dr. Myrna Lashley, Ph.D.
Chair, First Line Psychosocial Science Committee

Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal
Québec

2021-08-26

Dr. Carmen Loiselle
c/o: Saima Ahmed
email: saima.ahmed2@mail.mcgill.ca

Object: Project 2021-2861 - Final Research ethics committee Approval of the Project Following Conditional Approval
Feasibility, acceptability, and potential effects of a comprehensive oral chemotherapy intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial

---

Dear Dr. Loiselle,

The Psychosocial Research Ethics Committee (REC) of CIUSSS West-Central Montreal Research Ethics Board (REB), is pleased to inform you that the above-mentioned study received ethics approval.

A delegated review of the research project was provided by member(s) of the Psychosocial REC. The responses and revisions submitted via an F20 form were reviewed and approved by the Chair on 2021-08-26.

The following documents are granted final ethics approval by the Psychosocial REC:

- Initial Submission Form (F11P-22058)
- REC Conditions & PI Responses Form(s) (F20-23270)
- - Document(s) approved by the REC (1.Pain.pdf)
  - Document(s) approved by the REC (2.Fatigue.pdf)
  - Document(s) approved by the REC (3. Drowsiness.pdf)
  - Document(s) approved by the REC (4. Nausea and Vomiting.pdf)
  - Document(s) approved by the REC (5. Lack of Appetite.pdf)
  - Document(s) approved by the REC (6.SOB.pdf)
  - Document(s) approved by the REC (7.Depression.pdf)
  - Document(s) approved by the REC (8.Anxiety.pdf)
  - Document(s) approved by the REC (9.Wellbeing.pdf)
  - Document(s) approved by the REC (10.Insomnia.pdf)
  - Document(s) approved by the REC (11.FCR.pdf)
  - Document(s) approved by the REC (12.Work.pdf)
  - Document(s) approved by the REC (1.Douleur.pdf)
  - Document(s) approved by the REC (2.Fatigue.pdf)
  - Document(s) approved by the REC (3. Somnolence.pdf)
  - Document(s) approved by the REC (4. Nausées et vomissements.pdf)

- Document(s) approved by the REC (5. Manque d'appétit.pdf)
- Document(s) approved by the REC (6.Essoufflement.pdf)
- Document(s) approved by the REC (7.Dépression.pdf)
- Document(s) approved by the REC (8.Anxiété.pdf)
- Document(s) approved by the REC (9. Bien - être.pdf)
- Document(s) approved by the REC (10.Insomnie.pdf)
- Document(s) approved by the REC (11. Peur du cancer reviendra dans le futur.pdf)
- Document(s) approved by the REC (12. Travail.pdf)
- Document(s) approved by the REC (Baseline_Questionniare_EN_clean.docx)
- Document(s) approved by the REC (Baseline__FR_Aug4.docx)
- Document(s) approved by the REC (Debriefing Form_EN_clean.docx)
- Document(s) approved by the REC (Debriefing Form_FR_Aug4.docx)
- Document(s) approved by the REC (DataCollection_checklist.xlsx)
- Document(s) approved by the REC (Exit_Exp_EN_clean.docx)
- Document(s) approved by the REC (Exit_UsualCare_EN_clean.docx)
- Document(s) approved by the REC (ExitQ_ControlGroup.docx)
- Document(s) approved by the REC (ExitQ_Participants_clean.docx)
- Document(s) approved by the REC (Exit Q Exp_FR_Aug4.docx)
- Document(s) approved by the REC (Exit Q Usual Care_FR_Aug4.docx)
- Document(s) approved by the REC (Exit Q_Control_FR_Aug4.docx)
- Document(s) approved by the REC (Exit Q_Participants_FR_Aug4.docx)
- Document(s) approved by the REC (Follow up _FR_Aug4.docx)
- Document(s) approved by the REC (Prospective Acceptability_FR_Aug4.docx)
- Document(s) approved by the REC (FU_Questionniare_EN_clean.docx)
- Document(s) approved by the REC (Prospective Acceptability E_clean.docx)
- Document(s) approved by the REC (Rec Tool and Form_2021__FR_Aug4.docx)
- Document(s) approved by the REC (Recruitment Tool Form_EN_clean.docx)
- Document(s) approved by the REC (Verbal Screening_2021__FR.docx)
- Document(s) approved by the REC (Verbal Screening_EN_clean.docx)
- French Information & consent form (s) (Control_Consent_2021_FR_Aug23_clean.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Control_Consent_2021_FR_Aug23_tracked.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Control_electronic consent form_EN_Aug23_clean.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Control_electronic consent form_EN_Aug23_tracked.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Exp_electronic consent form_EN_Aug23_clean.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Exp_electronic consent form_EN_Aug23_tracked.docx) [Date: 2021-08-23]
- French Information & consent form (s) (Exp_Consent_2021_FR_Aug23.docx) [Date: 2021-08-23]
- ICF approved by the REC (Control_Consent_2021_FR_Aug23_Approved.docx)
- ICF approved by the REC (Control_electronic consent form_EN_Aug23_Approved.docx)
- ICF approved by the REC (Exp_Consent_2021_FR_Aug23_Approved.docx)
- ICF approved by the REC (Exp_electronic consent form_EN_Aug23_Approved.docx)

The responses and revisions will be reported to the Psychosocial REC and will be entered accordingly into the minutes of the next meeting, to be held on 2021-09-24.

The Psychosocial REC of CIUSSS West-Central Montreal REB had the necessary scientific expertise and carried out the scientific evaluation of the project. The Committee rendered a positive evaluation of the project.

The ethics approval is valid until 2022-08-26.

The COVID-19 pandemic and the state of emergency declared by the Province of Quebec create exceptional circumstances, having impacts on research activities, in particular their evaluation and conduct. In this context, the conduct of this study must be aligned with the specific guidelines in effect at the CIUSSS du Center-Ouest-de-l'Île-de-Montréal and in each respective participating institution, if applicable.

The Research Ethics Board of the CIUSSS West-Central Montreal Board (Federalwide Assurance Number: 0796) is designated by the province (MSSS) and follow the published guidelines of the TCPS 2 - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2018), in compliance with the "Cadre de référence ministériel pour la recherche avec des participants humains" (MSSS, 2020) , and the membership requirements for Research Ethics Board defined in Part C Division 5 of the Food and Drugs Regulations; and acts in conformity with standards set forth in the United States Code of Federal Regulations governing human subjects research, and functions in a manner consistent with internationally accepted principles of good clinical practice.

Duties of Researchers
Ethics approval may be withdrawn if the following stipulations are not met:

- To obtain prior written approval from the REB for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization, before initiating the change; except where urgent action is required to eliminate an immediate hazard to a study participant;
- To maintain confidentially, the updated Research Participants Registry is to be retained for the length of time required by regulations, and in accordance with institutional policy;
- To comply with all relevant regulations and guidelines governing the conduct of research involving human subjects and the requirements of the REB;
- To comply with all REB requests to report study information, including prompt reporting of unexpected or serious adverse events (SAEs) or alarming trends in expected SAEs, according to the policies and procedures of each institution where the study is conducted;
- To advise the REB and all study subjects of new significant findings emerging during the course of the study;
- To comply with quality assurance assessment as defined by each institution’s policy;
- To maintain study records according to regulatory requirements.

All research involving human participants requires review at recurring intervals. To comply with the

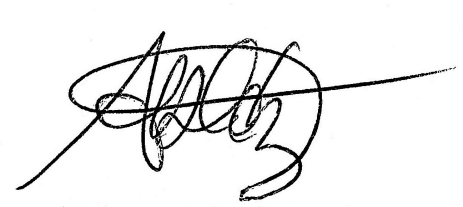
regulation for continuing review of at least once per year, it is the responsibility of the investigator to submit an Annual Renewal Submission Form (F9) to the REB prior to expiry. The annual renewal form that will be available to you approximately 60 days prior to the expiry date of this letter. Please note that if the protocol approval expires before its renewal is granted, the data collected after the expiration date may not be considered valid. However, should the research conclude for any reason prior to approval expiry, you are required to submit a Completion (End of a Study) Report (F10) to the REB once the data analysis is complete to give an account of the study findings and publication status.

Furthermore, should any revision to the project or other development occur prior to the next continuing review, you must advise the REB without delay, by submitting an amendment form to the committee. Regulation does not permit initiation of a proposed study modification prior to its approval by the REB.

Please note that that the CIUSSS WCM *Quality Assurance Program* aims to support 10% of active research in our institution. In order to promote best practices in research ethics, our team may contact you to schedule an on-site visit during the course of the study.

Please be advised that you may only initiate the research project after all required reviews and decisions are received and documented.

Respectfully,



Me Alain Klotz, LL.B., LL.M.
Chair, Psychosocial Research Ethics Committee

FWA 00000796

Hôpital général juif
Jewish General Hospital

Montreal, November 8th 2021

CENTRE GÉRIATRIQUE DONALD BERMAN MAIMONIDES GERIATRIC CENTRE

CENTRE D'HÉBERGEMENT FATHER DOWD RESIDENTIAL CENTRE

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HÔPITAL GÉNÉRAL JUIF JEWISH GENERAL HOSPITAL

HÔPITAL MONT-SINAÏ MOUNT SINAI HOSPITAL

HÔPITAL RICHARDSON HOSPITAL

Research Review Office
Suitability Committee, Office A-904
3755 Cote-Sainte-Catherine
Montreal (QC) H3T 1E2

RE: # 2021-2861
Nursing feasibility

Object: Feasibility Review Request

To whom it may concern,

The nursing department has reviewed the protocol entitled: "Feasibility, acceptability, and potential effects of a comprehensive oral chemotherapy intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial" by Dr. Carmen Loiselle.

Please be advised that there are no feasibility issues with this protocol but at every research follow-up, participants will be asked to rate their distress from 0 (none or best possible) to 10 (worst possible) for the following symptoms: pain, fatigue, drowsiness, nausea, lack of appetite, shortness of breath, depression, anxiety, wellbeing, sleep, fear of cancer recurrence, work-related problems, and self-reported diarrhea.

In order to ensure participant safety and to provide study participants with access to a complete interdisciplinary team (including Nursing, Medicine and Pharmacy) if needed, it is important to consider that the Oncology Clinic hours are between 8 am - 5 pm, Monday to Friday. As such, all study participants must have all study related activities (including monitoring) completed by 5 pm.

Please note that the nursing staff of the JGH cannot be responsible for any study related documentation or tracking of information which goes outside of what would normally be done in routine clinical care.

The Nursing Staff of the (Unit) Department would require ample time (ideally four weeks) to review the protocol, all potential study drug related adverse effects, and monitoring responsibilities, before the first participant is recruited into this study.

Given that there are no conditions, the nursing department is happy to support this project.

Please accept our best regards.

Lucie Tremblay

Lucie Tremblay inf., M.Sc., ASC, CHE
Director of Nursing
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal

Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal
Québec

2021-11-19

Dr. Carmen Loiselle
c/o: Saima Ahmed
email: saima.ahmed2@mail.mcgill.ca

Object: Project 2021-2861 - Final Authorization to conduct research at the CIUSSS West-Central Montreal
Feasibility, acceptability, and potential effects of a comprehensive oral chemotherapy intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial

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Dear Dr. Carmen Loiselle

We are pleased to grant you authorization to carry out the research identified above at the CIUSSS West-Central Montreal (WCM) and / or under its auspices. To grant this Institutional Authorization, it is understood that our Institution recognizes the approval granted by the CIUSSS WCM REB :

- who confirmed in its letter dated 2021-08-26, the positive result of the scientific and ethical review of the study; and
- who approved the consent forms, in English and in French, required to conduct this study.

This authorization is granted to you on the basis of the documents you have submitted to our Institution. Please note that should at any point the CIUSSS WCM REB revoke, modify or change the status of your approval for Research Ethics, the Person Formally Mandated by the CIUSSS WCM, retains the rights to revoke its authorization for the above-mentioned protocol.

This authorization also requires that you respect the terms and conditions listed below:

- Comply with the Regulatory Framework of our Institution with regards to research activities, including the requirements for the respect and privacy of research participants;
- Use the version of the research documents approved by the CIUSSS WCM REB, the only changes made, if any, being administrative and identified so that the CIUSSS WCM REB can read them;
- Respect the mechanisms required for annual review determined by the CIUSSS WCM REB;
- Respect the procedures of the MSSS Multicenter Mechanism with regards to respect and privacy of research participants specifically, the identification of the research participants at our Institution, that is maintaining and keeping up-to-date the list of the participants recruited into the study at our Institution. This list must be submitted to us upon request;
- Preserve the research files during the prescribed period of any applicable regulations or by the CIUSSS WCM REB, after the end of the project, in case of an audit; and

- To notify the reviewing REB and Person Formally Mandated the ongoing conduct of the project, with regards to any modification to the research.

*COVID-19
The COVID-19 pandemic and the state of emergency declared by the Province of Quebec create exceptional circumstances, having impacts on research activities, in particular their evaluation and conduct. In this context, the conduct of this study must be aligned with the specific guidelines in effect at the CIUSSS du Center-Ouest-de-l'Île-de-Montréal and in each respective participating institution, if applicable.

This authorization hereby grants you to perform research under the auspices of our Institution and must be prior to the date specified by the CIUSSS WCM REB decision to renew its research ethics approval of this research. It will be renewed without further procedure on the date indicated by the CIUSSS WCM REB in his decision to renew his approval ethics of this research.

Respectfully,

Geneviève Lamy
Directrice adjointe | Associate Director
Directrice adjointe des affaires académiques et de l'éthique de la recherche | Directorate of Academic Affaires and Research Ethics
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal | CIUSSS West-Central Montreal

Pour/For

Cindy Starnino
Directrice des Affaires académiques | Director of Academic Affairs
Personne mandatée par l'établissement pour autoriser la réalisation des projets de recherche
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal | CIUSSS West-Central Montreal

Appendix C

Intervention Components: Videos and e-handouts with additional resources

English videos: https://precare.ca/healthcare-guides/oral-chemotherapy/

- Part 1: General information
- Part 2: Side effects
- Part 3: Support, fertility & work
- Part 4: Concerning Symptoms

French videos: https://precare.ca/fr/chimiotherapie-orale/

- Partie 1 : Informations générales
- Partie 2 : Effets secondaires
- Partie 3 : Le soutien, la fertilité et le travail
- Partie 4 : Symptômes

TOPIC #1: PAIN

WHAT CAUSES PAIN?

Treatment, medical tests, medication, the tumour itself, surgery, or side effects from treatment. For example, tumours can push against a nerve, organ, or bone. Constipation or nausea can also be painful.

THE GOOD NEWS

No matter what is causing your pain or discomfort, you can work closely with your healthcare team to develop a pain management plan. Do not wait until the pain is severe before speaking up. There is no benefit to "toughing it out." It is easier to control pain when it starts rather than waiting until the pain becomes overwhelming.

A PAIN MANAGEMENT PLAN

A well-prepared plan can help lower pain, improve mood, sleep, and appetite, as well as lead to better relationships with others. When working with your healthcare team to develop a plan, have a goal in mind for pain relief, such as lowering your pain level from a 6 to a 4 on a 0-10 scale, as seen below.

TRACK YOUR PAIN

Using a notebook or your phone to keep records of your pain can help your healthcare team fine-tune the plan and manage your pain more effectively. Track your pain throughout the day, including 1-2 hours after having taken any medicine.

HOW TO TRACK YOUR PAIN

On a scale of 0 to 10, how severe is your pain? 0 is no pain, and 10 is the worst pain you can imagine.
Where is your pain? Is it in different parts of your body?
When do you have the pain and how long does it last?
Is it there all the time, or does it come and go? Is it worse in the morning or evening?
Describe the pain. Is the pain sharp or dull? Cramping?
Changes. Does anything help (medication, heating pad) or make it worse (certain positions)?
How does the pain affect your life? Does it interfere with your normal daily activities?
Current strategies? Are you already taking over-the-counter medications? Does relaxation help? Have you tried massage, physio, or acupuncture? Have you tried exercise, such as walking or swimming?

WHAT IF YOU ARE TAKING NEW PAIN MEDICATION?

Keep track of how much medication you are taking, and the times throughout the day you are taking it. Be sure to pick up your prescription in advance to avoid running out of medicine. If you are taking opioids, let them know right away if you begin to feel constipated.

Contact your healthcare team right away if the pain persists or gets worse, if you experience new pain, pain when you breathe or sudden leg weakness, especially if you have back pain.

THIS INFORMATION IS PROVIDED AS AN EDUCATIONAL SERVICE ONLY
IT IS NOT MEANT TO TAKE THE PLACE OF MEDICAL CARE OR THE ADVICE OF YOUR HEALTHCARE TEAM

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Additional Resources

Canadian Cancer Society: Pain

Canadian Cancer Society: Pain related to peripheral neuropathy.

Cancer Care Ontario: Patient guide for pain

Quebec Cancer Foundation: Peripheral neuropathy

SUJET N ° 1: DOULEUR

QU'EST CE QUI CAUSE LA DOULEUR?

Le traitement, les tests médicaux, les médicaments, la chirurgie ou les effets secondaires du traitement. Par exemple, les tumeurs peuvent appuyer sur un nerf, un organe, ou un os. La constipation et les nausées peuvent également être douloureuses.

LA BONNE NOUVELLE

Peu importe la cause de la douleur ou de l'inconfort, vous pouvez travailler en collaboration avec votre équipe de soins de santé pour établir un plan de gestion pour votre douleur. N'attendez pas jusqu'à ce que la douleur soit grave avant d'en parler; il n'y a aucun avantage à «résister ». Il est plus facile de contrôler la douleur une fois qu'elle commence plutôt que d'attendre que la douleur devienne accablante.

UN PLAN DE GESTION DE LA DOULEUR

Un bon plan de gestion peut aider à réduire la douleur, améliorer votre humeur, votre sommeil, alimentation, et relations avec ceux qui vous entourent. Lorsque vous travaillez avec votre équipe de soins pour élaborer un plan, gardez à l'esprit un objectif pour le soulagement de la douleur, comme la réduction de votre douleur d'un niveau 6 à un niveau 4 sur une échelle de 0-10, tel de démontré ci-dessous.

SUIVEZ VOTRE DOULEUR

Prendre note des détails concernant votre douleur dans un cahier ou sur votre téléphone peut aider votre équipe de soins à affiner le plan de gestion afin de mieux gérer votre douleur. Suivez votre douleur tout au long de la journée, incluant 1 à 2 heures après avoir pris tout médicament.

LES CARACTÉRISTIQUES IMPORTANTES DE VOTRE DOULEUR À NOTER

De 0 à 10, comment est votre douleur?
0 équivaut à aucune douleur, et 10 équivaut la pire douleur que vous puissiez imaginer.
Où est la douleur? Elle se présente à plusieurs endroits de votre corps?
Quand resentez-vous la douleur, et combien de temps dure-t-elle?
La douleur est-elle toujours présente, ou elle alterne? Semble-t-elle être pire le matin ou le soir?
Décrivez la douleur. Est-elle vive ou soude? Ressentez vous des crampes?
Des changements. Qu'est-ce qui réduit la douleur ou l'aggrave (certaines positions)?
Votre fonctionnement? Votre douleur interfère-t-elle avec vos activités quotidiennes?
Stratégies actuelles? Prenez-vous déjà des médicaments sans ordonnance? Est-ce que la relaxation vous aide? Avez-vous essayé le massage, la physiothérapie ou l'acupuncture? De l'exercice, comme la marche ou la natation?

ET SI VOUS PRENEZ DE NOUVEAUX MÉDICAMENTS CONTRE LA DOULEUR?

Suivez l'heure et la quantité de médicament que vous prenez. Récupérez votre ordonnance à l'avance pour être certain de ne pas manquer de médication. Si vous prenez des opioïdes, informez votre équipe immédiatement si vous commencez à vous sentir constipé.
Communiquez immédiatement avec votre équipe de soins si la douleur persiste ou s'aggrave, si vous ressentez une nouvelle douleur, une douleur lorsque vous respirez ou une faiblesse soudaine des jambes, surtout si vous avez un mal au dos.

CES INFORMATIONS SONT FOURNIES À TITRE DE SERVICE ÉDUCATIF UNIQUEMENT;
ILS NE PEUVENT PAS REMPLACER LES SOINS MÉDICAUX OU LES CONSEILS DE VOTRE ÉQUIPE DE SOINS DE SANTÉ

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Ressources supplémentaires

Société Canadienne du cancer: Douleur

Société canadienne du cancer: Douleur liée à la neuropathie périphérique

Action Cancer Ontario: Guide patient pour la douleur

Fondation québécoise du cancer: Neuropathie périphérique

TOPIC #2: FATIGUE OR FEELING TIRED

WHAT CAUSES FATIGUE?

Cancer itself, treatment side effects (nausea, vomiting, and pain), emotional stress, depression, anxiety, anemia (low red blood cell count), nutrition problems, lack of physical activity and exercise, fatigue before treatment, medications, and sleep problems.

WHAT ARE SIGNS OF FATIGUE?

- Feeling more tired than usual, even after rest or sleep
- Sleeping more
- Spending more time in bed

Regardless of the cause, it is essential to manage your daily fatigue to the best of your ability and continue being active despite low energy levels.

FATIGUE MANAGEMENT PLAN

1. Communicate with your healthcare team

Talk to your team about fatigue and how it is affecting your life. Together, develop a plan to manage it. Contact them right away if your fatigue is suddenly much worse.

2. Ask for help

Talk to your family and friends about how they can help you with your daily activities. There are also local support services that can help, so ask your cancer support community, such as Hope & Cope or CanSupport, for a list of resources.

3. Save your energy for things that are important

Using your phone or a diary to keep track of your fatigue patterns can help in planning.

4. Lower stress levels

Emotional stress can increase fatigue, so try to reduce your daily stress as much as possible. Try relaxing activities such as talking with loved ones and minimize your home or work responsibilities during cancer treatment.

5. Break things down into smaller tasks

Decide what the most important things are to get done each day and focus on those first. For instance, dealing with that mountain of dirty laundry may be a daunting task when you are tired, so instead, try running only one load at a time.

6. Be active

Physical activity can help give you energy, so try to keep active. Regular exercise can also improve your mood and overall health. You can exercise at any time during or after treatment. Start slowly at your own pace. Try a brief, low-intensity exercise such yoga, and see how your body reacts. Even if you have exercised in the past, your body might respond differently to exercise during cancer and treatment. Aim for 30 minutes of brisk activity, meaning it shouldn't be too easy nor too hard. You could even divide the activity into three 10-minute sessions. If you don't know where to begin, meet with an exercise specialist at your cancer center who can help design a personalized exercise plan. Be sure to also talk with your healthcare team before starting a new exercise program.

7. Eat well

Having a well-balanced diet can increase your energy levels. Eat more home-cooked meals and eat regularly throughout the day. A balanced diet consists of eating fresh vegetables and fruits, whole grains, and a source of protein. If you are experiencing a lack of appetite, or are losing weight without trying, it may be helpful to speak with a dietitian.

8. Improve your sleep

Sleep problems are common during cancer, so talk to your doctor if you have been having difficulty sleeping. Sometimes changing medications or talking with a sleep specialist may help.

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Additional Resources

BC Cancer Agency: Managing fatigue

Canadian Cancer Society: Managing cancer-related fatigue

Cancer Care Ontario: Patient guide for fatigue

Hope & Cope Wellness Centre: Exercise programs, dance classes, yoga, and nutrition workshops or call 514-340-3616

Quebec Cancer Foundation: Fatigue and anemia

SUJET N ° 2: FATIGUE

QU'EST-CE QUI CAUSE LA FATIGUE?

Le cancer, les effets secondaires du traitement (nausée, vomissement, douleur), le stress émotionnel, la dépression, l'anxiété, l'anémie (faible nombre de globules rouges), problèmes de nutrition, un manque d'activité physique et d'exercice, la fatigue avant le traitement, les médicaments et les problèmes de sommeil.

QUELS SONT LES SIGNES DE FATIGUE?

- Se sentir plus fatigué que d' habitude, même après le repos ou le sommeil
- Dormir plus
- Passer plus de temps au lit

Quelle que soit la cause, il est important de bien gérer votre fatigue quotidienne du mieux que vous ne le pouvez et de continuer à être actif malgré un faible niveau d'énergie.

PLAN DE GESTION DE LA FATIGUE

1. Communiquez avec votre équipe de soins de santé

Parlez à votre équipe de votre fatigue et de ses effets sur votre vie. Ensemble, élaborez un plan pour gérer votre fatigue. Contactez-les immédiatement si votre fatigue est soudainement plus intense.

2. Demander de l'aide

Discutez avec votre famille et vos amis pour savoir comment ils peuvent vous aider. Il existe également des services de soutien locaux. Demandez à votre communauté de soutien, telle que L'espoir, c'est la vie, de vous fournir une liste de ressources.

3. Économisez votre énergie pour les choses importantes

Suivre vos habitudes de fatigue en utilisant un téléphone ou journal peut aider votre planification.

4. Réduisez votre niveau de stress

Le stress émotionnel peut augmenter la fatigue, alors essayez de réduire votre stress quotidien autant que possible. Essayez des activités de détente comme discuter avec vos proches, et réduisez vos responsabilités à la maison ou au travail pendant votre traitement pour le cancer.

5. Réduisez vos grosses tâches en tâches plus petites

Décidez quelles sont les tâches les plus importantes à accomplir chaque jour et concentrez-vous d'abord sur ces tâches. Faire face à cette montagne de linge sale peut être intimidant quand vous êtes fatigué, donc essayer de faire une brassée de lavage à la fois.

6. Soyez actif

L'activité physique peut aider à vous donner de l'énergie et peut également améliorer votre humeur et votre santé globale. Vous pouvez faire de l'exercise à tout moment pendant ou après le traitement. Commencez lentement, à votre rythme. Essayez un exercice bref à basse intensité comme le yoga, et regardez comment votre corps réagit; il se peut que votre corps réagisse différemment pendant le traitement du cancer.Visez 30 minutes d'activité qui n'est pas trop facile, ni trop difficile. Vous pouvez même la diviser en 3 sessions de 10 minutes. Si vous ne savez pas par où commence**/**, rencontrez un spécialiste d'exercice à votre centre de cancérologie. Il pourra vous aider à concevoir un programme d'exercice personnalisé. Consulter votre équipe de soins de santé avant de commencer un nouveau programme d'exercice.

7. Mangez bien

Avoir un regime alimentaire bien équilibré peut augmenter votre niveau d'énergie. Cela signifie manger davantage de plats cuisinés à la maison et manger régulièrement tout au long de la journée. Mangez des légumes et des fruits frais, des grains entiers et une source de protéine. Si vous ressentez un manque d'appétit ou si vous perdez du poids sans le vouloir, il peut être utile de parler avec un diététicien.

8. Améliorez votre sommeil

Les problèmes de sommeil sont fréquents pendant le cancer. Parlez à votre médecin si vous avez du mal à dormir. Changer de médicaments ou parler à un spécialiste du sommeil pourrait vous aider.

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Ressources supplémentaires

CHU de Quebec: Comprendre et gérer la fatigue liée au cancer

Société canadienne du cancer: Gérer la fatigue liée au cancer

Action Cancer Ontario: Guide patient pour la fatigue

L'espoir c'est la vie: Programmes d'exercices, des cours de danse, du yoga et des ateliers sur la nutrition ou appeler 514-340-3616

Fondation québecoise du cancer: Fatigue et anémie

TOPIC #3: DROWSINESS

WHAT CAUSES DROWSINESS?

Cancer itself, medications, treatment, changes in your hormone levels or number of red blood cells, and the emotional impact from cancer such as stress, depression or anxiety.

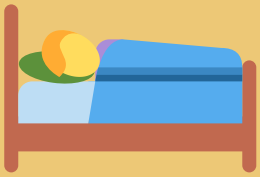
DROWSINESS IS FEELING EXCESSIVELY SLEEPY

It can mean feeling unusually sleepy during the day or sleeping more than usual at night. Drowsiness is different from fatigue, which is a lack of energy, even after sleeping.

Let your healthcare team know if you are experiencing drowsiness, the best way to manage depends on the cause.

WHAT ARE SIGNS OF DROWSINESS?

- Sleeping for more than 10 hours at night
- Having a hard time staying awake during the day
- Feeling very sleepy, even after a nap



DROWSINESS MANAGEMENT PLAN

1. Go to bed and wake up at the same time every day.

2. Go to bed 15 minutes earlier than you would typically. Fifteen minutes may not seem like a lot, but slowly moving to an earlier bedtime will help you get more sleep.

DROWSINESS MANAGEMENT PLAN

3. If possible, exercise in the morning or early afternoon. These are times when you might feel sleepy, and exercise will help wake you up. Remember that exercise does not have to be intense; try going for a morning or early afternoon walk around your neighbourhood.

4. Do not nap too late in the day. It will interfere with your sleep at night.

5. Avoid alcohol or caffeine.

DROWSINESS MANAGEMENT PLAN

6. Light during the day is the way your body keeps track of your sleeping pattern, known as your circadian rhythm. In the morning, try to get at least 30 minutes of sun exposure. It can be light from the sun or a specialized white light from a sun lamp.

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Additional Resources

Canadian Cancer Society: Sleep problems

Canadian Cancer Society: What is the circadian rhythm?

SUJET N ° 3: SOMNOLENCE

QU'EST-CE QUI CAUSE LA SOMNOLENCE?

- Le cancer, les médicaments et/ou le traitement
- Un changement de vos niveaux d'hormones ou l'anémie (faible nombre de globules rouges)
- Le fardeau émotionnel du cancer, le stress, la dépression ou l'anxiété

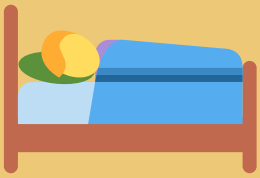
LA SOMNOLENCE EST UNE SENSATION DE SOMMEIL EXCESSIF

Cela peut signifier se sentir exceptionnellement somnolent pendant la journée ou dormir plus que d'habitude la nuit. La somnolence est différente de la fatigue, qui est un manque d'énergie, même après avoir dormi.

Informer votre équipe de soins si vous avez de la somnolence. La gestion de la somnolence dépend de sa cause.

QUELQUES SIGNES DE SOMNOLENCE

- Dormir plus de 10 heures la nuit
- Difficulté à rester éveillé pendant la journée
- Se sentir très fatigué, même après une sieste



PLAN DE GESTION DE LA SOMNOLENCE

1. Essayez de vous coucher et de vous lever à la même heure tous les jours.

2. Allez vous couchez 15 minutes plus tôt que vous ne le feriez typiquement. 15 minutes peuvent sembler minimes, mais vous coucher plus tôt vous aidera à mieux dormir graduellement.

PLAN DE GESTION DE LA SOMNOLENCE

3. Si possible, faites de l'exercice le matin ou en début d'après-midi. Vous pouvez vous sentir somnolent à ces moments et l'exercice vous aidera à vous réveiller. L'exercice ne doit pas être intense, essayez de vous promener le matin ou en début de l'après-midi dans votre quartier.

4. Ne faites pas la sieste trop tard dans la journée. Cela nuira à votre sommeil la nuit.

5. Évitez l'alcool et la caféine.

PLAN DE GESTION DE LA SOMNOLENCE

6. L'exposition à la lumière pendant la journée permet votre corps de suivre un rythme de sommeil que l'on appelle le rythme circadien. Essayez de vous exposer à au moins 30 minutes de lumière naturelle le matin –elle peut provenir du soleil ou d'une lampe solaire spéciale à lumière blanche.

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ONcology - Bolstering Oral Agent Reporting related to Distress

Ressources supplémentaires

Société canadienne du cancer: Troubles de sommeil

Société canadienne du cancer: Qu'est-ce que le rythme circadien?

TOPIC #4: NAUSEA AND VOMITING

WHAT CAUSES NAUSEA AND VOMITING?

Cancer itself, medications, treatment, constipation, infection, motion sickness, pain, headache, and the emotional impact from cancer such as stress or anxiety.

LET YOUR HEALTHCARE TEAM KNOW IF YOU ARE EXPERIENCING NAUSEA OR VOMITING

They may be able to help by prescribing anti-nausea medications. Your doctor may have already prescribed medications to you in case you need them. If you have trouble keeping the medicine down, speak to your doctor, nurse, or pharmacist. When working with your healthcare team to develop a plan, have a goal for nausea/vomiting in mind, such as being able to keep your breakfast down.

NAUSEA AND VOMITING MANAGEMENT PLAN

1. Drink plenty of water, in small amounts. If you have trouble drinking water, speak to your healthcare team, they may provide you with an IV to make sure that you are getting plenty of fluids.

2. Do not rush to eat. Take your time.

3. After you are done eating, try to stay standing or sitting upright for the next 30-60 minutes.

NAUSEA AND VOMITING MANAGEMENT PLAN

4. Snack or eat small meals every 2-3 hours throughout the day.

5. Limit alcohol, coffee, and caffeinated drinks.

6. Avoid food or drinks with strong smells. If you can, open a window, use a fan or eat outside, fresh air will get rid of the smell from food and may help you feel better.

NAUSEA AND VOMITING MANAGEMENT PLAN

7. If you are vomiting, wait 30-60 minutes until after the vomiting stops before eating. First sip clear fluids, like water or soup broth. If they stay down, try eating dry or starchy foods like crackers, toast, or rice. Then, try lean proteins such as chicken or eggs.

8. Try relaxation techniques such as listening to calming music or progressive muscle relaxation.

9. Tight clothes around the waist can worsen nausea, try wearing looser fitting clothing.

CALL YOUR HEALTHCARE TEAM OR GO TO THE EMERGENCY DEPARTMENT RIGHT AWAY IF YOU:

- Experience severe nausea, even with medication
- Experience nausea and vomiting with constipation
- Feel weak, dizzy and confused

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Additional Resources

Canadian Cancer Society: Nausea and vomiting

Cancer Care Ontario: Patient guide for nausea and vomiting

Health Link BC: Home treatment for nausea and vomiting

Quebec Cancer Foundation: Nausea and vomiting

SUJET N ° 4: NAUSÉES ET VOMISSEMENTS

QU'EST-CE QUI CAUSE LES NAUSÉES ET VOMISSEMENTS?

Le cancer, les médicaments, le traitement, la constipation, une infection, le mal des transports, la douleur, un mal de tête, le fardeau émotionnel du cancer tel que le stress ou l'anxiété.

SI VOUS AVEZ DES NAUSÉES OU DES VOMISSEMENTS, INFORMEZ VOTRE ÉQUIPE DE SOINS DÈS QUE POSSIBLE

Ils peuvent vous aider en ordonnant des médicaments contre la nausée. Votre médecin vous a peut-être déjà prescrit ces médicaments au cas où vous en auriez besoin. Si vous avez des difficultés à prendre vos médicaments, parlez-en à votre médecin, votre infirmière, ou votre pharmacien. Lorsque vous travaillez avec votre équipe de soins pour élaborer un plan, gardez à l'esprit un objectif pour les nausées/vomissements, comme être en mesure de garder votre petit-déjeuner.

PLAN DE GESTION POUR LES NAUSÉES ET VOMISSEMENTS

1. Buvez beaucoup d'eau, en petites quantités. Si vous avez de la difficulté à boir de l'eau potable, parlez à votre équipe soignante, qui peut vous fournir une solution intraveineuse pour assurer que vous obtenez assez de liquides.

2. Ne vous précipitez pas pour manger, prenez votre temps.

3. Une fois que vous avez fini de manger, essayez de rester debout pendant les prochaines 30 à 60 minutes.

PLAN DE GESTION POUR LES NAUSÉES ET VOMISSEMENTS

4. Prenez une collation ou petit-repas toutes les 2 à 3 heures tout au long de la journée.

5. Limitez l'alcool, le café et les boissons avec la caféine.

6. Évitez les aliments ou les boissons à forte odeur. Si vous le pouvez, ouvrez une fenêtre, utilisez un ventilateur ou mangez à l'extérieur. L'air frais éliminera l'odeur des aliments et pourra vous aider à mieux sentir.

PLAN DE GESTION POUR LES NAUSÉES ET VOMISSEMENTS

7. Si vous vomissez, attendez 30 à 60 minutes après que les vomissements cessent avant de manger. Sirotez d'abord des liquides clairs, comme de l'eau ou du bouillon de soupe. S'ils restent, essayez de manger des aliments secs ou féculents comme des craquelins, des toasts ou du riz. Ensuite, essayez des protéines maigres comme le poulet ou les œufs.

8. Essayez des techniques de relaxation comme écouter la musique apaisante ou la relaxation musculaire progressive.

9. Des vêtements trop serrés autour de la taille peuvent aggraver la nausée. Essayez de porter des vêtements plus amples.

APPELEZ VOTRE ÉQUIPE DE SOINS OU ALLEZ IMMÉDIATEMENT À L'URGENCE SI VOUS:

- Avez des nausées sévères, même avec des medicaments
- Avez des nausées et vomissements avec constipation
- Vous sentez faible, étourdi et confus

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Ressources supplémentaires

Société canadienne du cancer: Nausées et vomissements

Action Cancer Ontario: Guide patient pour les nausées et vomissements

CHU Montreal: Ce que vous pouvez faire pour les nausées et vomissements liés à la chimiothérapie

Fondation québécoise du cancer: Nausées et vomissements

TOPIC #5: LACK OF APPETITE

WHAT CAUSES LACK OF APPETITE?

Some people have trouble eating because of symptoms, medications, or treatment side effects. Cancer-related issues such as pain, fatigue, constipation, diarrhea, dietary restrictions, and nausea, may also make it difficult to enjoy or eat meals.

TALK TO YOUR HEALTHCARE TEAM IF YOU ARE EXPERIENCING SYMPTOMS LIKE PAIN OR NAUSEA THAT ARE INTERFERING WITH YOUR EATING. TOGETHER, WITH A GOAL IN MIND, DEVELOP A PLAN TO MANAGE YOUR APPETITE.

MANAGING A LACK OF APPETITE

Drink liquids throughout the day, at least 6-8 cups each day. Liquids include water, juice, soup, milk, and fruit smoothies. Try to limit caffeine and alcohol.

Don't worry about a schedule, eat whatever foods taste good to you, whenever you feel like it.

MANAGING A LACK OF APPETITE

Emotions can influence your appetite. Sometimes going out to eat with friends or family or asking someone to come over to eat with you can increase your appetite.

Keep a diary to track your food and weight. If you are experiencing a lack of appetite, or are losing weight without trying to, speaking with a dietitian may be beneficial.

MANAGING A LACK OF APPETITE

Foods may have changed in taste because of your treatment. For example, you may experience a metallic taste in your mouth. Try to eat with plastic cutlery or eat certain foods cold. Rinse your mouth before and after eating to maintain good mouth care. If food or drink odours bother you, open a window, use a fan, or eat outside.

MANAGING A LACK OF APPETITE

Things to try:

1. Small meals and snacks instead of big meals throughout the day.
2. Foods that are high in protein, as they help your body heal during treatment. Foods high in protein include meat, dairy, tofu, lentils, and eggs. You can also add vegan protein powder to certain foods to add protein in your diet.
3. Foods higher in calories. Try adding fats such as butter, cream, olive oil, nut butters, and avocado.

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Additional Resources

L'Association des popotes roulantes du Montréal métropolitain (APRMM): Home delivery of meals at affordable prices

Canadian Cancer Society: Eat well

Canadian Cancer Society: Food safety

Cancer Care Ontario: Patient guide for loss of appetite

Hope & Cope Wellness Centre: Nutrition program and workshops or call 514-340-3616

Jewish General Hospital: Cancer nutrition-rehabilitation program or call (514) 340-8222 x 23150

SUJET N ° 5: MANQUE D'APPÉTIT

QU'EST-CE QUI CAUSE UN MANQUE D'APPÉTIT?

Certaines personnes ont de la difficulté à manger à cause des symptômes du cancer, des medicaments ou les effets secondaires du traitement. Les symptômes liées au cancer tels que la douleur, la fatigue, la constipation, la diarrhée, les restrictions alimentaires et les nausées peuvent rendre manger et apprécier ses repas plus difficile.

PARLEZ À VOTRE ÉQUIPE DE SOINS DE SANTÉ SI VOUS AVEZ DES SYMPTÔMES COMME LA DOULEUR OU DES NAUSÉES QUI PERTUBENT VOTRE ALIMENTATION. ENSEMBLE, AVEC UN OBJECTIF EN TÊTE, ÉLABOREZ UN PLAN POUR GÉRER VOTRE APPÉTIT.

GÉRER UN MANQUE D'APPÉTIT

Buvez des liquides tout au long de la journée, au moins 6 à 8 tasses par jour. Les liquides peuvent être de l'eau, les jus, les soupes, le lait et les smoothies aux fruits. Essayez de limiter la caféine et l'alcool.

Mangez la nourriture qui vous plait quand vous en avez envie, ne vous inquiétez pas de manger selon un horaire.

GÉRER UN MANQUE D'APPÉTIT

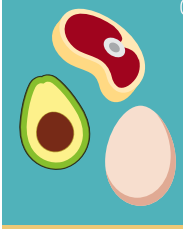
Les émotions peuvent influencer notre appétit. Parfois, votre appétit peut augmenter si vous allez manger avec des amis, en famille ou si vous demandez à quelqu'un de venir avec vous.

Gardez un journal de ce que vous mangez et votre poids. Si vous éprouvez un manque d'appétit ou si vous perdez du poids sans essayer, il peut être avantageux de parler à un diététiste.

GÉRER UN MANQUE D'APPÉTIT

Le goût des aliments peut avoir changé en raison de votre traitement. Par exemple, vous avez peut-être un goût métalique dans la bouche. Essayer de manger avec des ustensiles en plastique ou de manger certains aliments froids. Il est également recommandé de se rincer la bouche avant et après les repas pour maintenir une bonne hygiène orale. Si les odeurs de nourriture ou de boisson vous dérangent, ouvrez une fenêtre, utilisez un ventilateur ou mangez dehors.

GÉRER UN MANQUE D'APPÉTIT



Choses à essayer:

1. Petits repas et collations au lieu de gros repas tout au long de la journée.
2. Les aliments riches en protéines, car ils aident votre corps à guérir pendant le traitement. Les aliments riches en protéines comprennent la viande, les produits laitiers, le tofu, les lentilles et les œufs. Vous pouvez également ajouter de la poudre de protéine à certains aliments.
3. Les aliments riches en calories. Essayez d'ajouter des matières grasses telles que le beurre, la crème, l'huile d'olive, le beurre de noix et l'avocat.

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Ressources supplémentaires

L'Association des popotes roulantes du Montréal métropolitain (APRMM): Livraison de repas à domicile à des prix abordables

Société canadienne du cancer: Mangez bien

Société canadienne du cancer: Salubrité des aliments

Action Cancer Ontario: Guide patient pour perte d'appétit

L'espoir c'est la vie: Ateliers de cuisine et de nutrition ou appeler 514-340-3616

Hôpital général juif: Programme de nutrition-réadaptation pour le cancer ou appeler (514) 340-8222 x 23150

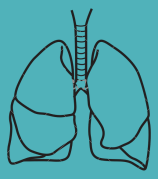
TOPIC #6: SHORTNESS OF BREATH

WHAT CAUSES SHORTNESS OF BREATH?

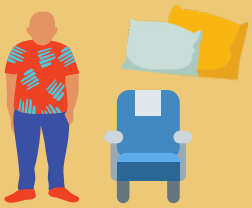
Cancer itself, treatment that affects your lungs, build-up of fluid in your lungs or stomach, chest infections, anemia, weak muscles, pain, blood clots, smoking, and the emotional impact from cancer, stress or anxiety.

It is important to let your healthcare team know if you are experiencing shortness of breath as the best way to manage it will depend on the cause.

Shortness of breath is an uncomfortable feeling of not having enough air to breathe. Typically, when you breathe in, your lungs fill with air. They extract oxygen from the air, and your blood carries this oxygen to different parts of your body. When you experience shortness of breath, your lungs are not able to get as much oxygen from your breath.



MANAGING SHORTNESS OF BREATH



Positions that may help you breathe easier:

Standing - Stand against a wall with your chin a little towards your chest, shoulders relaxed and arms by your side.
Sitting - Sit and lean forward with both feet on the floor, with palms and wrists resting on your thighs.
Laying down - Using pillows, sit up in bed, and slope your upper body at a 45-degree angle.

MANAGING SHORTNESS OF BREATH

Try deep breathing, it is a technique that involves using your diaphragm, a muscle in your lower chest. It may help make breathing more comfortable if you are feeling out of breath.

1. Place the palm of your hand just below your chest, on your stomach.
2. Breathe in slowly, counting from 1 to 4. You will feel your stomach fill with air as your hand rises.
3. Purse your lips and slowly breathe out, counting from 1 to 6.

MANAGING SHORTNESS OF BREATH

Relaxing can help slow down your breathing. Close your eyes and do something that helps you relax such as:

- Think of a favourite memory
- Create a picture in your mind
- Listen to music

Increasing airflow to your face can help you feel better. Try to cool down the room temperature by using a fan or opening a window.

CALL YOUR HEALTHCARE TEAM OR GO TO THE EMERGENCY DEPARTMENT RIGHT AWAY IF YOU EXPERIENCE ANY SUDDEN SHORTNESS OF BREATH, SHARP PAIN WHEN YOU BREATHE, OR FEEL IT IS HARD TO BREATHE.

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Additional Resources

BC Cancer Agency: Breathlessness

Canadian Cancer Society: Difficulty breathing

Cancer Care Ontario: Patient guide for dyspnea (shortness of breath)

Progressive muscle relaxation (video): Guided

TEDx x Talks (video): Breath – Five minutes

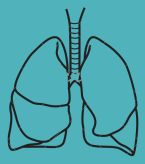
SUJET N ° 6: ESSOUFFLEMENT

QU'EST-CE QUI CAUSE L'ESSOUFFLEMENT?

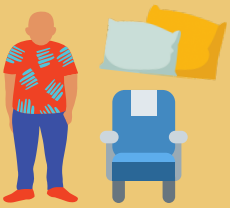
Le cancer, les traitements qui affecte les poumons, une accumulation de liquide dans les poumons ou l'estomac, des infections de la poitrine , l'anémie, la faiblesse musculaire, la douleur, des caillots sanguins, du tabagisme, et le fardeau émotionnel du cancer tel que le stress ou l'anxiété.

Il est important que vous informez votre équipe de soins de votre essoufflement. La meilleure façon de le gérer dépend de la cause.

L'essoufflement est une sensation inconfortable où vous n'avez pas assez d'air pour respirer. Généralement, lorsque vous inspirez, vos poumons se remplissent d'air et extraient l'oxygène de l'air. Votre sang transporte cet oxygène vers diverses parties de votre corps, mais lorsque vous éprouvez un essoufflement, vos poumons ne peuvent plus absorber autant d'oxygène.



GÉRER L'ESSOUFFLEMENT



Positions qui peuvent vous aider à mieux respirer:

Debout - Tenez-vous contre un mur, le menton légèrement vers la poitrine, les épaules détendues et les bras de chaque côté.
Assis - Asseyez-vous et penchez-vous en avant, les pieds au sol, les paumes des mains et les poignets reposants sur vos cuisses.
Se couchant - En utilisant un oreiller, asseyez-vous dans votre lit et penchez votre corps à un angle de 45 degrés.

GÉRER L'ESSOUFFLEMENT

La respiration en profondeur est une technique qui consiste à utiliser votre diaphragme, un muscle dans la poitrine inférieure, pour respirer. La respiration en profondeur peut aider à mieux respirer si vous vous sentez essoufflé.

1. Placez la paume de votre main juste sous votre poitrine, sur votre ventre.
2. Respirez lentement en comptant de 1 à 4 . Vous sentirez votre estomac se remplir d'air lorsque la main se lèvera.
3. Pincez vos lèvres et lentement expirer, comptant de 1 à 6.

GÉRER L'ESSOUFFLEMENT

Vous détendre peut aider à ralentir votre respiration. Fermez les yeux et faites quelque chose qui vous aide à vos relaxer, tel que:

- Pensez à votre meilleur souvenir
- Créez une image relaxante dans votre tête
- Écoutez de la musique

Augmenter le flux d'aire vers votre visage peut vous aider à mieux vous sentir. Essayez de refroidir la température ambiante en utilisant un ventilateur ou en ouvrant une fenêtre.

APPELEZ VOTRE ÉQUIPE DE SOINS OU ALLER À L'URGENCE IMMÉDIATEMENT SI VOUS AVEZ UN ESSOUFFLEMENT SOUDAIN, DE LA DOULEUR LORSQUE VOUS RESPIREZ, OU LE SENTIMENT QU'IL EST DIFFICILE DE RESPIRER.

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Ressources supplémentaires

Passeport Santé: L'essoufflement

Société canadienne du cancer: Difficulté à respirer

Action Cancer Ontario: Guide patient pour la dyspnée (essoufflement)

Relaxation musculaire progressive (vidéo): Guidée

TEDx x Talks (vidéo): Souffle - Cinq minutes *(selectioner sous-titres en français)*

TOPIC #7: DEPRESSION

WHAT CONTRIBUTES TO DEPRESSION?

Symptoms can be emotional such as sadness, irritability, feeling hopeless, not enjoying things you once did, and having trouble concentrating. Symptoms can also be physical such as having difficulty sleeping, feeling low in energy, not being hungry or eating too much, and other issues that can cause problems in daily life.

IT IS NORMAL TO FEEL SAD WHEN COPING WITH CANCER

Everyone's reaction to cancer may be different. Negative emotions are to be expected during this stressful time. If your sadness is difficult to deal with, lasts for a long time, or has a negative impact on your life, you should talk with your healthcare team. Find out if a referral to oncology support services would be appropriate for you.

MANAGEMENT PLAN

It is important to remember that you are not alone. You can talk to your family, friends, and your healthcare team about your feelings, which may change over time. You can also talk to other people with cancer, and ask them how they are managing emotionally. The volunteer organization Hope & Cope offers support through group or individual meetings.

MANAGEMENT PLAN

Taking care of yourself can help you feel better. Surround yourself with people you like, eat healthy foods, exercise, maintain a regular sleep schedule, and take time to relax.

FOCUS ON:

- **What you can do rather than what you can't control**. Learn more about cancer and what to expect, take an active role in your treatment planning, come up with a list of questions for the healthcare team, and figure out new ways of dealing with your illness.
- **The positive rather than the negative.** Things and people that make you laugh, happy or bring you joy. Make a list of activities you enjoy such as watching a movie, listening to music, reading a book, or taking a bath. Choose one whenever you feel sad.

IF YOUR EMOTIONS ARE DIFFICULT TO BEAR OR ARE HURTING YOUR LIFE

The first step is to discuss your symptoms with a health care professional to find out what support services are right for you. We encourage you to talk with a professional such as a psychologist, social worker, nurse, or psychiatrist experienced in working with individuals with cancer. **If you are thinking about committing suicide or have tried to commit suicide, go to the emergency room, call 911 right or Suicide Action Montreal 1-866-277-3553 right away.**

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Additional resources:

Canadian Cancer Society: Coping with your emotions

Canadian Cancer Society: Your emotions and cancer

Canadian Cancer Society: Talk to an informational specialist, call 1-888-939-3333

Cancer Care Ontario: Patient guide for depression

Cancer Chat Canada: Online support groups

Hope & Cope: support groups and one-to-one peer support programs
Contact Hinda Goodman at 514-340-8222 ext. 25531 or hgoodman@onco.jgh.mcgill.ca.

Progressive muscle relaxation (video): Guided

Quebec Cancer Foundation: Anxiety and depression

Suicide Action Montreal: 24-hour hotline, call 1-866-277-3553 or 514-723-4000

SUJET N° 7: DÉPRESSION

QU'EST-CE QUI CONTRIBUE À LA DÉPRESSION?

Les symptômes peuvent être émotionnel tels que des sentiments de tristesse, d'irritabilité, de désespoir, ne jouir pas des activités que vous aimiez faire dans le passé, et avoir de la difficulté à vous concentrer. Les symptômes peuvent aussi être physiques comme avoir de la difficulté à dormir, se sentir faible en énergie, ne pas avoir faim ou trop manger, et d'autres problèmes qui peuvent nuire à votre vie quotidienne.

IL EST NORMAL DE SE SENTIR TRISTE FACE AU CANCER

La réaction de chaque personne face au cancer peut être différente. Des émotions négatives sont à prévoir lors de cette période stressante. Si vous éprouvez de la difficulté à surmonter votre tristesse, si elle dure longtemps ou a un impact négatif sur votre vie, vous devriez parler avec votre équipe de soins. Renseigner vous si une référence aux services de soutien en oncologie vous conviendrait.

PLAN DE GESTION

Il est important de se souvenir que vous n'êtes pas seul(e). Vos sentiments peuvent changer avec le temps. Vous pouvez en parler avec votre famille, vos amis et votre équipe de soins. Vous pouvez également demander à d'autres personnes atteintes de cancer comment ils gèrent leurs émotions. L'organisation bénévole L'espoir c'est la vie offre du soutien en group ou en forme individuelle.

PLAN DE GESTION

Prendre soin de vous-même peut vous aider à mieux vous sentir. Entourez-vous de gens que vous aimez, manger sainement, faites de l'exercice, maintenez un horaire de sommeil régulier et participez à des activités de détente.

CONCENTREZ VOUS SUR:

- **Ce que vous pouvez faire plutôt que ce que vous ne pouvez pas contrôler.**

Apprenez davantage sur le cancer. Prenez un rôle actif dans la planification de votre traitement et préparez une liste de questions pour votre équipe de soins. Sachez à quoi vous attendre et déterminez de nouvelles façons pour affronter votre maladie.

- **Le positif plutôt que le négatif.**

Concentrez-vous sur les choses et les personnes qui vous font rire, qui vous rendent heureux ou vous apportent de la joie. Faites une liste d'activités que vous aimez telles que regarder des films, écouter de la musique, lire ou prendre un bain. Faites une de ces activités chaque fois que vous vous sentez triste.

SI VOS ÉMOTIONS SONT DIFFICILES À SUPPORTER OU ONT UN IMPACT NÉGATIF SUR VOTRE VIE

La première étape consiste à discuter de vos symptômes avec un professionnel de la santé afin de déterminer quelles services de soutien sont appropriés pour vous. Nous vous encourageons à parler à un professionnel tel qu'un psychologue, un travailleur social, une infirmière ou un psychiatre ayant déja travaillé avec des gens atteints de cancer. **Si vous envisagez de vous suicider ou si vous avez essayé de vous suicider, rendez-vous aux urgences, composez le 911 ou Suicide Action Montréal 1-866-277-3553 immédiatement.**

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Ressources supplémentaires

Passeport Santé: La dépression chronique ou déprime ?

Société canadienne du cancer: Vos émotions et le cancer

Société canadienne du cancer: Faire face à vos émotions

Société canadienne du cancer: Parlez à un spécialiste en information, appelez 1-888-939-3333

Action Cancer Ontario: Guide patient pour la dépression

Fondation québécoise du cancer: Anxiété et dépression

L'espoir c'est la vie: Groupes de soutien et programme de soutien par les pairs, contactez Hinda Goodman au 514-340-8222 ext. 25531 ou hgoodman@onco.jgh.mcgill.ca .

Relaxation musculaire progressive (vidéo): Guidée

Suicide Action Montreal: Assistance téléphonique 24h par jour, 7 jours sur 7, 1-866-277-3553 ou 514-723-4000

TOPIC #8: ANXIETY

WHAT CONTRIBUTES TO ANXIETY?

Anxiety includes feelings of worry, fear, or nervousness. Many people have concerns about the future when coping with cancer. Each person has a different response to cancer and its treatment. You may feel nervous or afraid because you do not know how cancer will impact your life and the lives of those around you.

EMOTIONS COME AND GO OVER TIME

It may be helpful to talk with people who have been through cancer to ask about their experiences and useful coping strategies. Local community organizations, including Hope & Cope, usually offer assistance through mentoring and support groups for people who are dealing with cancer. If your anxiety is difficult to deal with, lasts for a long time, or has a negative impact on your life, you can also talk with your healthcare team. Find out if a referral to oncology support services would be right for you.

MANAGEMENT PLAN

1. Ask questions and express your concerns to your healthcare team and loved ones. It is okay to let them know how you feel and to ask for support.

2. Take good care of yourself. Eat well, have a regular sleep schedule, and focus on enjoyable activities that can help you feel better mentally and physically.

3. Are there specific thoughts that make you feel more nervous or afraid? For example, are you worried about how cancer will affect your family? Are there things that you can do to help ease these concerns, such as expressing your worries to your family or attending a support group? Learn more about programs that may help, such as cognitive behavioural therapy or mindfulness-based stress reduction.

4. Are there specific thoughts or activities that you have been avoiding because they make you feel anxious or afraid? Try your best to face these fears. Overtime, facing them can lessen them while avoiding them can increase them.

5. Try to focus on what you can do rather than what you can't control. Learn more about cancer and what to expect, take an active role in your treatment planning, come up with a list of questions for the healthcare team, and figure out new ways of dealing with your illness.

6. Try to focus on the positive rather than the negative. Focus on things and people that make you laugh, happy, or bring you joy. Make a list of activities you enjoy, such as watching a movie, listening to music, reading a book, or taking a bath. Choose one whenever you feel anxious.

7. Engage in relaxation techniques. Try progressive muscle relaxation, which involves paying attention to the tensing then relaxing of your muscles. Other relaxation techniques to try include deep breathing, mindfulness, massage, yoga, guided imagery, or art therapy.

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Additional resources

Canadian Cancer Society: Coping with your emotions

Canadian Cancer Society: Your emotions and cancer

Canadian Cancer Society: Coping with anxiety and stress

Canadian Cancer Society: Talk to an informational specialist, call 1-888-939-3333

Cancer Chat Canada: Online support groups

Cancer Care Ontario: Patient guide for anxiety

Hope & Cope: support groups and one-to-one peer support programs
Contact Hinda Goodman at 514-340-8222 ext. 25531 or hgoodman@onco.jgh.mcgill.ca.

Progressive muscle relaxation (video): Guided

Quebec Cancer Foundation: Anxiety and depression

SUJET N ° 8 : ANXIÉTÉ

QU'EST-CE QUI CONTRIBUE À L'ANXIÉTÉ?

L'anxiété liée au cancer est un sentiment d'inquiétude, de crainte ou de nervosité. Plusieurs personnes craignent le futur lorsqu'ils affrontent le cancer. Chaque personne réagit différemment au cancer et au traitement. Vous pouvez être inquiet ou avoir peur, car vous ne savez pas comment le cancer affectera votre vie et celle de ceux qui vous entourent.

LES ÉMOTIONS VONT ET VIENNENT AVEC LE TEMPS

Il peut être utile pour vous de parler avec des gens qui ont déjà affronté un cancer et de leur poser des questions sur leurs expériences et stratégies d'adaptation. Les organisations communautaires local, tel que L'espoir C'est la Vie, offrent de l'aide et du soutien en formule de groupe et de mentorat pour les personnes atteintes du cancer. Si votre anxiété est difficile à gérer, dure longtemps ou si elle a un impact négatif sur votre vie, vous devriez en parler avec votre équipe de soins. Renseignez-vous pour voir si une référence aux services de soutiens en oncologie pourrait vous être bénéfique.

PLAN DE GESTION

1. Posez des questions et exprimez vos inquiétudes à votre équipe de soins et à vos proches. Vous pouvez leur dire ce que vous ressentez et demander de l'aide.

2. Prenez bien soin de vous. Mangez bien, suivez un horaire de sommeil régulier et concentrer vous sur des activités agréables qui peuvent vous aider à vous sentir mieux mentalement et physiquement.

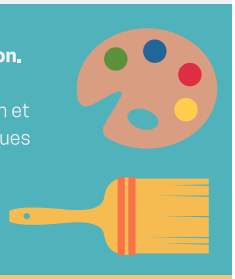
3. Y a-t-il des pensées particuliers qui vous rendent nerveux ou effrayé? Par exemple, êtes - vous inquiet de la façon dont le cancer affectera votre famille? Y a-t-il des choses que vous pouvez faire pour atténuer vos inquiétudes, comme les exprimer à votre famille ou participer à un groupe de soutien? Apprenez davantage sur des programmes qui peuvent vous aider, comme la thérapie cognitivo-comportementale ou la réduction du stress basée sur la pleine conscience.

4. Y a-t-il des pensées ou des activités particuliers que vous avez évitées parce qu'elles vous font sentir anxieux ou effrayé? Affrontez ces activités, si vous en êtes capable, avec l'aide de vos amis, de votre famille ou de la communauté. Plus vous les évitez, plus vous deviendrez inquiet.

5. Concentrez-vous sur ce que vous pouvez faire plutôt que ce que vous ne pouvez pas contrôler. Apprenez davantage sur le cancer. Prenez un rôle actif dans la planification de votre traitement et préparez une liste de questions pour votre équipe de soins.Sachez à quoi vous attendre et déterminez de nouvelles façons pour affronter votre maladie.

6. Concentrez-vous sur le positif plutôt que le négatif. Concentrez-vous sur les choses et les personnes qui vous font rire, qui vous rendent heureux ou vous apportent de la joie. Faites une liste d'activités que vous aimez telles que regarder des films, écouter de la musique, lire ou prendre un bain. Faites une de ces activités chaque fois que vous vous sentez triste.

7. Engagez vous dans des techniques de relaxation. Essayez la relaxation musculaire progressive, une technique qui consiste à prêter attention à la tension et ensuite la détente de vos muscles. D'autres techniques de relaxation à essayer comprennent la respiration profonde, la pleine conscience, le massage, le yoga, l'imagerie guidée ou la thérapie par l'art.



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Ressources supplémentaires

Société canadienne du cancer: Vos émotions et le cancer

Société canadienne du cancer: Faire face à vos émotions

Société canadienne du cancer: Composer avec l'anxiété et le stress

Société canadienne du cancer: Parlez à un spécialiste en information, appelez 1-888-939-3333

Action Cancer Ontario: Guide patient pour l'anxiété

Fondation québécoise du cancer: Anxiété et dépression

L'espoir c'est la vie: Groupes de soutien et programme de soutien par les pairs, contactez Hinda Goodman au 514-340-8222 ext. 25531 ou hgoodman@onco.jgh.mcgill.ca .

Relaxation musculaire progressive (vidéo): Guidée

TOPIC #9: WELLBEING

WHAT CONTRIBUTES TO WELLBEING?

Wellbeing is the state of feeling healthy and/or happy. This includes good mental health, being satisfied with your life, and a sense of purpose.

YOU ARE IN CHARGE OF YOUR WELLBEING

It is not something you have or do, but rather something that you are. A cancer diagnosis can come with difficult emotions, but you can still be well through how you deal with them. Mental wellbeing means having the ability to value your life and take on its challenges.

MANAGEMENT PLAN

1. SPEND TIME WITH OTHERS

Relationships allow us to share how we are feeling and get support from others.
Spend time with people you care about, but also build new relationships.

- Take time each day to be with your friends and/or family. If you are too tired to leave your house, arrange visits with them to come over and chat. When you feel up to it, try to schedule activities with others, such as watching a movie or meeting for tea or coffee.
- It may help to connect with people who have been through or are going through similar experiences as you. Local community organizations, such as Hope & Cope, offer mentoring and support groups for people dealing with cancer.

2. EXERCISE

Regular exercise can help improve your mood and overall health. Before starting any exercise program, talk with your doctor. Drink plenty of water when exercising to avoid dehydration.

- Try a brief, low-intensity exercise to see how your body reacts. Walk briskly for a few minutes, slow down, and walk quickly again, until you have done 30 minutes of brisk activity. You could even divide the activity into three 10-minute sessions.
- Think of a fun physical activity that you would enjoy regularly doing (examples: hiking, swimming). You are more likely to persevere with activities that you enjoy.
- Avoid any activity that puts you at risk for falls or injury. If you notice swelling, nausea/vomiting, breathing issues, pain, dizziness, or blurred vision, call your doctor right away.

3. LEARN SOMETHING NEW

Learning new things can help you feel more satisfied with your life and build your self-esteem.

- Watch a movie or read a book about a topic that interests you.
- Rediscover an old hobby or develop hobbies that challenge you to set activity goals, such as knitting, sewing, reading, writing, photography, painting, cooking, or baking.

4. BE MINDFUL

Mindfulness means being aware of yourself at all times, both physically and emotionally. It includes being aware of your thoughts and feelings, but also the sights, smells, sounds, tastes, and touch of each moment.

- Stop and take a moment to notice things throughout the day, such as the smell of your coffee.
- Take a step back and observe your thoughts, think of them as clouds in the sky. Mindfulness is not about making good thoughts come, or bad thoughts go away, but seeing them as they come and go.
- Name your thoughts and feelings as they arise. Some people find it helpful to write them down through journaling.

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Additional Resources

Canadian Cancer Society: Coping with anxiety and stress

Canadian Cancer Society: Meditation

Fondation Virage: Therapeutic Yoga for individuals with cancer, 514-890-8000 ext 28139 or virage@viragecancer.org

Happify (video): Why Mindfulness is a Superpower

Hope & Cope: Wellness centre, online classes, and health workshops

How to Practice Mindfulness (video): Meditate During Day To Day Life

Quebec Cancer Foundation: Adapted physical exercise

SUJET N ° 9: LE BIEN - ÊTRE

QU'EST-CE QUI CONTRIBUE AU BIEN-ÊTRE?

Le bien-être consiste à se sentir bien, en bonne santé et/ou heureux. Cela inclut une bonne santé mentale, être satisfait avec sa vie et sentir que celle-ci à un but.

VOUS ÊTES RESPONSABLE DE VOTRE PROPRE BIEN-ÊTRE

Ce n'est pas quelque chose que vous avez ou faites, mais plutôt quelque chose que vous êtes. Un diagnostic de cancer peut apporter des émotions difficiles , mais vous pouvez quand même vous sentir bien dans la façon dont vous les gérer. Le bien-être psychologique signifie que vous avez la capacité de valoriser votre vie et d'affronter ses épreuves.

PLAN DE GESTION

1. PASSEZ DU TEMPS AVEC LES AUTRES

Les relations nous permettent de partager nos sentiments et d'obtenir le soutien des autres.
Passez du temps avec vos proches, mais explorez de nouvelles relations également.

- Prenez du temps pour être avec votre famille ou vos amis. Si vous êtes trop fatigué pour quitter la maison, organisez des visites chez vous. Lorsque vous vous sentez à l'hauteur, prévoyez des activités telles que regarder un film ou prendre un thé ou un café.
- Il peut être utile pour vous de crée des liens avec des personnes qui ont vécu ou vivent des expériences semblables à celles que vous vivez. Les organisations communautaires locales, telles que L'espoir c'es la vie offrent de l'aide et du soutien sous forme de groupe et de mentorat pour les personnes atteinte du cancer.

2. EXERCICE

L'exercice régulier vous peut améliorer votre santé et votre humeur. Buvez beaucoup d'eau lorsque vous faites de l'exercice pour éviter la déshydratation.

- Essayez un bref exercice de faible intensité pour voir comment votre corps réagit. Par exemple, marchez rapidement pendant quelques minutes, ralentissez et reprenez la marche rapidement jusqu'à ce que vous ayez terminé 30 minutes d'activité physique. Vous pouvez même diviser l'activité en trois sessions de 10 minutes.
- Pensez à une activité amusante que vous aimeriez pratiquer régulièrement, comme la randonnée ou la natation. Vous avez plus de chances de vous tenir aux activités que vous aimez.
- Évitez toute activité qui vous expose à un risque de chute ou de blessure. Si vous remarquez du gonflement, nausées/vomissements, problèmes de respiration, douleurs, vertiges ou trouble de vision, appelez votre médecin immédiatement.

3. APPRENEZ QUELQUE CHOSE DE NOUVEAU

Apprendre de nouvelles choses peut vous aider à vous sentir plus satisfait de votre vie et à renforcer votre estime de soi.

- Regarder un film ou lisez un livre sur un sujet qui vous intéresse.
- Redécouvrez un ancien passe-temps ou découvrez-en un nouveau qui vous mettra au défi. Le tricot, la couture, la lecture, l'écriture, la photographie, la peinture, la cuisine ou la pâtisserie en sont des exemples.

4. SOYEZ CONSCIENT

La pleine conscience signifie être conscient de vous-même à tout moment, physiquement et émotionnellement. Cela implique de prendre conscience de vos pensées et de vos sentiments, mais également des images, des odeurs, des sons, des goûts et des sensations de chaque instant.

- Prenez un moment pour remarquer des choses au long de la journée, comme l'odeur de votre café.
- Prenez du recul et observez vos pensées. Voyez-les comme des nuages dans le ciel. La pleine conscience ne consiste pas à faire disparaître les bonnes ou les mauvaises pensées, mais à les voir aller et venir.
- Nommez vos pensées et vos sentiments au fur et à mesure qu'ils se présentent. Certaines personnes trouvent qu'il est utile de les écrire dans un journal.

CES INFORMATIONS SONT FOURNIES À TITRE DE SERVICE ÉDUCATIF UNIQUEMENT;
ILS NE PEUVENT PAS REMPLACER LES SOINS MÉDICAUX OU LES CONSEILS DE VOTRE ÉQUIPE DE SOINS DE SANTÉ

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Ressources supplémentaires

Société canadienne du cancer: Composer avec l'anxiété et le stress

Société canadienne du cancer: La méditation

Fondation Virage : Yoga thérapeutique pour les personnes avec le cancer, 514-890-8000 poste 28139 ou virage@viragecancer.org

Happify (video): Pourquoi la pleine conscience est une superpuissance (mettre sous-titres en français)

L'espoir c'est la vie: Centre de bien-être, programme et activités en ligne

Comment vivre en pleine conscience? Vidéo

Le forum cancerpole: La méditation, la pleine conscience et le cancer

Fondation québécoise du cancer: Activité physique adaptée

TOPIC #10: INSOMNIA

WHAT CAUSES INSOMNIA?

Insomnia is trouble falling and staying asleep. It may be due to cancer symptoms, treatment side effects, or the psychological stress of dealing with cancer. If you notices changes in your sleep pattern, keeping a sleep diary can be useful.
Regardless of the reason(s), it is important to talk with your healthcare team if you are having trouble sleeping.

TIPS FOR MANAGING INSOMNIA

1. KEEP A REGULAR BEDTIME ROUTINE

- Go to bed and wake up at the same time every day (even on the weekends)
- Trouble falling or staying asleep? Avoid daytime naps as they change your sleep pattern

2. RELAX BEFORE BEDTIME

- Clear your head before going to bed
- Start relaxing 90 minutes before bedtime: lights down, listen music, yoga, etc.
- Tense muscles can lead to difficulty falling asleep, try Progressive Muscle Relaxation (PMR), the tensing and relaxing muscles while paying attention to associated feelings

3. TEACH YOUR BRAIN TO RECOGNIZE THAT THE BEDROOM IS FOR SLEEP OR SEXUAL ACTIVITY

- When texting, watching T.V., or working on a laptop in bed, your mind doesn't know whether the bedroom is for rest or these other activities
- Artificial light from screens before bed can delay your sleep
- Keeping your bedroom temperature relatively cool can also be helpful

4. IF YOU CAN'T FALL ASLEEP OR ARE AWAKE FOR MORE THAN 30 MINUTES, GET UP AND OUT OF THE BEDROOM

- It will reinforce the idea that the bedroom is for sleeping
- Perform a calming activity such as reading a book, until you feel sleepy

5. AVOID CAFFEINE, TOBACCO, OR ALCOHOL IN THE EVENING

- Alcohol may help you fall asleep quicker, but deep sleep is harder to achieve
- Instead, try warm milk or a cup of herbal tea

6. REDUCE YOUR STRESS BEFORE BED

- Avoid activities that make you anxious before bed
- If you think a lot about tomorrow's challenges while in bed, keep a notepad next to your bed and write them down

7. REGULAR EXERCISE IMPROVES HEALTH AND CAN IMPROVE YOUR SLEEP

- If you are new to physical activity, start with a daily short walk
- Do not exercise too close to bedtime as your body needs time to calm down after exercise

8. UNLESS RECOMMENDED BY YOUR HEALTHCARE TEAM, AVOID SLEEPING PILLS, HERBAL REMEDIES, OR MELATONIN

- They can be habit-forming, ineffective, or interact poorly with medications, so talk to your doctor first

If you have tried the above strategies, and are still having sleep problems, talk to your healthcare team. Ask if you may benefit from being professionally assessed for sleep problems.

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Additional resources

Canadian Cancer Society: Sleep Problems

HealthLink BC: Insomnia

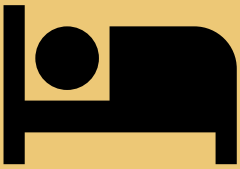
Jewish General Hospital: Sleep resources

Progressive muscle relaxation (video): Guided

SUJET N ° 10: INSOMNIE

QU'EST-CE QUI CAUSE L'INSOMNIE?

L'insomnie est une difficulté à vous endormir et rester endormi. Elle peut être due aux symptômes du cancer, aux effets secondaires du traitement ou au stress psychologique. Si vous remarquez des changements dans votre cycle de sommeil, essayez de garder un journal du sommeil. Parlez à votre équipe de soins de santé si vous éprouvez du mal à dormir, peut importe la/les raison(s).



CONSEILS POUR GÉRER L'INSOMNIE

1. GARDEZ UNE ROUTINE DE SOMMEIL RÉGULIÈRE

- Couchez et réveillez-vous à la même heure tous les jours (même le week-end)
- Du mal à vous endormir? Évitez les siestes pendant la journée

2. DÉTENDEZ - VOUS AVANT DE VOUS COUCHER

- Videz-vous le cerveau avant de vous coucher
- Commencez à vous détendre 90 minutes avant de vous coucher: éteignez les lumières, écoutez de la musique, faites du yoga, etc.
- Les muscles tendus peuvent entraîner des difficultés à vous endormir, essayez la relaxation musculaire progressive, tendez et relaxer vos muscles tout en faisant attention aux sentiments

3. APPRENEZ À VOTRE CERVEAU DE RECONNAÎTRE QUE LA CHAMBRE À COUCHER EST POUR LE SOMMEIL OU L'ACTIVITÉ SEXUELLE

- Si vous envoyez des SMS, regardez la TV, ou travaillez sur un ordinateur portable dans votre lit, votre cerveau ne sait pas si la chambre est pour dormir ou d'autres activités
- La lumière artificielle des écrans avant de vous coucher peut retarder votre sommeil
- Il peut être utile de garder la température de votre chambre assez fraiche

4. SI VOUS NE POUVEZ PAS VOUS ENDORMIR OU SI VOUS ÊTES ÉVEILLÉ PLUS DE 30 MINUTES, LEVEZ-VOUS ET SORTEZ DE VOTRE CHAMBRE

- Cela renforcera la connection entre la chambre à coucher et le sommeil
- Lisez un livre ou faites une activité apaisante jusqu'à ce que vous vous sentez somnolent puis essayer de dormir à nouveau

5. PAS DE CAFÉINE, DE TABAC OU D'ALCOOL DURANT LA SOIRÉE

- L'alcool peut vous aider à vous endormir plus rapidement, mais le sommeil profond viendra moins facilement
- Essayez plutôt du lait chaud ou une tisane

6. RÉDUISEZ VOTRE STRESS AVANT DE VOUS COUCHEZ

- Évitez des activités qui vous inquiètent avant de vous coucher
- Si vous pensez aux épreuves du lendemain, gardez un bloc-notes à côté de votre lit et notez-le

7. DE L'EXERCICE RÉGULIER AMÉLIORE LA SANTÉ ET PEUT AMÉLIORER VOTRE SOMMEIL

- Si vous êtes débutant en activité physique, commencez par une courte promenade
- Ne faites pas d'exercice trop près de l'heure à laquelle vous vous coucher, car votre corps a besoin de temps pour se calmer

8. À MOINS QUE VOTRE ÉQUIPE DE SOINS NE VOUS LE RECOMMANDE, ÉVITEZ LES SOMNIFÈRES, LES PLANTES MÉDICINALES ET LA MÉLATONINE

- Ils peuvent créer une dépendance, être inefficaces ou mal interagir avec d'autres médicaments. Parlez-en d'abord avec votre médecin

Si vous avez essayé les stratégies ci-dessus et vous éprouvez encore des problèmes de sommeil, parlez-en à votre équipe de soins. Demandez si vous ne pourriez bénéficier d'une évaluation professionnelle pour les troubles du sommeil.

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Ressources supplémentaires

Société canadienne du cancer: Troubles de sommeil

Hôpital général juif: Ressources pour le trouble du sommeil

Passeport santé: L'insomnie

CHU de Québec: Insomnie et cancer

Relaxation musculaire progressive (vidéo): Guidée

TOPIC #11: FEAR THAT CANCER MAY RETURN IN THE FUTURE

WHAT CAUSES FEAR THAT CANCER MAY RETURN IN THE FUTURE? THE UNCERTAINTY RELATED TO NOT KNOWING WHAT COMES NEXT

Fear, worry or concern that cancer will come back in the future is very common and normal. If you are feeling anxious, reach out to a trusted friend, your healthcare team, and your cancer support community. Explain your concerns and ask questions. You may find that some of your fears can be cleared up through a better understanding of the next chapter in your life.

RECOGNIZE YOUR FEAR AND WHAT MAY TRIGGER IT: BEING AWARE AND ACKNOWLEDGING YOUR FEAR CAN HELP REDUCE IT

Ask yourself: Am I afraid that my cancer will come back? If so, then ask yourself, what are the proofs that my cancer has come back or can come back? If there is no proof, remind yourself that your fears of your cancer coming back at this point are just thoughts. There is no proof your cancer has come back at this point. Are there specific situations that trigger your fear or worry, such as appointments or specific dates? Find in advance strategies that will help you get your mind off the worry. Perhaps go for a walk, read a book, call a friend.

MANAGEMENT PLAN

1. GET SUPPORT

Talk to someone you are comfortable with. It will help you get your worries out, rather than continually going over things in your head. Sometimes saying things out loud can help us better understand and put them into perspective.

2. TAKE RESPONSIBILITY FOR WHAT YOU HAVE CONTROL OVER

Uncertainty can be difficult and sometimes makes us feel like we are not in control. Try to focus on what you can do rather than what you can't control. Become more involved in your care.

- Talk to your healthcare team and develop a survivorship plan
- Understand what you can do to reduce the likelihood of cancer coming back, signs and symptoms to look out for, when to follow-up with them, and lifestyle changes that can improve your overall health, such as healthy eating or being more active
- For situations that trigger fear or worry, have a plan that will help to help ease your feelings, such as bring a supportive friend, research online, talk to your healthcare provider, or do a relaxing activity before like listening to calming music or deep breathing

3. FOCUS ON UNDERSTANDING AND MANAGING YOUR FEELINGS

Avoiding your feelings may feel comfortable in the moment. However, it is not helpful in the long term. It will make the feelings more intense.

- Mindfulness can help, this means being aware of yourself at all times, physically and emotionally
- Break the cycle of fearful thoughts by challenging them
- Make an objective list with facts that challenge some of your thoughts about cancer coming back, like Canadian cancer statistics or things your doctor has told you - this process is called Cognitive Restructuring
- Try progressive muscle relaxation (PMR) which is tensing and relaxing muscles while paying attention to associated feelings

IS THE FEAR, WORRY, OR CONCERN ABOUT CANCER COMING BACK IN THE FUTURE MONOPOLIZING YOUR THOUGHTS, OR GETTING IN THE WAY OF YOU ENJOYING LIFE?

Speaking to a professional can help.
JGH: 514-340-8222 ext. 23223
MUHC: 514-934-1934 ext. 45502
SMHC: 514-345-3511 ext. 5051

You can also talk with your healthcare team to find out if a referral to oncology support services would be right for you.

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Additional resources

Canadian Cancer Society: Talk to an informational specialist, call 1-888-939-3333

Cancer Chat Canada: Online support groups

Hope & Cope: support groups and one-to-one peer support programs
Contact Hinda Goodman at 514-340-8222 ext. 25531 or hgoodman@onco.jgh.mcgill.ca.

Memorial Sloan Kettering Cancer Centre: Six tips for managing Fear of Cancer Recurrence by Esther Napolitano

SUJET N ° 11: LA PEUR QUE LE CANCER REVIENDRA DANS LE FUTUR

QU'EST-CE QUI CAUSE LA PEUR QUE LE CANCER REVIENNE? L'INCERTITUDE DE NE PAS CONNAITRE L'AVENIR.

La peur, l'inquiétude ou la préoccupation que le cancer revienne sont commune et normale. Si vous vous sentez anxieux, contactez un ami de confiance, votre équipe de soins ou votre communauté de soutien. Expliquez vos craintes et posez des questions. Une meilleure compréhension de ce chapitre de votre vie peut résoudre certaines de vos craintes.

RECONNAISSEZ VOTRE PEUR ET CE QUI LA DÉCLENCHE: ÊTRE CONSCIENT ET LA RECONNAÎTRE PEUT AIDER À LA RÉDIURE

Demandez-vous: Est-ce que j'ai peur que mon cancer revienne? Si oui, alors demandez-vous quelles sont les preuves que mon cancer a réapparu ou peut réapparaître? S'il n'y a aucune preuve, rappelez-vous que vos craintes d'un retour de votre cancer ne sont que des pensées. Il n'y a aucune preuve que votre cancer est revenu. Si vous trouvez qu'il y a des situations spécifiques qui déclenches votre peur ou inquiétude, comme des rendez-vous ou certaines dates, trouvez à l'avance des stratégies qui vous aideront à affronter votre inquiétude. Par exemple, faites une promenade, lisez un livre, appelez un ami.

PLAN DE GESTION

1. OBTENEZ DU SOUTIEN

Parlez à quelqu'un avec qui vous êtes à l'aise. Cela vous aidera à résoudre vos problèmes plutôt que de trop analyser ce qui se passe dans votre tête. Parfois, parler à haute voix peut nous aider à mieux comprendre et mettre les choses en perspective.

2. PRENEZ DE LA RESPONSABILITÉ POUR CE QUE VOUS CONTRÔLEZ

L'incertitude est difficile et parfois elle nous fait sentir que nous ne sommes pas en contrôle. Concentrez-vous sur ce que vous pouvez faire plutôt que sur ce que vous ne contrôlez pas.

- Parlez à votre équipe de soins et développez un plan de survie. Comprenez ce que vous pouvez faire pour réduire les chances de récidive du cancer, les signes et symptômes à surveiller, quand renter en contact avec votre équipe et les changements dans votre style de vie qui peuvent améliorer votre santé général – comme une alimentation saine ou être plus actif.
- Dans des situations qui suscitent la peur ou l'inquiétude, ayez un plan. Emmenez un ami, recherchez en ligne, parlez à votre équipe de soins ou faites une activité relaxante avant la situation, comme écouter de la musique ou des exercices de respiration profonde.

3. LA COMPRÉHENSION ET LA GESTION DE VOS SENTIMENTS

Fuir vos émotions peut sembler facile dans l'immédiat, mais cela n'est pas utile au long terme et peut rendre vos émotions plus intenses.

- La pleine conscience peut aider, cela signifie que vous devez être physiquement et émotionnellement conscient de vous-même à tout moment.
- Brisez le cycle des pensées effrayantes en les mettant au défi. Faites une liste objective avec des faits qui remettent en question certaines de vos idées sur le retour du cancer, cela peut inclure les statistiques canadiennes du cancer, ou des choses que votre médecin vous a dites.
- Essayez la relaxation musculaire progressive - tendez et détendez les muscles tout en faisant attention aux sentiments qui y sont associés.

LA PEUR OU L'INQUIÉTUDE QUE LE CANCER REVIENNE MONOPOLIZE VOS PENSÉES OU VOUS EMPÊCHE DE PROFITER DE LA VIE?

Parler à un professionnel pourrait vous aider.
Hôpital général juif: 514-340-8222 ext. 23223
Centre universitaire de santé McGill : 514-934-1934 ext. 45502
Centre hospitalier de St. Mary: 514-345-3511 ext. 5051

Discutez avec votre équipe de soins pour savoir quels services de soutien oncologique vous sont appropriés.

CES INFORMATIONS SONT FOURNIES À TITRE DE SERVICE ÉDUCATIF UNIQUEMENT;
ILS NE PEUVENT PAS REMPLACER LES SOINS MÉDICAUX OU LES CONSEILS DE VOTRE ÉQUIPE DE SOINS DE SANTÉ

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Ressources supplémentaires

Société canadienne du cancer: Parlez à un spécialiste en information, appelez 1-888-939-3333

L'espoir c'est la vie: Groupes de soutien et programme de soutien par les pairs, contactez Hinda Goodman au 514-340-8222 ext. 25531 ou hgoodman@onco.jgh.mcgill.ca

La Presse: Cancer - vivre la peur d'une récidive

Ordre des psychologues du Québec: La peur de la récidive du cancer: comment vivre avec une épée de Damonclès au-dessus de la tête?

Relaxation musculaire progressive (vidéo): Guidée

TOPIC #12: WORK-RELATED ISSUES

WHAT CONTRIBUTES TO WORK-RELATED ISSUES?

Depending on your situation, you may be wondering if you can work or attend school during cancer treatment. This decision depends on how you feel, the flexibility of your workplace, the kind of work, how treatment affects your health, your finances, your home life, and other considerations. Figure out what is best for your situation.

WORKING WHILE RECEIVING TREATMENT OR RETURNING TO WORK AFTER COMPLETING TREATMENT REQUIRES COMMUNICATION WITH YOUR HEALTHCARE TEAM, YOUR WORKPLACE, AND, IF NECESSARY, YOUR INSURANCE PROVIDER.

MANAGEMENT PLAN

1. WORK FROM HOME SOME DAYS
You might feel less tired and will be able to take care of yourself more easily.

2. DIVIDE DAILY CHORES AMONG FRIENDS AND FAMILY
Help at home means more energy for work.

3. IT IS UP TO YOU TO DECIDE HOW OPEN YOU ARE WITH YOUR COWORKERS ABOUT YOUR HEALTH
Sometimes they can be sources of support, and may even be able to help you come up with ways to manage your work during this time better. Other times coworkers may not be helpful, so use your best judgment.

4. COMMUNICATE WITH YOUR SUPERVISOR
Keep your supervisor informed of any changes you may need to make at work, such as reduced hours, and updates how they are working out.

5. MAKE A LOG OF YOUR USUAL WORK SCHEDULE AND A DETAILED LIST OF DUTIES
Refer to it when you set up flex-time, shifted responsibilities, time off, and direct others in handling things when you're out of the office.

REMEMBER THAT YOUR SITUATION MAY CHANGE

You may decide that you're okay to work while receiving treatment, but a few weeks later realize that you need medical leave. Alternatively you may take medical leave, then change your mind and go back to work. It is okay to change your mind—do what is best for your situation.

THIS INFORMATION IS PROVIDED AS AN EDUCATIONAL SERVICE ONLY
IT IS NOT MEANT TO TAKE THE PLACE OF MEDICAL CARE OR THE ADVICE OF YOUR HEALTHCARE TEAM

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Additional resources

Canadian Cancer Society: Work and cancer

Canadian Breast Cancer Network: Facing Financial Issues

Cancer and Work: Survivors

University Health Network: Prepare to Return to Work After Treatment for Cancer

SUJET N ° 12: TRAVAIL

QU'EST-CE QUI CONTRIBUE AUX PROBLÈMES LIÉS AU TRAVAIL?

Selon votre situation, vous vous demandez peut-être si vous pouvez travailler ou aller à l'école pendant votre traitement pour le cancer. Cette décision dépend sur comment vous vous sentez, la flexibilité de votre lieu de travail, le genre de travail, comment le traitement affecte votre santé, vos finances, votre vie familiale et d' autres considérations. Déterminez ce qui convent le mieux à votre situation.

TRAVAILLER DURANT LE TRAITEMENT OU RETOURNER AU TRAVAIL APRÈS LA FIN DU TRAITEMENT NÉCESSITE UNE COMMUNICATION AVEC VOTRE ÉQUIPE DE SOINS, VOTRE LIEU DE TRAVAIL ET POSSIBLEMENT VOTRE FOURNISSEUR D'ASSURANCES.

PLAN DE GESTION

1. TRAVAILLEZ DE CHEZ VOUS CERTAINS JOURS

Vous pourriez vous sentir moins fatigué et serez en mesure de prendre soins de vous-même plus facilement.

2. DIVISER VOS TÂCHES QUOTIDIENNES ENTRE VOS AMIS ET FAMILLE

De l'aide à la maison signifiera plus d' énergie pour le travail.

3. C'EST À VOUS DE DÉCIDER CE QUE VOUS PARTAGEZ AVEC VOS COLLÈGUES EN CE QUI CONCERNE VOTRE SANTÉ

Parfois, ils peuvent être d'excellentes sources de soutien et être en mesure de vous aider à trouver les moyens de mieux gérer votre travail pendant cette période. D'autres fois, les collègues ne peuvent vous aider – utilisez votre bon jugement.

4. COMMUNIQUEZ AVEC VOTRE SUPERVISEUR

Informez votre superviseur de tout changement que vous pourriez apporter au travail, comme des heures de travail réduites et des mises à jour sur comment ça se passe.

5. FAITES UN JOURNAL DE VOTRE HORAIRE DE TRAVAIL HABITUEL ET UNE LISTE DE TACHES DÉTAILLÉE

Consultez-le lorsque vous définissez des horaires variables, des tâches modifiées, des congés et déléguez des tâches lorsque vous êtres hors du bureau.

RAPPELEZ-VOUS QUE VOTRE SITUATION PEUT CHANGER

Vous pouvez décider que vous êtes en mesure de travailler pendant le traitement, mais quelques semaines plus tard, réalisez que vous avez besoin d'un congé de maladie. Vous pouvez également prendre un congé de maladie puis changer d'avis et retourner au travail. Il est correct de changer d'avis. Faites ce qui est le mieux pour vous selon votre situation.

CES INFORMATIONS SONT FOURNIES À TITRE DE SERVICE ÉDUCATIF UNIQUEMENT;
ILS NE PEUVENT PAS REMPLACER LES SOINS MÉDICAUX OU LES CONSEILS DE VOTRE ÉQUIPE DE SOINS DE SANTÉ

ON-BOARD
ONcology - Bolstering Oral Agent Reporting related to Distress

Ressources supplémentaires

Société canadienne du cancer: Travail et cancer

Réseau canadien du cancer du sein: Faire face aux problèmes financiers

Cancer et travail: Survivants

University Health Network: Préparer son retour au travail après un traitement du cancer

Sanofi (vidéo): Le choix du bien - Cancer et Travail

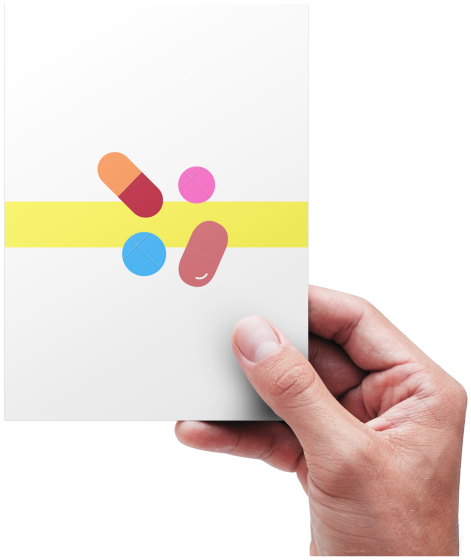
Appendix D

Recruitment documents

- Recruitment Poster (EN and FR)
- Recruitment Form (EN and FR)
- Verbal Screening Script (EN and FR)

ARE YOU ON ORAL CHEMOTHERAPY?

WE'D LIKE TO HEAR FROM YOU!



We are conducting a study to better understand how to support individuals with cancer who are receiving oral chemotherapy treatment.

WHAT IS REQUIRED?

Completing online questionnaires (20 minutes) every 1-2 weeks over 5 months. As a token of appreciation, you will receive 10$ when you enroll, and an additional 10$ for each questionnaire completed (for a maximum of $120).

This study led by Dr. Carmen Loiselle, Segal Cancer Centre and Faculty of Medicine and Health Sciences, McGill University.

WOULD YOU LIKE MORE INFORMATION ABOUT THIS STUDY?

Call: 514-398-8977,
Email: loiselle-research@mcgill.ca,
or visit our site via the QR code provided

Réseau de cancérologie Rossy | Rossy Cancer Network
Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal Québec
McGill

RECEVEZ-VOUS UNE CHIMIOTHÉRAPIE ORALE ?

NOUS AIMERIONS CONNAÎTRE VOTRE EXPÉRIENCE!

Nous menons une étude qui vise à mieux comprendre comment soutenir les personnes avec un cancer qui reçoivent un traitement de chimiothérapie orale.

QUE DOIS-JE FAIRE ?

Remplir des questionnaires en ligne (20 minutes) toutes les 1 à 2 semaines pendant 5 mois. En guise d'appréciation, vous recevrez 10$ lors de votre inscription, et 10$ additionnels pour chaque questionnaire complété (pour un maximum de 120$).

Cette étude est menée par la Dre Carmen Loiselle, Centre du cancer Segal et la Faculté de médecine et des sciences de la santé, Université McGill.

VOUS VOULEZ EN SAVOIR PLUS SUR CETTE ÉTUDE ?

Téléphone: 514-398-8977,
courriel: loiselle-research@mcgill.ca,
ou visitez notre site via le QR code fourni

Réseau de cancérologie Rossy — Rossy Cancer Network

Centre intégré universitaire de santé et de services sociaux du Centre-Ouest-de-l'Île-de-Montréal — Québec

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Recruitment Tool and Form

Are You Receiving oral chemotherapy for your cancer?
We'd like to hear from you!

We're conducting a study that offers support to patients during their oral chemotherapy treatment.

We're looking for adults with cancer 18 years or older who are starting oral chemotherapy. We would ask you questions about how you are feeling and the problems you may be having (for example, fatigue, pain, sleep) and the best ways to provide you with support.

What is required? You will be asked to:
Complete an online questionnaire (20 minutes) from home on a computer, every 1-2 weeks for 5 months.

Are you eligible?

- 18 years or older
- A diagnosis of cancer
- About to start or within the first cycle of oral chemotherapy
- Have a computer, smartphone, or tablet with internet access
- Able to communicate, read, and write in English or French

As a token of appreciation for participating and time spent filling out questionnaires, you will receive 10$ when you enroll, and an additional 10$ for each questionnaire completed (for a maximum of $120).

If you would like to participate, please complete the short form below.
By providing your contact information, you agree to be contacted by a member of the study team.
If you have any questions, or prefer to contact us directly, please contact our research group at 514-398-8977 or Loiselle-research@mcgill.ca

This study led by Dr. Carmen Loiselle, Co-Director (Academic) of the Segal Cancer Centre and Professor in McGill University's Department of Oncology and Ingram School of Nursing.

Contact Form (on a separate page)

Please provide:

1. Your name
   First Name:
   Last Name:

2. Your email address:

3. The best phone number to contact you at:

4. Additional telephone number, just in case:

5. Best times to call? (select all that apply)
   Mornings
   Afternoons
   Evenings
   Any additional Comments:

Formulaire De Recrutement

Recevez-vous une chimiothérapie orale pour votre cancer ?
Nous aimerions connaître votre expérience !

Nous menons une étude qui offre un soutien aux patients pendant leur traitement de chimiothérapie orale.

Nous recherchons des adultes de 18 ans ou plus avec un cancer et qui commencent la chimiothérapie orale. Nous vous poserions des questions sur votre bien-être et les problèmes que vous pourriez avoir (par exemple, fatigue, douleur, trouble du sommeil) et les meilleures façons de vous soutenir.

Que faudra-t-il faire ? Il vous sera demandé de :
Remplir un questionnaire en ligne de 20 minutes, à l'aide d'un ordinateur à la maison, toutes les 1 à 2 semaines pendant 5 mois.

Êtes-vous éligible ?

- 18 ans ou plus
- Un diagnostic de cancer
- Sur le point de commencer ou dans le premier cycle de chimiothérapie orale
- Access à un ordinateur, un téléphone intelligent ou une tablette avec accès Internet
- Capable de communiquer, lire et écrire en anglais ou en français

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En guise de d'appréciation pour le temps que vous passerez à remplir les questionnaires de l'étude, vous recevrez 10$ lors de votre inscription, et 10$ supplémentaires pour chaque questionnaire rempli (pour un maximum de 120$).

Si vous souhaitez participer, veuillez remplir le court formulaire ci-dessous.
En fournissant vos coordonnées, vous acceptez d'être contacté par un membre de l'équipe de recherche. Si vous avez des questions, ou préférez nous contacter directement, veuillez contacter notre groupe de recherche au 514-398-8977 ou Loiselle-research@mcgill.ca

Cette étude dirigée par la Dre Carmen Loiselle, codirectrice (académique) du Centre du cancer Segal et professeure au Département d'oncologie de l'Université McGill et à l'École des sciences infirmières Ingram.

Formulaire des coordonnées (sur une page séparée)

1. Votre nom
   Prénom :
   Nom de famille :

2. Votre adresse courriel :

3. Le meilleur numéro de téléphone pour vous contacter :

4. Numéro de téléphone supplémentaire, en cas de besoin :

5. Les meilleurs moments pour vous appeler ? (Sélectionnez tout ce qui s'applique)
   Les matins
   Les après-midis
   Soirées
   Tout commentaire supplémentaire :

Verbal Script: Screening

Note: Individuals who are interested in the study will have completed the recruitment form, agreeing to be contacted for the study. Screening will take place over the phone. The contact form will be completed electronically on Qualtrics by the study team member who recruits participants. Two databases will be used to store patient data; one will include the contact form and e-consent, the other will include de-identified questionnaire data.

Screening for eligibility

Inclusion Criteria

1. Are you 18 years old?
2. Have you been diagnosed with cancer?
3. Are you followed by an oncology team at the Segal Cancer Centre?
4. Are you about to start or within the first cycle of oral chemotherapy treatment?
5. Do you have access to a computer/tablet/smartphone device with internet?

Exclusion Criteria

1. Are you receiving intravenous chemotherapy, immunotherapy and/or targeted therapy?
2. Are you able to understand and read French or English?
3. Are you participating in a clinical trial?

Ineligible script

The patient is ineligible to participate in the ON-BOARD Study.

- *Document reason for ineligibility (only if offered voluntarily, do not ask)*

Given the information provided, you do not fulfil the criteria for this specific study.

Thank the participant for his/her time, leave the contact information and consent forms blank, then click "submit"

Eligible script: Verbal Explanation

The patient is eligible to participate in the ON-BOARD Study.

Explain the study then follow the steps below.

Study Description:

- Dr. Carmen Loiselle, a McGill Professor and the Co-Director of the Segal Cancer Centre is conducting a study on oral anticancer agents and patients' issues.
- We aim to recruit 52 participants for this study.
- The study requires that you complete questionnaires online from a computer, tablet or smartphone.
- The first questionnaire, which will be sent to you right after you provide your e-consent for the study, includes questions about your background, medical history, physical/emotional health, and knowledge on oral anticancer agents. The first questionnaire is a bit longer than the following ones– it might take about 20 – 25 minutes to complete.
- Some participants in the study will be randomly selected and contacted after the first questionnaire for follow-up questions.
- Then every week for the first month and every 2 weeks for the following 4 months, you will receive an online questionnaire to complete. This one is shorter and should take about 10-15 minutes of your time.
- The entire study is for a period of 5 treatment cycles, which is about 5 months, or less, if you complete your oral anticancer treatment earlier.

- Over the course of the study, you will be reminded of remote oncology support services that you can access at any time. Each time you need to complete a questionnaire, you will be reminded of this.
- As a token of appreciation for participating and time spent completing questionnaires, you will receive a 10$ gift card when you enroll, and an additional 10$ for each questionnaire completed, for a maximum of 120$.

- You will be assigned a unique identification number. With this, you will be able to login online to complete the questionnaires.
- All the information you will give us will remain confidential. All information will be kept in secure databases on a secure server in Qualtrics.
- With your authorization, the research team will also have access to your hospital medical records to collect information about your cancer (type, stage, date of diagnosis), current medications, previous and current treatments for cancer, and any other medical conditions.
- We would like information on the chemo medication that you will get from the pharmacy during the study. To do obtain this information, we will contact your usual pharmacy with your authorization.
- At the end of the study, you will be invited to take part in a one-on-one telephone interview to share your experience regarding the information and support you have received during your oral anticancer treatment.
- This study is voluntary, and you can stop at any time for any reason.

Benefits & Risks

- Participating in this study may involve some psychological risks. It is possible that you may become fatigued or upset when asked questions about your cancer diagnosis.
- If in the questionnaire, you respond that you are feeling a high level of distress, you will receive a notification with instructions on who to contact to take appropriate action.
- Anytime you receive a call from a nurse, your symptom scores will be shared with the nurse.
- Taking part in this study may also help scientists and clinicians in the future better understand how to best provide support to individuals with cancer.

Do you have any questions? (Answer their questions)
Would you like time to think about it and we can schedule a second meeting?

Would you like to participate in this study?

If the individual is not interested in participating in the study

- Document reason not interested (only if offered voluntarily, do not ask)

If the individual is interested in participating in the study

- Fill out contact form
- Send e-consent

Electronic Contact Information Form

Study team member name (the name of the person completing this form):

Now I'm going to enter your contact information. All of the information I am asking for is completely confidential. The information that I'm collecting will be kept separate from any of the research questionnaires you complete for the study. Only the researcher in charge of the study, Dr. Carmen Loiselle and the study coordinator, Saima Ahmed, will have access to this personal information.

First name:

Last name:

Preferred language for communication purposes:
French
English

Email address:

Your email will only be used to send the study's consent form, electronic questionnaires and send study reminders, as all the study components will be available to you at home online.

Address:

Telephone number:
Secondary telephone number:

When are the best times to contact you?

- Mondays (please specify times in the box to the right)
- Tuesdays (please specify times in the box to the right)
- Wednesdays (please specify times in the box to the right)
- Thursdays (please specify times in the box to the right)
- Fridays (please specify times in the box to the right)
- Saturdays (please specify times in the box to the right)
- Sundays (please specify times in the box to the right)

Comments (optional)

Compensation

You will initially receive a 10$ gift card as compensation for your time. You will also receive an additional 10$ gift card each time you complete follow-up questionnaires. These follow-up questionnaires will be every two weeks for five months. You will receive a gift card at the end of each month.

What gift cards would you like to receive?

- Starbucks card
- Best Buy card
- Amazon card
- A mixture of the above (please specify: _____)

You will be receiving your gift card each month by email

- Preferred email

Verbal Script: Screening (Fr)

Verification d’éligibilité

Critères d’inclusion

1. Avez-vous 18 ans ?
2. Avez-vous reçu un diagnostic de cancer?
3. Êtes-vous suivi par une équipe d'oncologie au Centre du cancer Segal?
4. Êtes-vous sur le point de commencer ou dans le premier cycle de traitement de chimiothérapie orale ?
5. Avez-vous accès à un ordinateur/tablette/smartphone avec Internet ?

Critères d'exclusion

1. Recevez-vous une chimiothérapie intraveineuse, une immunothérapie et/ou une thérapie ciblée ?
2. Êtes-vous capable de comprendre et de lire le français ou l'anglais ?
3. Participez-vous à un essai clinique ?

Script non éligible

Le patient n'est pas éligible pour participer à l'étude ON-BOARD.

- *Documenter la raison de l'inéligibilité (uniquement si elle est offerte volontairement, ne pas demander)*

Compte tenu des informations fournies, vous ne remplissez pas les critères de cette étude spécifique.
Remerciez le participant pour son temps, laissez les informations de contact et les formulaires de consentement vides, puis cliquez sur « envoyer ».

Script éligible : explication verbale

Le patient est éligible pour participer à l'étude ON-BOARD.
Expliquez l'étude puis suivez les étapes ci-dessous.

Description de l'étude :

- Dre Carmen Loiselle, professeure à McGill et codirectrice du Centre du cancer Segal, mène une étude sur les agents anticancéreux oraux et les problèmes des patients.
- Nous visons à recruter 52 participants pour cette étude.
- L'étude nécessite que vous remplissiez des questionnaires en ligne à partir d'un ordinateur, d'une tablette ou d'un smartphone.
- Le premier questionnaire, qui vous sera envoyé juste après que vous aurez fourni votre consentement électronique pour l'étude, comprend des questions sur vos antécédents, vos antécédents médicaux, votre santé physique/émotionnelle et vos connaissances sur les agents anticancéreux oraux. Le premier questionnaire est un peu plus long que les suivants – il peut prendre environ 20 à 25 minutes à remplir.
- Certains participants à l'étude seront sélectionnés au hasard et contactés après le premier questionnaire pour des questions de suivi.
- Ensuite toutes les semaines pendant le premier mois et toutes les 2 semaines pendant les 4 mois suivants, vous recevrez un questionnaire en ligne à remplir. Celui-ci est plus court et devrait prendre environ 10 à 15 minutes de votre temps.
- L'ensemble de l'étude porte sur une période de 5 cycles de traitement, soit environ 5 mois, ou moins, si vous terminez votre traitement oral plus tôt.

- Au cours de l'étude, vous serez rappelé de services d'assistance et de soutien en oncologie à distance auxquels vous pouvez accéder à tout moment. Chaque fois que vous devrez remplir un questionnaire, cela vous sera rappelé.

- En guise de d'appréciation pour le temps passé à remplir les questionnaires de l'étude, vous recevrez une carte-cadeau de 10$ lors de votre inscription, et 10$ supplémentaires pour chaque questionnaire complété, pour un maximum de 120$.

- Un numéro d'identification unique vous sera attribué. Grâce à cela, vous pourrez vous connecter en ligne pour remplir les questionnaires.
- Toutes les informations que vous nous communiquerez resteront confidentielles. Toutes les informations seront conservées dans des bases de données sécurisées sur un serveur sécurisé dans Qualtrics.
- Avec votre autorisation, l'équipe de recherche aura également accès à vos dossiers médicaux hospitaliers pour recueillir des informations sur votre cancer (type, stade, date du diagnostic), les médicaments actuels, les traitements antérieurs et actuels pour le cancer et toute autre condition médicale
- Nous aimerions avoir des informations sur les médicaments de chimiothérapie que vous obtiendrez de la pharmacie pendant l'étude. Pour obtenir ces informations, nous contacterons votre pharmacie avec votre autorisation.
- À la fin de l'étude, vous serez invité à participer à un appel téléphonique individuel pour partager votre expérience concernant les informations et le soutien que vous avez reçus pendant votre traitement oral.
- Cette étude est volontaire et vous pouvez l'arrêter à tout moment pour n'importe quelle raison.

Avantages et risques

- La participation à cette étude peut comporter certains risques psychologiques. Il est possible que vous deveniez fatigué ou contrarié lorsqu'on vous pose des questions sur votre diagnostic de cancer.
- Si dans le questionnaire, vous répondez que vous ressentez un niveau élevé de détresse, vous recevrez une notification avec des instructions sur qui contacter pour prendre les mesures appropriées.
- Chaque fois que vous recevez un appel d'une infirmière, vos scores de symptômes seront partagés avec l'infirmière.
- Participer à cette étude peut également aider les scientifiques et les cliniciens à mieux comprendre à l'avenir comment mieux soutenir les personnes atteintes de cancer**.**

Avez-vous des questions? (Répondez à leurs questions)
Souhaitez-vous avoir le temps de réfléchir et nous pouvons planifier une deuxième réunion?
Souhaitez-vous participer à cette étude?

Si la personne n'est pas intéressée à participer à l'étude

- Documentez la raison pour laquelle vous n'êtes pas intéressé (seulement si offert volontairement, ne demandez pas)

Si la personne est intéressée à participer à l'étude

- Remplissez le formulaire de contact
- Envoyer un e-consentement

Formulaire de contact électronique

Nom du membre de l'équipe d'étude (le nom de la personne qui remplit ce formulaire) :

Je vais maintenant saisir vos coordonnées. Toutes les informations que je demande sont totalement confidentielles. Les informations que je collecte seront conservées séparément de tous les questionnaires de recherche que vous remplissez pour l'étude. Seuls la chercheuse en charge de l'étude, la Dre Carmen Loiselle et la coordonnatrice de l'étude, Saima Ahmed, auront accès à ces renseignements personnels.

Prénom:

Nom de famille:

Langue préférée à des fins de communication :
Français
Anglais

Adresse e-mail:

Votre e-mail sera utilisé que pour envoyer le formulaire de consentement à l'étude, les questionnaires électroniques et les rappels de l'étude, car tous les composants de l'étude seront disponibles en ligne à la maison.

Adresse:

Numéro de téléphone:
Numéro de téléphone secondaire :

Quels sont les meilleurs moments pour vous contacter ?

- Lundi (veuillez préciser les horaires dans la case à droite)
- Mardi (veuillez préciser les horaires dans la case à droite)
- Mercredi (veuillez préciser les horaires dans la case à droite)
- Jeudi (veuillez préciser les horaires dans la case à droite)
- Vendredi (veuillez préciser les horaires dans la case à droite)
- Samedi (veuillez préciser les horaires dans la case à droite)
- Dimanche (veuillez préciser les horaires dans la case à droite)

Commentaires (optionnel)

Compensation

Vous recevrez initialement une carte-cadeau de 10$ en compensation de votre temps. Vous recevrez également une carte-cadeau supplémentaire de 10$ à chaque fois que vous remplirez des questionnaires de suivi. Ces questionnaires de suivi seront effectués toutes les deux semaines pendant cinq mois. Vous recevrez une carte cadeau à la fin de chaque mois.

Quelles cartes-cadeaux aimeriez-vous recevoir?

- Starbucks
- Best Buy
- Amazon
- Un mélange (veuillez préciser : _____)

Vous recevrez votre carte cadeau chaque mois par email

- Adresse e-mail préférée

Appendix E

Consent Forms

- Control (EN and FR)
- Experimental (EN and FR)

INFORMATION AND CONSENT FORM (CONTROL)

RESEARCH STUDY TITLE: Feasibility, acceptability, and potential effects of a comprehensive oral anticancer agent intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial
SHORT TITLE: Oncology – Bolstering Oral Agent Reporting related to Distress (ON-BOARD)
PRINCIPAL INVESTIGATOR: Carmen G. Loiselle, R.N., Ph.D.
CO-INVESTIGATOR: Christine Maheu, R.N. Ph.D.
STUDY COORDINATOR: Saima Ahmed, B.Sc.
SOURCE OF FUNDING: Rossy Cancer Network

You are invited to participate in a research study. Take the time to carefully read, understand and think about the information that has been explained and given to you included in this form. If you choose to take part in this research study, we will ask you to sign this consent form. A copy of the signed consent form will be emailed to you.

This form may contain some words or information that you do not understand. We encourage you to ask the researcher responsible for this research study or a member of the research team all questions that you may have. Ask them to explain all words and information that are unclear. They have the obligation to answer in such a way that you can understand all the information presented to you.

This study is being conducted by Dr. Carmen Loiselle, Co-Director (Academic) of the Segal Cancer Centre and Professor in McGill University's Department of Oncology and Ingram School of Nursing.

What is the purpose of the study?

This research study aims to better understand how to support individuals with cancer who are receiving oral chemotherapy treatment.

Participants in the study must be 18 years of age or older, have a diagnosis of cancer of any stage, and about to start or within the first cycle of their oral anticancer treatment (traditional, targeted, or hormonal therapy as active treatment). They must have a computer, tablet or smartphone with internet access, and be able to communicate, read, and write in English or French. Individuals receiving IV chemotherapy, immunotherapy or oral hormonal therapy as preventative treatment are not able to participate. You are being invited to take part in this study because you meet the participation criteria.

The study will involve 52 patients receiving cancer treatment at the Segal Cancer Centre of the Jewish General Hospital and will last five cycles of oral chemotherapy (five months).

What am I expected to do?

If you agree to participate in this study, you will be able to complete your tasks from your home using the internet on a smartphone, tablet, and/or computer.

Once you complete this form, you will get an email with a unique study identification number (Login ID). You will use it throughout the entire study to log in online and complete questionnaires.

The first questionnaire, which will be sent after signing this form, will include questions about your background, medical history, physical/emotional health, and knowledge of oral chemotherapy. The first questionnaire is longer, it may take 20 to 25 minutes to fill out. Some participants in the study will be randomly selected and contacted after the first questionnaire for follow-up questions.

Following this, you will complete questionnaires every week for the first month, then every two weeks for the following four months. These questionnaires are shorter and may take 10 to 15 minutes to fill out. You will receive reminders by email when it is time to fill out the questionnaires. They will include questions about your oral chemotherapy medication and cancer-related issues that may be important to you, for example, fatigue, pain, wellbeing, etc. If you rate in the questionnaire that you are feeling a high level of distress, you will receive instructions on who to contact to take appropriate action.

At the end of the study, you will be invited to take part in a one-on-one telephone interview to share your experience regarding the information and support you have received during your oral chemotherapy treatment.

Your overall time involvement will be five months. You will finish the study earlier if you complete your oral chemotherapy treatment in less than five months. With your permission, we will also access your medical records and contact your pharmacist, to collect information about your cancer diagnosis, treatment, and oral chemotherapy medication.

If I participate, are there any risks or inconveniences?

Participating in this study may involve some psychological risks. Some participants may experience distress or other negative emotions when asked questions about their cancer diagnosis. You are free to refuse to answer any questions. If you report high distress when you complete questionnaires, you will receive a notification with instructions on who to contact to take appropriate action. Additionally, a list of professional psychosocial oncology support services will be provided and listed at the bottom of each questionnaire. Filling out the questionnaire every one or two weeks will take about 15-minutes, this extra time may be an inconvenience.

If I participate, are there any potential benefits?

You will not receive any personal benefit by participating in this research study. However, taking part in this study may help scientists and clinicians better understand the types of support cancer patients on oral chemotherapy treatment need.

Will I receive any compensation for participating?

As a token of appreciation for the time spent completing study questionnaires, you will receive a 10$ gift card when you enroll, and an additional 10$ for each questionnaire you complete, for a maximum of 120$ over the 5-month study period.

If you choose to withdraw from the study at any time, you will receive a minimum of 10$, with an additional 10$ for each questionnaire completed before withdrawal.

You will have the choice of Amazon, Starbucks, or Best Buy gift cards and will receive these cards by email at the end of each month.

Will my information be kept confidential?

Qualtrics, a secure survey and database application commonly used by McGill University researchers will be used in this study. Qualtrics is a secure server that uses https data encryption in transit and AES 256-bit encryption at rest.

To help meet the purpose of the study, personal and identifiable information about you will be collected and stored. Only information necessary for the research study will be collected. It will remain confidential and protected within the limits of the law. Only the principal investigator and study coordinator will have access to your personal information. The information that is collected from your medical chart and pharmacy records for the study will be kept in a password protected and secure folder on the CIUSSS du Centre-Ouest-de-l'Île de Montréal server. All information collected from questionnaires will be kept in secure databases on Qualtrics; the consent form, screening and contact information, and questionnaire responses will be linked to your Login ID number. By responding to the online questionnaires, your responses will be linked to your Login ID number, which is linked your name. Therefore, the risk of identifying you as a participant in this study is very low as your name will be replaced with this unique number code. The link between the code and your identity will be held in a secure Qualtrics database. Only the principal investigator, research manager and study coordinator will have access to the list of participants and to corresponding code. The information collected from you in the study will be destroyed 10 years after the study is completed.

For monitoring, control and protection purposes, your research study file could be checked by a person authorized by the Research Ethics Committee of the CIUSSS du Centre-Ouest-de-l'Île de Montréal or by persons mandated by authorized public agencies. These persons are bound by a confidentiality agreement.

Can I withdraw from the study after I consent?

Your participation in this study is completely voluntary. If you agree to take part in the study, you will be asked to give your consent at the end of this document. You have the right to withdraw (stop participating) from this study at any time without providing a reason and without any impact on the care you receive at the hospital. If you withdraw from this study, the information gathered will be kept, unless you ask us to destroy it. If you withdraw from this study, we will stop accessing your medical chart and pharmacy record.

What will the data collected in the study be used for?

With your permission, the depersonalized data collected from you could be used for future research related to this study or for future studies. The data collected during the research study will not be accessible to your oncologist, even if they request it. The results may be presented at conferences, published in specialized journals or be the subject of scientific discussions. Your identity and any identifying information will not be revealed in any reports or publications.

Who do I contact if I have questions?

If you have any questions about the research study, you can contact the researcher in charge of the study (PI), Dr. Carmen G. Loiselle, or the study coordinator, Saima Ahmed (SA).

Carmen G. Loiselle, R.N., Ph.D.
E-mail: Loiselle-research@mcgill.ca
Phone: 514-398-8977

Saima Ahmed
E-mail: saima.ahmed2@mail.mcgill.ca
Phone: 514-690-7860

For all questions concerning your rights during your participation in this study, or if you have any complaints or comments regarding your experience in taking part in this study, you can contact the Local Commissioner of Complaints and Quality of Service of the CIUSSS Centre-Ouest-de-l'Île-de-Montréal or the ombudsman of the institution au (514) 340-8222, ex. 24222.

STATEMENT OF CONSENT

Feasibility, acceptability, and potential effects of a comprehensive oral anticancer agent intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial

PARTICIPANT STATEMENT

I understand the information that was explained to me as contained in this consent form. All my questions were answered to my satisfaction. I will receive an electronic copy of this consent form. My participation is voluntary, and I can withdraw from the research study at any time without any consequences and without having to give a reason. Withdrawing from this research study, at any time, will not affect my medical care now, or later, in any way (where applicable). By signing this consent form, I do not give up any of my legal rights.

1. Do you agree to participate in this study?
- Yes
- No

Initials:

2. Do you authorize the PI or the research coordinator (SA) to contact the pharmacy from where you get your oral chemotherapy medication (this is to gather information on your medication and refills during your participation in the study) ?
- Yes
- No

Initials:
If yes: Name and telephone number of pharmacy

3. Do you give permission for PI or the research coordinator (SA) to access your hospital records?
- Yes
- No

Initials:

4. Do you give permission to be contacted by the research coordinator (SA) for this study (phone, email, and mail) over the duration of the study?
- Yes
- No

Initials:

5. Do you give permission to use the depersonalized (no way to identify information) data collected from to be for future research related to this study or for future studies?
- Yes
- No

Initials:
Your name:

Date:

RESEARCHER STATEMENT
I, as the person obtaining consent, certify that I have explained to the participant or his/her legal representative (where applicable) the research study information contained in this consent form and have answered all questions. I have clearly explained to the participant that s/he is free to withdraw at any time without providing a reason, and without any consequences. I commit, together with the members of the research team to respect all conditions described in this consent form and to give a signed copy of the consent form to the participant.

_____
Name of the researcher or person delegated to obtained consent:

Date:

Additional support:

Psychosocial Oncology at the Jewish General Hospital
(514) 340-8222 ext. 23223
Talk to an information specialist at the Canadian Cancer Society
1-888-939-3333
Info-cancer hotline from the Quebec Cancer Foundation
1-800-363-0063

INFORMATION ET FORMULAIRE DE CONSENTEMENT (CONTROLE)

Titre de la recherche: Feasibilité, acceptabilité et effets potentiels d'une intervention complète d'agent anticancéreux oral sur l'auto-efficacité de l'observance du traitement, l'observance du traitement et la détresse liée aux symptômes : un essai pilote randomisé de contrôle
Titre court : Oncologie – Basée sur Oral Agent Rapportant de la Détresse (ON-BOARD)
Chercheuse principale: Carmen G. Loiselle, Inf., Ph.D
Co-chercheuse: Christine Maheu, Inf., Ph.D.
Coordinatrice de l'étude: Saima Ahmed, B.Sc.
Fonds: Réseau de cancérologie Rossy

Vous êtes invité à participer à une étude de recherche. Prenez le temps de lire attentivement, de comprendre et de réfléchir aux informations qui vous ont été expliquées et fournies par l'entremise de ce formulaire. Si vous choisissez de participer à cette étude, nous vous demanderons de signer ce formulaire de consentement. Une copie du formulaire de consentement signé vous sera envoyée par courriel.

Ce formulaire peut contenir des mots ou des informations que vous ne comprenez pas. Nous vous encourageons à demander au chercheur responsable de cette étude ou à un membre de l'équipe de recherche toutes les questions que vous pourriez avoir. Demandez-leur d'expliquer tous les mots et toutes les informations qui ne sont pas clairs. Ils ont l'obligation de répondre de manière à ce que vous puissiez comprendre toutes les informations qui vous sont présentées.

Cette étude est menée par la Dre Carmen Loiselle, codirectrice (académique) du Centre du cancer Segal et professeure au département d'oncologie de l'Université McGill et à l'École des sciences infirmières Ingram.

Quel est le but de l'étude?

Cette étude de recherche vise à mieux comprendre comment soutenir les personnes atteintes de cancer qui reçoivent un traitement de chimiothérapie orale.

Les participants à l'étude doivent être âgés de 18 ans ou plus, avoir un diagnostic de cancer de n'importe quel stade et être sur le point de commencer ou au cours du premier cycle de leur traitement anticancer orale (traditionelle, thérapie ciblée, ou l'hormonothérapie comme traitement actif). Ils doivent avoir un ordinateur, une tablette ou un téléphone intelligent avec accès à Internet et être capable de communiquer, lire et écrire en anglais ou en français. Les personnes recevant une chimiothérapie IV, une immunothérapie ou l' hormonothérapie comme traitement préventatif ne peuvent pas participer. Vous êtes invité à participer à cette étude parce que vous répondez aux critères de participation.

Cette étude impliquera 52 patients recevant un traitement contre le cancer au Centre du cancer Segal de l'Hôpital général juif et durera cinq cycles de chimiothérapie orale (cinq mois).

Que dois-je faire?

Si vous acceptez de participer à cette étude, vous pourrez effectuer vos tâches à partir de votre ordinateur à la maison (ou si vous préférez, au centre du cancer).

Une fois que vous avez complété ce formulaire, vous recevrez un courriel avec un numéro d'identification d'étude unique (Login ID). Vous utiliserez ce numéro tout au long de l'étude pour vous connecter en ligne et remplir des questionnaires.

Le premier questionnaire, qui vous sera envoyé après la signature de ce formulaire, comprendra des questions sur vous, vos antécédents médicaux, votre santé physique/émotionnelle et vos connaissances en chimiothérapie orale. Le premier questionnaire est plus long, il peut prendre 20 à 25 minutes à remplir. Certains participants à l'étude seront sélectionnés au hasard et contactés après le premier questionnaire pour des questions de suivi.

Ensuite, vous remplirez des questionnaires chaque semaine pendant le premier mois, puis toutes les deux semaines pendant les quatre mois qui suivent. Ces questionnaires sont plus courts et peuvent prendre de 10 à 15 minutes à remplir. Vous recevrez des rappels par courriel lorsqu'il sera temps de remplir les questionnaires. Ils comprendront des questions sur vos médicaments de chimiothérapie orale et les problèmes liés au cancer qui peuvent être importants pour vous, par exemple, la fatigue, la douleur, le bien-être, etc. Si vous indiquez dans le questionnaire que vous ressentez un niveau élevé de détresse, vous recevrez des instructions sur la personne à contacter pour prendre les mesures appropriées.

À la fin de l'étude, vous serez invité à participer à un appel téléphonique individuel pour partager votre expérience concernant les informations et le soutien que vous avez reçus pendant votre traitement de chimiothérapie orale.

Votre participation globale à l’étude dura cinq mois. Vous terminerez l'étude plus tôt si vous terminez votre traitement de chimiothérapie orale en moins de cinq mois. Avec votre permission, nous allons également accéder à vos dossiers médicaux et contacter votre pharmacie pour recueillir des informations sur votre diagnostic de cancer, traitement et médicaments de chimiothérapie orale.

Si je participe, il y a-t-il des risques ou des inconvénients?

La participation à cette étude peut comporter des risques psychologiques. Certains participants peuvent ressentir de la détresse ou d'autres émotions négatives lorsqu'on leur pose des questions sur leur diagnostic de cancer. Vous êtes libre de refuser de répondre aux questions. Si vous signalez une détresse élevée lorsque vous remplissez des questionnaires, vous recevrez une notification avec des instructions sur les personnes à contacter pour prendre les mesures appropriées. De plus, une liste de services professionnels de soutien psychosocial en oncologie sera fournie et indiquée au bas de chaque questionnaire. Remplir le questionnaire chaque une ou deux semaines prendra environ 15 minutes, le temps nécessaire peut être un inconvénient.

Si je participe, il y a-t-il des avantages potentiels?

Vous ne recevrez aucun avantage personnel en participant à cette étude de recherche. Cependant, participer à cette étude peut aider les scientifiques et les cliniciens à mieux comprendre quel soutien ont besoin les patients atteints de cancer qui suivent un traitement de chimiothérapie orale.

Vais-je recevoir une compensation pour ma participation?

En guise de d'appréciation pour le temps passé à remplir les questionnaires de l'étude, vous recevrez une carte-cadeau de 10$ lors de votre inscription, et 10$ supplémentaires pour chaque questionnaire complété, pour un maximum de 120$ sur la période d'étude de 5 mois.

Si vous choisissez de vous retirer de l'étude à tout moment, vous recevrez un minimum de 10$, avec un supplément de 10$ pour chaque questionnaire rempli avant le retrait.

Vous aurez le choix entre des cartes-cadeaux Amazon, Starbucks ou Best Buy et recevrez ces cartes par e-mail à la fin de chaque mois.

Mes informations demeureront-elles confidentielles?

Qualtrics, une application sécurisée de sondage et de base de données utilisée par les chercheurs de l'Université McGill, sera utilisée dans cette étude. Qualtrics est un serveur sécurisé qui utilise le cryptage des données https en transit et le cryptage AES 256 bits au repos.

Pour aider à atteindre l'objectif de l'étude, certaines de vos informations personnelles et identifiables seront collectées et conservées. Seules les informations nécessaires à la recherche seront collectées. Toutes les informations collectées sur vous au cours de l'étude resteront confidentielles dans les limites de la loi. Seule la chercheuse principale et la coordonnatrice de l'étude auront accès à vos renseignements personnels. Les informations recueillies à partir de votre dossier médical et de vos dossiers de pharmacie pour l'étude seront conservées dans un dossier protégé par mot de passe et sécurisé sur le serveur du CIUSSS du Centre-Ouest-de-l'Île de Montréal. Toutes les informations recueillies à partir des questionnaires seront conservées dans des bases de données distinctes et sécurisées sur Qualtrics; le formulaire de consentement, la sélection et les coordonnées, ainsi que les réponses aux questionnaires liés à votre numéro d'identification (Login ID). En répondant aux questionnaires en ligne, vos réponses seront liées à votre identifiant de connexion (Login ID), qui est lié à votre nom. Par conséquent, le risque de vous identifier en tant que participant à cette étude est très faible car votre nom sera remplacé par ce code numérique unique. Le lien entre le code et votre identité sera conservé dans une base de données Qualtrics sécurisée. Seule la chercheuse principale, la directrice de recherche et la coordinatrice de l'étude auront accès à la liste des participants et au code correspondant clé. Les informations recueillies auprès de vous dans le cadre de l'étude seront détruites 10 ans après la fin de l'étude.

À des fins de surveillance, de contrôle et de protection, votre dossier d'étude de recherche pourrait être vérifié par une personne autorisée par le Comité d'éthique de la recherche du CIUSSS du Centre-Ouest-de-l'Île de Montréal ou par des personnes mandatées par des organismes publics autorisés. Ces personnes sont liées à un accord de confidentialité.

Puis-je me retirer de l'étude après avoir donné mon consentement?

Votre participation dans cette étude est complètement volontaire. Si vous acceptez de participer à l'étude, il vous sera demandé de donner votre consentement à la fin de ce document. Vous avez le droit de vous retirer de cette étude à tout moment sans indiquer de motif et sans aucune incidence sur les soins que vous recevez à l'hôpital. Si vous vous retirez de cette étude, les informations recueillies seront conservées, à moins que vous nous demandiez de les détruire. Si vous vous retirez de cette étude, nous cesserons d'accéder à votre dossier médical et à votre dossier pharmaceutique.

À quoi serviront les données recueillies dans l'étude?

Avec votre permission, les données recueillies dépersonnalisées pourraient être utilisées pour des recherches futures liées à cette étude ou pour des études ultérieures. Les données ne seront pas accessibles à votre médecin, même s'il le demande. Les résultats de l'étude seront présentés sous forme de données groupées. Cela signifie qu'aucun résultat individuel ne sera partagé. Les résultats pourraient être présentés à des conférences, publiés dans des revues spécialisées ou faire l'objet de discussions scientifiques. Votre identité et toute information d'identification ne seront révélées dans aucun rapport ou publication.

Qui dois-je contacter si j'ai des questions?

Si vous avez des questions sur l'étude, vous pouvez contacter la chercheuse principale de l'étude, Dre Carmen G. Loiselle, ou la coordinatrice de l'étude, Saima Ahmed.

Carmen G. Loiselle, R.N., Ph.D.
Courriel : Loiselle-research@mcgill.ca
Téléphone: 514-398-8977

Saima Ahmed
Courriel : saima.ahmed2@mail.mcgill.ca
Téléphone: 514-398-8977

Pour toute question concernant vos droits lors de votre participation à cette étude, ou si vous avez des plaintes ou des commentaires à propos de votre expérience en tant que participant à cette étude, vous pouvez contacter le Commissaire local aux plaintes et à la qualité de service du CIUSSS Centre-Ouest- de l'Île-de-Montréal ou l'ombudsman de l'institution au (514) 340-8222, poste 24222.

DÉCLARATION DE CONSENTEMENT

Faisabilité, acceptabilité et effets potentiels d'une intervention complète d'agent anticancéreux oral sur l'auto-efficacité de l'observance du traitement, l'observance du traitement et la détresse liée aux symptômes : un essai pilote randomisé de contrôle

DÉCLARATION DU PARTICIPANT

Les informations contenues dans ce formulaire de consentement m'ont été expliquées et toutes mes questions ont reçu une réponse satisfaisante. Une copie de ce formulaire de consentement électronique me sera remise. Ma participation est volontaire et je peux me retirer de l'étude à tout moment sans devoir donner de raison. Le retrait de l'étude n'affectera en aucun cas mes soins médicaux ni maintenant, ni plus tard. Je ne renonce à aucun de mes droits légaux en signant ce formulaire de consentement.

1. Acceptez-vous de participer à cette étude?
□ Oui
□ Non
Initiales :

2. Autorisez-vous la chercheuse principale ou la coordinatrice de l'étude (SA) à contacter la pharmacie où vous vous procurez vos médicaments de chimiothérapie orale (il s'agit de recueillir des informations sur vos médicaments et renouvellements lors de votre participation à l'étude)?
□ Oui
□ Non
Initiales :
Si oui : Nom et numéro de téléphone de la pharmacie

3. Autorisez-vous la chercheuse principale ou la coordinatrice de l'étude (SA) à accéder à vos dossiers médicaux de l'Hôpital général juif?
□ Oui
□ Non
Initiales :

4. Autorisez-vous à être contacté par la coordinatrice de l'étude (SA) pour cette étude (téléphone, e-mail et courrier) pendant la durée de l'étude ?
□ Oui
□ Non
Initiales :

5. Donnez-vous la permission d'utiliser les données dépersonnalisées (aucun moyen d'identifier les informations) collectées pour de futures recherches liées à cette étude ou pour de futures études ?
□ Oui
□ Non

Initiales :

Votre nom :
Date :

DÉCLARATION DU CHERCHEUR
Je certifie que nous avons expliqué les informations contenues dans ce formulaire de consentement, que nous avons répondu à toutes les questions que le participant aurait pu avoir concernant la participation à cette étude. Nous avons clairement expliqué que le participant est libre de se retirer à tout moment et pour n'importe quelle raison, sans conséquences. Je m'engage avec les membres de l'équipe de recherche à respecter toutes les conditions décrites dans le présent formulaire de consentement et à en remettre une copie signée au participant à la recherche.

Nom du membre de l'équipe de recherche ayant obtenu le consentement :
Date :

Soutien additionel

Programme d'oncologie psychosociale à l'Hôpital général juif
(514) 340-8222 poste 23223
Parlez à un spécialiste en information à la société canadienne du caner
1-888-939-3333
Ligne Info-cancer de la fondation québecoise du cancer
1-800-363-0063

INFORMATION AND CONSENT FORM (EXP)

RESEARCH STUDY TITLE: Feasibility, acceptability, and potential effects of a comprehensive oral anticancer agent intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial
SHORT TITLE: Oncology – Bolstering Oral Agent Reporting related to Distress (ON-BOARD)
PRINCIPAL INVESTIGATOR: Carmen G. Loiselle, R.N., Ph.D.
CO-INVESTIGATOR: Christine Maheu, R.N. Ph.D.
STUDY COORDINATOR: Saima Ahmed, B.Sc.
SOURCE OF FUNDING: Rossy Cancer Network

You are invited to participate in a research study. Take the time to carefully read, understand and think about the information that has been explained and given to you included in this form. If you choose to take part in this research study, we will ask you to sign this consent form. A copy of the signed consent form will be emailed to you.

This form may contain some words or information that you do not understand. We encourage you to ask the researcher responsible for this research study or a member of the research team all questions that you may have. Ask them to explain all words and information that are unclear. They have the obligation to answer in such a way that you can understand all the information presented to you.

This study is being conducted by Dr. Carmen Loiselle, Co-Director (Academic) of the Segal Cancer Centre and Professor in McGill University's Department of Oncology and Ingram School of Nursing.

What is the purpose of the study?

This research study aims to better understand how to support individuals with cancer who are receiving oral chemotherapy treatment.

Participants in the study must be 18 years of age or older, have a diagnosis of cancer of any stage, and about to start or within the first cycle of their oral anticancer treatment (traditional, targeted, or hormonal therapy as active treatment). They must have a computer, tablet or smartphone with internet access, and be able to communicate, read, and write in English or French. Individuals receiving IV chemotherapy, immunotherapy or oral hormonal therapy as preventative treatment are not able to participate. You are being invited to take part in this study because you meet the participation criteria.

The study will involve 52 patients receiving cancer treatment at the Segal Cancer Centre of the Jewish General Hospital and will last five cycles of oral chemotherapy (five months).

What am I expected to do?
After filling out the first questionnaire, half the participants (26 out of the total 52) were randomly chosen to receive an oral chemotherapy information and support program. You are part of this group.
You will be able to access the program online at any time. It will all be available in a mobile application called BELONG – Beating Cancer Together. We ask that you download the application on your smartphone or tablet and enter the code ONBOARD. Once you have set up the App, you will be able to access:

1. Tip sheets on common oral chemotherapy related-topics: these handouts will provide knowledge, facts, tips, and additional online or telephone resources.
2. Oral chemotherapy informational videos: general information on oral chemotherapy, side effects, support, fertility & work, and symptoms.
3. A call from a nurse in oncology: If you want to talk to a nurse, you can let us know when you complete your questionnaire and clicking on "I would like a phone call from a nurse". You will receive a phone call within the next few days.
4. Reminders: receive reminder notifications to take your OC medication.

You have already completed the first questionnaire for the study. Now every week for the first month and every two weeks for the four months after that, you will receive another online questionnaire to complete. You will continue to use the same unique study identification number (Login ID) throughout the entire study to log in online and complete questionnaires.
If you rate in the questionnaire that you are feeling a high level of distress, you will receive instructions on who to contact to take appropriate action.

At the end of the study, you will be invited to take part in a one-on-one telephone interview to share your experience regarding the information and support you have received in relation to the study. The questions will center around what you liked, disliked and any suggestions you may have for improvement. It will take 30 to 60 minutes to participate in the interview. Depending on your preference, the interview will be conducted by phone or Zoom. The interview will be recorded in audio format.

Your overall time involvement will be five months. You will finish the study earlier if you complete your oral chemotherapy treatment in less than five months. With your permission, we will also access your medical records and contact your pharmacist, to collect information about your cancer diagnosis, treatment, and oral chemotherapy medication.

If I participate, are there any risks or inconveniences?

Participating in this study may involve some psychological risks. Some participants may experience distress or other negative emotions when asked questions about their cancer diagnosis. You are free to refuse to answer any questions. If you report high distress when you complete questionnaires, you will receive a notification with instructions on who to contact to take appropriate action. Additionally, a list of professional psychosocial oncology support services will be provided and listed at the bottom of each questionnaire. Filling out the

questionnaire every one or two weeks will take about 15-minutes, this extra time may be an inconvenience.

If I participate, are there any potential benefits?

It is possible that you will benefit personally as a result of participating in this study because you may be offered additional information and support for cancer-related issues you may be having. In addition, taking part in this study may also help scientists and clinicians better understand the types of support cancer patients on oral chemotherapy treatment need.

Will I receive any compensation for participating?

As a token of appreciation for the time spent completing study questionnaires, you will receive a 10$ gift card when you enroll, and an additional 10$ for each questionnaire you complete, for a maximum of 120$ over the 5-month study period.

If you choose to withdraw from the study at any time, they will receive a minimum of 10$, with an additional 10$ for each questionnaire completed before withdrawal.

You will have the choice of Amazon, Starbucks, or Best Buy gift cards and will receive these cards by email at the end of each month.

Will my information be kept confidential?

Qualtrics, a secure survey and database application commonly used by McGill University researchers will be used in this study application, will be used in this study. Qualtrics is a secure server that uses https data encryption in transit and AES 256-bit encryption at rest. Keep in mind, with all information sent over the internet, it is not necessarily secure.

To help meet the purpose of the study, personal and identifiable information about you will be collected and stored. Only information necessary for the research study will be collected. It will remain confidential and protected within the limits of the law. Only the principal investigator and study manager will have access to your personal information. The information that is collected from your medical chart and pharmacy records for the study will be kept in a password protected and secure folder on the CIUSSS du Centre-Ouest-de-l'Île de Montréal server. All information collected from questionnaires will be kept in secure databases on Qualtrics; the consent form, screening and contact information, and questionnaire responses will be linked to your Login ID number. By responding to the online questionnaires, your responses will be linked to your Login ID number, which is linked your name. Therefore, the risk of identifying you as a participant in this study is very low as your name will be replaced with this unique number code. The link between the code and your identity will be held in a secure Qualtrics database. Only the principal investigator, research manager and study coordinator will have access to the list of participants and to corresponding code. The information collected from you in the study will be destroyed 10 years after the study is completed.

For monitoring, control and protection purposes, your research study file could be checked by a person authorized by the Research Ethics Committee of the CIUSSS du Centre-Ouest-de-l'Île de Montréal or by persons mandated by authorized public agencies. These persons are bound by a confidentiality agreement.

Can I withdraw from the study after I consent?

Your participation in this study is completely voluntary. If you agree to take part in the study, you will be asked to give your consent at the end of this document. You have the right to withdraw (stop participating) from this study at any time without providing a reason and without any impact on the care you receive at the hospital. If you withdraw from this study, the information gathered will be kept, unless you ask us to destroy it. If you withdraw from this study, we will stop accessing your medical chart and pharmacy record.

What will the data collected in the study be used for?

With your permission, the depersonalized data collected from you could be used for future research related to this study or for future studies. The data collected during the research study will not be accessible to your oncologist, even if they request it. The results may be presented at conferences, published in specialized journals or be the subject of scientific discussions. Your identity and any identifying information will not be revealed in any reports or publications.

Who do I contact if I have questions?

If you have any questions about the research study, you can contact the researcher in charge of the study (PI), Dr. Carmen G. Loiselle, or the study coordinator, Saima Ahmed (SA).

Carmen G. Loiselle, R.N., Ph.D.
E-mail: Loiselle-research@mcgill.ca
Phone: 514-398-8977

Saima Ahmed
E-mail: saima.ahmed2@mail.mcgill.ca
Phone: 514-690-7860

For all questions concerning your rights during your participation in this study, or if you have any complaints or comments regarding your experience in taking part in this study, you can contact the Local Commissioner of Complaints and Quality of Service of the CIUSSS Centre-Ouest-de-l'Île-de-Montréal or the ombudsman of the institution au (514) 340-8222, ex. 24222.

STATEMENT OF CONSENT

Feasibility, acceptability, and potential effects of a comprehensive oral anticancer agent intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial

PARTICIPANT STATEMENT

I understand the information that was explained to me as contained in this consent form. All my questions were answered to my satisfaction. I will receive an electronic copy of this consent form. My participation is voluntary, and I can withdraw from the research study at any time without any consequences and without having to give a reason. Withdrawing from this research study, at any time, will not affect my medical care now, or later, in any way (where applicable). By signing this consent form, I do not give up any of my legal rights.

1. Do you agree to participate in this study?
- Yes
- No

Initials:

2. Do you authorize the PI or the research coordinator (SA) to contact the pharmacy from where you get your oral chemotherapy medication (this is to gather information on your medication and refills during your participation in the study) ?
- Yes
- No

Initials:

3. Do you give permission for PI or the research coordinator (SA) to access your hospital records?
- Yes
- No

Initials:

4. Do you give permission to be contacted by the research coordinator (SA) for this study (phone, email, and mail) over the duration of the study?
- Yes
- No

Initials:

5. Do you give permission to use the depersonalized (no way to identifying information) data collected from to be for future research related to this study or for future studies?
- Yes
- No

Initials:
Your name:
Date:

RESEARCHER STATEMENT

I, as the person obtaining consent, certify that I have explained to the participant or his/her legal representative (where applicable) the research study information contained in this consent form and have answered all questions. I have clearly explained to the participant that s/he is free to withdraw at any time without providing a reason, and without any consequences. I commit, together with the members of the research team to respect all conditions described in this consent form and to give a signed copy of the consent form to the participant.

_____

Name of the researcher or person delegated to obtained consent:
Date:

Additional support:

Psychosocial Oncology at the Jewish General Hospital
(514) 340-8222 ext. 23223
Talk to an information specialist at the Canadian Cancer Society
1-888-939-3333
Info-cancer hotline from the Quebec Cancer Foundation
1-800-363-0063

INFORMATION ET FORMULAIRE DE CONSENTEMENT (EXP)

Titre de la recherche: Faisabilité, acceptabilité et effets potentiels d'une intervention complète d'agent anticancéreux oral sur l'auto-efficacité de l'observance du traitement, l'observance du traitement et la détresse liée aux symptômes : un essai pilote randomisé de contrôle
Titre court : Oncologie – Basée sur Oral Agent Rapportant de la Détresse (ON-BOARD)
Chercheuse principale: Carmen G. Loiselle, Inf., Ph.D
Co-chercheuse: Christine Maheu, Inf., Ph.D.
Coordinatrice de l'étude: Saima Ahmed, B.Sc.
Fonds: Réseau de cancérologie Rossy

Vous êtes invité à participer à une étude de recherche. Prenez le temps de lire attentivement, de comprendre et de réfléchir aux informations qui vous ont été expliquées et fournies par l'entremise de ce formulaire. Si vous choisissez de participer à cette étude, nous vous demanderons de signer ce formulaire de consentement. Une copie du formulaire de consentement signé vous sera envoyée par courriel.

Ce formulaire peut contenir des mots ou des informations que vous ne comprenez pas. Nous vous encourageons à demander au chercheur responsable de cette étude ou à un membre de l'équipe de recherche toutes les questions que vous pourriez avoir. Demandez-leur d'expliquer tous les mots et toutes les informations qui ne sont pas clairs. Ils ont l'obligation de répondre de manière à ce que vous puissiez comprendre toutes les informations qui vous sont présentées.

Cette étude est menée par la Dre Carmen Loiselle, codirectrice (académique) du Centre du cancer Segal et professeure au département d'oncologie de l'Université McGill et à l'École des sciences infirmières Ingram.

Quel est le but de l'étude?

Cette étude de recherche vise à mieux comprendre comment soutenir les personnes atteintes de cancer qui reçoivent un traitement de chimiothérapie orale.

Les participants à l'étude doivent être âgés de 18 ans ou plus, avoir un diagnostic de cancer de n'importe quel stade et être sur le point de commencer ou au cours du premier cycle de leur traitement anticancer orale (traditionelle, thérapie ciblée, ou l'hormonothérapie comme traitement actif). Ils doivent avoir un ordinateur, une tablette ou un téléphone intelligent avec accès à Internet et être capable de communiquer, lire et écrire en anglais ou en français. Les personnes recevant une chimiothérapie IV, une immunothérapie ou l'hormonothérapie comme traitement préventatif ne peuvent pas participer. Vous êtes invité à participer à cette étude parce que vous répondez aux critères de participation.

Cette étude impliquera 52 patients recevant un traitement contre le cancer au Centre du cancer Segal de l'Hôpital général juif et durera cinq cycles de chimiothérapie orale (cinq mois).

Que dois-je faire?

Après avoir rempli le premier questionnaire, la moitié des participants (26 sur un total de 52) ont été choisis au hasard pour recevoir un programme d'information et de soutien sur la chimiothérapie orale. Vous faites partie de ce groupe.

Vous pourrez accéder au programme en ligne à tout moment. Tout cela sera disponible dans une application mobile appelée BELONG – Beating Cancer Together. Nous vous demandons de télécharger l'application sur votre smartphone ou votre tablette et de saisir le code ONBOARD. Une fois l'application configurée, vous pourrez accéder à :

1. des fiches de conseils sur des sujets courants liés à la chimiothérapie orale : ces documents fourniront des connaissances, des faits, des conseils et des ressources supplémentaires en ligne ou par téléphone
2. des vidéos d'information sur la chimiothérapie orale : informations générales sur la chimiothérapie orale, les effets secondaires, le soutien, la fertilité et le travail, et les symptômes
3. un appel d'une infirmière en oncologie : si vous souhaitez parler à une infirmière, vous pouvez nous le signaler en remplissant votre questionnaire et en cliquant sur « Je souhaite un appel téléphonique d'une infirmière ». Vous recevrez un appel téléphonique dans les prochains jours
4. des rappels : recevez des notifications de rappel pour prendre vos médicaments OC.

Vous avez déjà rempli le premier questionnaire de l'étude. Désormais, chaque semaine pendant le premier mois et toutes les deux semaines pendant les quatre mois suivants, vous recevrez un autre questionnaire en ligne à remplir. Vous continuerez à utiliser le même numéro d'identification unique de l'étude (Login ID) tout au long de l'étude pour vous connecter en ligne et remplir les questionnaires. Si vous indiquez dans le questionnaire que vous ressentez un niveau élevé de détresse, vous recevrez des instructions sur les personnes à contacter pour prendre les mesures appropriées.

À la fin de l'étude, vous serez invité à participer à un appel téléphonique individuel pour partager votre expérience concernant les informations et le soutien que vous avez reçus dans le cadre de l'étude. Les questions seront centrées sur ce que vous avez aimé, n'avez pas aimé et toutes les suggestions d'amélioration que vous pourriez avoir. Il faudra 30 à 60 minutes pour participer à l'appel. Selon votre préférence, l'appel se déroulera par téléphone ou Zoom. L''appel sera enregistré en format audio.

Votre participation à l'étude sera de cinq mois au total. Vous terminerez l'étude plus tôt si vous terminez votre traitement de chimiothérapie orale en moins de cinq mois. Avec votre permission, nous allons également accéder à vos dossiers médicaux et contacter votre pharmacie pour recueillir des informations sur votre diagnostic de cancer, traitement et médicaments de chimiothérapie orale.

Si je participe, il y a-t-il des risques ou des inconvénients?

La participation à cette étude peut comporter des risques psychologiques. Certains participants peuvent ressentir de la détresse ou d'autres émotions négatives lorsqu'on leur pose des questions sur leur diagnostic de cancer. Vous êtes libre de refuser de répondre aux questions. Si vous signalez une détresse élevée lorsque vous remplissez des questionnaires, vous recevrez une notification avec des instructions sur les personnes à contacter pour prendre les mesures appropriées. De plus, une liste de services professionnels de soutien psychosocial en oncologie sera fournie et indiquée au bas de chaque questionnaire. Remplir le questionnaire chaque une ou deux semaines prendra environ 15 minutes, le temps nécessaire peut être un inconvénient

Si je participe, il y a-t-il des avantages potentiels?

Il est possible que votre participation à cette étude vous profite personnellement, car vous pouvez recevoir des informations et soutien supplémentaires pour les problèmes liés au cancer que vous pourriez avoir. De plus, participer à cette étude peut aider les scientifiques et les cliniciens à mieux comprendre le soutien dont les patients atteints de cancer sous chimiothérapie orale ont besoin.

Vais-je recevoir une compensation pour ma participation?

En guise de d'appréciation pour le temps passé à remplir les questionnaires de l'étude, vous recevrez une carte-cadeau de 10$ lors de votre inscription, et 10$ supplémentaires pour chaque questionnaire complété, pour un maximum de 120$ sur la période d'étude de 5 mois.

Si vous choisissez de vous retirer de l'étude à tout moment, vous recevrez un minimum de 10$, avec un supplément de 10$ pour chaque questionnaire rempli avant le retrait.

Vous aurez le choix entre des cartes-cadeaux Amazon, Starbucks ou Best Buy et recevrez ces cartes par e-mail à la fin de chaque mois.

Mes informations demeureront-elles confidentielles?

Qualtrics, une application sécurisée de sondage et de base de données utilisée par les chercheurs de l'Université McGill, sera utilisée dans cette étude. Qualtrics est un serveur sécurisé qui utilise le cryptage des données https en transit et le cryptage AES 256 bits au repos.

Pour aider à atteindre l'objectif de l'étude, certaines de vos informations personnelles et identifiables seront collectées et conservées. Seules les informations nécessaires à la recherche seront collectées. Toutes les informations collectées sur vous au cours de l'étude resteront confidentielles dans les limites de la loi. Seule la chercheuse principale et la coordonnatrice de l'étude auront accès à vos renseignements personnels. Les informations recueillies à partir de votre dossier médical et de vos dossiers de pharmacie pour l'étude seront conservées dans un dossier protégé par mot de passe et sécurisé sur le serveur du CIUSSS du Centre-Ouest-de-l'Île de Montréal. Toutes les informations recueillies à partir des questionnaires seront conservées

dans des bases de données distinctes et sécurisées sur Qualtrics; le formulaire de consentement, la sélection et les coordonnées, ainsi que les réponses au questionnaires liés à votre numéro d'identification (Login ID). En répondant aux questionnaires en ligne, vos réponses seront liées à votre identifiant de connexion (Login ID), qui est lié à votre nom. Par conséquent, le risque de vous identifier en tant que participant à cette étude est très faible car votre nom sera remplacé par ce code numérique unique. Le lien entre le code et votre identité sera conservé dans une base de données Qualtrics sécurisée. Seule la chercheuse principale, la directrice de recherche et la coordinatrice de l'étude auront accès à la liste des participants et au code correspondant clé. Les informations recueillies auprès de vous dans le cadre de l'étude seront détruites 10 ans après la fin de l'étude.

À des fins de surveillance, de contrôle et de protection, votre dossier d'étude de recherche pourrait être vérifié par une personne autorisée par le Comité d'éthique de la recherche du CIUSSS du Centre-Ouest-de-l'Île de Montréal ou par des personnes mandatées par des organismes publics autorisés. Ces personnes sont liées à un accord de confidentialité.

Puis-je me retirer de l'étude après avoir donné mon consentement?

Votre participation dans cette étude est complètement volontaire. Si vous acceptez de participer à l'étude, il vous sera demandé de donner votre consentement à la fin de ce document. Vous avez le droit de vous retirer de cette étude à tout moment sans indiquer de motif et sans aucune incidence sur les soins que vous recevez à l'hôpital. Si vous vous retirez de cette étude, les informations recueillies seront conservées, à moins que vous nous demandiez de les détruire. Si vous vous retirez de cette étude, nous cesserons d'accéder à votre dossier médical et à votre dossier pharmaceutique.

À quoi serviront les données recueillies dans l'étude?

Avec votre permission, les données dépersonnalisées recueillies pourraient être utilisées pour des recherches futures liées à cette étude ou pour des études ultérieures. Les données ne seront pas accessibles à votre médecin, même s'il le demande. Les résultats de l'étude seront présentés sous forme de données groupées. Cela signifie qu'aucun résultat individuel ne sera partagé. Les résultats pourraient être présentés à des conférences, publiés dans des revues spécialisées ou faire l'objet de discussions scientifiques. Votre identité et toute information d'identification ne seront révélées dans aucun rapport ou publication.

Qui dois-je contacter si j'ai des questions?

Si vous avez des questions sur l'étude, vous pouvez contacter la chercheuse principale de l'étude, Dre Carmen G. Loiselle, ou la coordinatrice de l'étude, Saima Ahmed.

Carmen G. Loiselle, R.N., Ph.D.
Courriel : Loiselle-research@mcgill.ca
Téléphone: 514-398-8977

Saima Ahmed
Courriel : saima.ahmed2@mail.mcgill.ca
Téléphone: 514-398-8977

Pour toute question concernant vos droits lors de votre participation à cette étude, ou si vous avez des plaintes ou des commentaires à propos de votre expérience en tant que participant à cette étude, vous pouvez contacter le Commissaire local aux plaintes et à la qualité de service du CIUSSS Centre-Ouest- de l'Île-de-Montréal ou l'ombudsman de l'institution au (514) 340-8222, poste 24222.

DÉCLARATION DE CONSENTEMENT

Faisabilité, acceptabilité et effets potentiels d'une intervention complète d'agent anticancéreux oral sur l'auto-efficacité de l'observance du traitement, l'observance du traitement et la détresse liée aux symptômes : un essai pilote randomisé de contrôle

DÉCLARATION DU PARTICIPANT

Les informations contenues dans ce formulaire de consentement m'ont été expliquées et toutes mes questions ont reçu une réponse satisfaisante. Une copie de ce formulaire de consentement électronique me sera remise. Ma participation est volontaire et je peux me retirer de l'étude à tout moment sans devoir donner de raison. Le retrait de l'étude n'affectera en aucun cas mes soins médicaux ni maintenant, ni plus tard. Je ne renonce à aucun de mes droits légaux en signant ce formulaire de consentement.

1. Acceptez-vous de participer à cette étude?
□ Oui
□ Non
Initiales :

2. Autorisez-vous la chercheuse principale ou la coordinatrice de l'étude (SA) à contacter la pharmacie où vous vous procurez vos médicaments de chimiothérapie orale (il s'agit de recueillir des informations sur vos médicaments et renouvellements lors de votre participation à l'étude)?
□ Oui
□ Non
Initiales :

3. Autorisez-vous la chercheuse principale ou la coordinatrice de l'étude (SA) à accéder à vos dossiers médicaux de l'Hôpital général juif?
□ Oui
□ Non
Initiales :

4. Autorisez-vous à être contacté par la coordinatrice de l'étude (SA) pour cette étude (téléphone, e-mail et courrier) pendant la durée de l'étude ?
□ Oui
□ Non
Initiales :

5. Donnez-vous la permission d'utiliser les données dépersonnalisées (aucun moyen d'identifier les informations) collectées pour de futures recherches liées à cette étude ou pour de futures études ?
□ Oui
□ Non
Initiales :

Votre nom :
Date :

DÉCLARATION DU CHERCHEUR
Je certifie que nous avons expliqué les informations contenues dans ce formulaire de consentement, que nous avons répondu à toutes les questions que le participant aurait pu avoir concernant la participation à cette étude. Nous avons clairement expliqué que le participant est libre de se retirer à tout moment et pour n'importe quelle raison, sans conséquences.

Je m'engage avec les membres de l'équipe de recherche à respecter toutes les conditions décrites dans le présent formulaire de consentement et à en remettre une copie signée au participant à la recherche.

Nom du membre de l'équipe de recherche ayant obtenu le consentement :
Date :

Soutien additionel

Programme d'oncologie psychosociale à l'Hôpital général juif
(514) 340-8222 poste 23223
Parlez à un spécialiste en information à la société canadienne du caner
1-888-939-3333
Ligne Info-cancer de la fondation québecoise du cancer
1-800-363-0063

Appendix F

Randomization sequence

Participant number	Participant type
1	Experimental
2	Control
3	Control
4	Experimental
5	Control
6	Control
7	Experimental
8	Control
9	Experimental
10	Experimental
11	Experimental
12	Experimental
13	Control
14	Experimental
15	Control
16	Control
17	Control
18	Control
19	Control
20	Control
21	Control
22	Control
23	Experimental
24	Experimental
25	Experimental
26	Experimental
27	Experimental
28	Control
29	Experimental
30	Control
31	Control
32	Control

33	Control
34	Experimental
35	Experimental
36	Control
37	Control
38	Experimental
39	Experimental
40	Control
41	Experimental
42	Experimental
43	Control
44	Experimental
45	Experimental
46	Control
47	Control
48	Experimental
49	Experimental
50	Control
51	Experimental
52	Experimental

Appendix G

Prospective Acceptability E-Scale (Tariman et al., 2011)

1. How helpful do you anticipate the oral chemotherapy information and support offered in this study will be in helping you manage your treatment?

1 - Very unhelpful
2 - Unhelpful
3 - Neither helpful nor unhelpful
4 - Helpful
5 - Very helpful

2. How helpful do you anticipate the information and support offered in this study will be in reminding you to take your medication?

1 - Very unhelpful
2 - Unhelpful
3 - Neither helpful nor unhelpful
4 - Helpful
5 - Very helpful

3. Do you anticipate the amount of time you will spend reading and watching video(s) in this study will be acceptable?

1 - Very unacceptable
2 - Unacceptable
3 - Neither acceptable nor unacceptable
4 - Acceptable
5 - Very acceptable

Acceptabilité prospective (Tariman et al., 2011)

1. À quel point pensez-vous que les informations et le soutien sur la chimiothérapie orale offerts dans cette étude seront utiles pour vous aider à gérer votre traitement ?
   1- Très inutile
   2- Inutile
   3- Ni utile ni inutile
   4- Utile
   5- Très utile

2. À quel point pensez-vous que les informations et le soutien offerts dans cette étude seront utiles pour vous aider à vous rappeler de prendre vos médicaments ?
   1- Très inutile
   2- Inutile
   3- Ni utile ni inutile
   4- Utile
   5- Très utile

3. Pensez-vous que le temps que vous passerez à lire et à regarder des vidéos dans cette étude sera acceptable ?
   1- Très inacceptable
   2- Inacceptable
   3- Ni acceptable ni inacceptable
   4- Acceptable
   5- Très acceptable

Appendix H

Baseline socio-demographic and medical questionnaire

1. To which gender do you most identify?

	Female	
	Male	
	Trans woman	
	Trans man	
	Non-binary/genderqueer/gender nonconforming	
	Other identity. Please specify:	

2. What sex were you assigned at birth, meaning on your original birth certificate?

	Female
	Male
	Other sex. Please specify:

3. What is your age?

4. What is your current marital status? (please check one only)

	Single (never legally married)
	Married /common law (two people living together but not legally married to each other)
	Separated / divorced
	Widowed

5. Among the people you know, can you discuss problems with some of them?

	No
	Yes.
	If yes, with how many individuals can you discuss problems?

6. Which of the following describes your current work status? (please check all that apply)

	Full time in the paid work force (30 hours or more per week)
	Part time in the paid work force (less than 30 hours per week)
	Self-employed
	Unemployed
	Disability / Sick leave
	Homemaker
	Student
	Retired

	Other. Please specify:

7. Do you have children?

☐ Yes
☐ No

If yes, how many children do you have?
If yes, how many dependent children or under the age of 18 do you have living with you?

8. In which country where you born?

	Canada	
	Other. Please specify:	

9. With which of the following group(s) do you identify? (select all that apply)

	Aboriginal (Inuit, Métis, Indigenous American)	
	North African (e.g. Algerian, Egyptian, Libyan, Moroccan, Tunisian)	
	Central/West African (e.g. Chadian, Congolese, Nigerian)	
	South/East African (e.g. Ethiopian, Mauritian, South African)	
	Middle Eastern (e.g., Armenian, Emirati, Iranian, Lebanese)	
	Caribbean	
	Chinese	
	Filipino	
	Japanese	
	Korean	
	Latin American	
	South Asian	
	South East Asian	
	White (Caucasian)	
	Other. Please specify:	

10. What language do you speak most often at home?

	English	
	French	
	Other. Please specify:	

11. What is the highest level of education you have completed? (check one only)

	Elementary School
	High School
	Technical or vocational or pre-university degree
	University (undergraduate: bachelor)
	University (graduate: masters, doctorate or post-doctorate)

12. *Income is known to be related to health. For this reason,* can you provide your best estimate of your family's total income last year from all sources before taxes?

	Less than $20,000
	$20,000 - $39,999
	$ 40,000 - $ 59,999
	$ 60,000 - $79,999
	$ 80,000 or more
	Don't know / Prefer not to answer

Medical Information

1. You are diagnosed with (select all that apply):
   Note: If you have more than one cancer, select the cancer being treated with oral chemotherapy.

	Bladder Cancer
	Brain/CNS Tumours
	Breast Cancer
	Cervical Cancer
	Colon/Rectum Cancer
	Esophagus Cancer
	Kidney Cancer
	Laryngeal and Hypopharyngeal Cancer
	Leukemia
	Liver Cancer
	Lung Cancer
	Multiple Myeloma
	Non-Hodgkin Lymphoma
	Oral Cavity and Oropharyngeal Cancer
	Ovarian Cancer
	Pancreatic Cancer
	Prostate Cancer
	Stomach Cancer
	Testicular Cancer
	Thyroid Cancer
	Uterine Sarcoma
	Other. Please specify:

2. When were you diagnosed with cancer? *Note: If you have more than one cancer, select the date of diagnosis for the cancer being treated with oral chemotherapy.*

3. Do you know the stage of your cancer?

	No	
	Yes. If yes, please indicate the stage:	0 I II III IV

4. Have you previously received other treatment for your cancer? (check all that apply)
Note: If you have more than one cancer, select any previous treatment(s) for the cancer being treated with oral chemotherapy.

	No
	Yes. If yes, please indicate, check all that apply:
	Surgery
	Radiotherapy
	Oral Chemotherapy (taken by your mouth)
	IV Chemotherapy (injected in a vein)
	Immunotherapy
	Targeted Therapy

4. Besides oral chemotherapy, are you taking any other medications on a regular basis?

	No
	Yes. If yes, please name:

Questions sociodémographiques et médicales

1. À quel genre vous identifiez-vous le plus?

	Femme
	Homme
	Femme trans
	Homme trans
	Non binaire/genderqueer/genre non conforme
	Autre. Précisez, svp:

2. Indiquez votre sexe à la naissance (ce qui est indiqué sur votre certificat de naissance) :

	Femme
	Homme
	Autre. Précisez, svp:

3. Quel est votre âge ?

4. Quel est votre état civil actuel? (S.V.P cochez une seule case)

	Célibataire (jamais marié(e))
	Marié(e) / conjoints de fait (deux personnes vivant ensemble mais non mariés l'un l'autre)
	Séparé(e) / divorcé(e)
	Veuf ou veuve

5. Parmi les personnes que vous connaissez, pouvez-vous discuter de vos préoccupations ou de vos problèmes avec certains d'entre elles ?

	Non
	Oui.
	Si oui, avec combien de personnes pouvez-vous discuter de vos problèmes ?

6. Lequel des énoncés suivants décrit le mieux votre statut de travail actuel ? (Veuillez sélectionnez toutes les réponses qui s'appliquent)

	À temps plein (travail rémunéré de 30 heures ou plus par semaine)
	À temps partiel (travail rémunéré, moins de 30 heures par semaine)
	Travailleur/Travailleuse autonome
	Sans emploi
	En congé maladie/ handicap
	Travail au foyer

	Étudiant
	À la retraite
	Autre. Précisez, svp:

7. Avez-vous des enfants ?
   - ☐ Yes
   - ☐ No

Si oui, combien d'enfants avez-vous ?
Si oui, combien d'enfants à charge ou moins de 18 ans vivent avec vous ?

8. Dans quel pays êtes-vous né(e) ?

	Canada	
	Autre. Précisez, svp:	

9. Veuillez indiquer à quel groupe(s) vous vous identifiez le plus (Veuillez sélectionnez toutes les réponses qui s'appliquent)

	Autochtone (Inuit, Métis, indigène d'Amérique du Nord etc.)	
	Nord-africain (algérien, égyptien, libyen, marocain, tunisien)	
	Afrique centrale/occidentale (tchadien, congolais, nigérian)	
	Afrique du Sud/Est (éthiopien, mauricien, sud-africain)	
	Moyen-Orient (arménien, émirati, iranien, libanais)	
	Antillais (Caraïbes)	
	Chinois	
	Flipino	
	Japonais	
	Coréen	
	Latino-Américain	
	Sud-Asiatique	
	Sud-Est-Asiatique	
	Blanc (caucasien)	
	Autre groupe. Précisez, svp:	

10. Quelle langue parlez-vous le plus souvent à la maison?

	Anglais	
	Français	
	Autre. Précisez, svp :	

11. Quel est votre plus haut niveau de scolarité complété ? (Cochez une seule case)

	École primaire
	École secondaire

	École technique, professionnelle ou pré-universitaire
	Université (premier cycle : baccalauréat)
	Université (études supérieures : maîtrise, doctorat ou post-doctorat)

12. *Il est reconnu qu'un lien existe entre la situation économique familiale et la santé. Pour cette raison,* pourriez-vous fournir votre meilleure estimation du revenu total de votre familial l'année dernière (toutes sources et avant impôts) ?

	Moins de 20,000$
	$20,000 - $39,999
	$ 40,000 - $ 59,999
	$ 60,000 - $79,999
	$ 80,000 ou plus
	Je ne sais pas / Je préfère ne pas répondre

Information Médical

1. Vous êtes diagnostiqué avec quel type de cancer ?
Si vous avez plus d'un cancer, sélectionnez le cancer traité par chimiothérapie orale.

	Cancer de la vessie
	Tumeur au cerveau ou SNC
	Cancer du sein
	Cancer du col de l'utérus
	Cancer du côlon et du rectum
	Cancer de l'œsophage
	Cancer du rein
	Cancer du larynx et des glandes hyopharyngiennes
	Leucémie
	Cancer du foie
	Cancer du poumon
	Lymphome non-Hodgkinien
	Cancer dans la cavité buccale et oropharyngien
	Cancer de l'ovaire
	Cancer du pancréas
	Cancer de la prostate
	Cancer de l'estomac
	Cancer des testicules
	Cancer de la thyroïde
	Sarcome utérin
	Autre. Précisez :

2. Quand avez-vous été diagnostiqué ? *Si vous avez plus d'un cancer, sélectionnez la date du diagnostic du cancer traité par chimiothérapie orale*

3. Connaissez-vous le stade de votre cancer ?

	Non	
	Oui. Si oui, veuillez indiquer le stade :	0 I II III IV

4. Avez-vous antérieurement reçu d'autres traitements pour votre cancer ? (Veuillez sélectionnez toutes les réponses qui s'appliquent) *Si vous avez plus d'un cancer, sélectionnez le(s) traitement(s) antérieur(s) pour le cancer traité par chimiothérapie orale.*

	Non
	Oui. Si oui, sélectionnez toutes les cases qui s'appliquent
	Chirurgie
	Radiothérapie
	Chimiothérapie orale (pris par ta bouche)
	Chimiothérapie intraveineuse (par injection à l'aide d'une seringue)
	Immunothérapie
	Thérapie ciblée

5. En plus de la chimiothérapie orale, prenez-vous régulièrement d'autres médicaments?

	Non
	Oui, s.v.p. indiquez le/les nom(s) :

Appendix I

Cancer Information-Seeking Preferences (Loiselle, 2019; 2023)

Which of the following statements best describes how you go about getting information about your cancer (choose only the statement that describes you best):

	I seek as much information as possible about my cancer.
	I seek information about my cancer that adds to what I was told.
	I seek cancer information from others diagnosed with the same cancer.
	I do not seek information about my cancer.
	Cancer is stressful enough; I only seek information about my cancer that is hopeful.

Préférences pour l'information reliée au cancer (Loiselle, 2019; 2023)

Lequel des énoncés suivants décrit le mieux vos démarches afin d'obtenir de l'information concernant votre cancer (cocher seulement l'énoncé qui vous décrit le mieux) :

	Je cherche le plus d'information possible sur mon cancer.
	Je cherche de l'information sur mon cancer qui ajoute à ce qui m'a été communiqué
	Je cherche de l'information sur le cancer qui provient des personnes diagnostiquées avec le même cancer que moi.
	Je ne cherche pas d'information sur mon cancer.
	Être atteint d'un cancer est suffisamment pénible; Je cherche seulement de l'information sur mon cancer qui est encourageante

Appendix J

Oral Anticancer Agent Knowledge Questionnaire (Ahmed & Loiselle, 2019)
Please choose whether you think the statements below are true or false. If you do not know the answer, please choose "I don't know."

1. It is fine for me to take my oral chemo at any time of the day.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: You should take your oral chemo at the same time every day; it will help them be as effective as possible. Please ask your doctor or pharmacist when the best time is to take your oral chemo.

2. If I forget to take my oral chemo, I should not double the next dose.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: True: If you miss a dose, do not double your dose or take an extra dose the following day. Instead, call your pharmacist, nurse, or doctor.

3. Oral chemo can be left on the windowsill.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: Oral chemo should stay in their original container, in a sealed plastic, and away from sunlight.

4. Exercising while on oral chemo causes more fatigue.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: Exercise during chemo can help give you energy leading to improved mood and overall health. Be sure to talk with your doctor before starting a new exercise program.

5. Drinking lots of water while on oral chemo makes mouth sores worse.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: Keeping your lips and mouth moist can help with mouth sores. This includes drinking plenty of water and applying lip balm.

7. If my treatment plan involves stopping oral chemo, I should flush my pills down the toilet or throw them in the garbage.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: If your treatment plan changes and you are no longer taking oral chemo, ask your pharmacist for the best way to safely dispose of any unused pills. Do not flush your pills down the toilet or throw them in the garbage.

7. If I have a fever over 38º Celsius (or 100.4º Fahrenheit), I should not worry about it.
   - ☐ True
   - ☐ False
   - ☐ I don't know

Pop-up answer: False: A fever of over 38º Celsius could be a sign of infection. You should immediately contact your healthcare team or go to the emergency room.

Questions sur les connaissances liées aux agents anticancéreux oraux (AAO) (Ahmed & Loiselle, 2019)

S. V. P. choisissez si les affirmations suivantes sont vraies ou fausses. Si vous ne le savez pas, S. V. P., choisissez “Je ne sais pas.”

1. Je peux prendre ma chimiothérapie orale à tout moment de la journée.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : Vous devriez prendre votre chimiothérapie orale à la même heure tous les jours, cela les aidera à être le plus efficace possible. Demandez à votre médecin ou à votre pharmacien quel est le meilleur moment pour prendre votre chimiothérapie orale.

2. Si j'oublie de prendre mes médicaments de chimiothérapie orale, je ne devrais pas doubler la dose suivante.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Vrai : Si vous oubliez une dose, ne doublez pas votre prochaine dose et ne prenez pas de dose supplémentaire le lendemain. Appelez plutôt votre pharmacien, votre infirmier (ère) ou votre médecin.

3. Les pilules de chimio orale peuvent rester sur le rebord de la fenêtre.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : Les pilules de chimiothérapie doivent rester dans leur contenant original, dans un sac en plastique scellé, loin du soleil.

4. Faire de l’exercice pendant que je suis aussi en traitement de chimiothérapie orale cause plus de fatigue.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : L'exercice pendant la chimiothérapie peut vous aider à améliorer votre humeur et votre santé en général. Assurez-vous de parler à votre médecin avant de commencer un nouveau programme d'exercice.

5. Boire beaucoup d'eau pendant la chimiothérapie orale aggrave les lésions dans la bouche.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : Garder vos lèvres et votre bouche humides peut aider à soulager les lésions dans la bouche. Cela inclut boire beaucoup d'eau et mettre du baume à lèvres.

6. Si mon plan de traitement implique l'arrêt de la chimiothérapie orale, je devrais jeter les pilules de chimiothérapie inutilisées à la toilette.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : Si votre plan de traitement change et que vous ne prenez plus de chimiothérapie orale, demandez à votre pharmacien quel est le meilleur moyen d'éliminer en toute sécurité les pilules non utilisées. Ne jetez pas vos comprimés dans les toilettes et ne les jetez pas à la poubelle.

7. Si j'ai de la fièvre plus de 38 ° Celsius (ou 100,4 ° Fahrenheit), je ne devrais pas m'inquiéter.
   - ☐ Vrai
   - ☐ Faux
   - ☐ Je ne sais pas

Pop-up: Faux : Une fièvre de plus de 38 ° Celsius (ou 100,4 ° Fahrenheit) pourrait être un signe d'infection. Contacter immédiatement votre équipe soignante ou vous rendre à l’urgence.

Appendix K

Medication Adherence Self-Efficacy Scale (MASES) (Ogedge et al., 2003)

How confident are you in taking your oral chemotherapy drugs:

	Extremely sure (3)	Somewhat (2)	Not sure (1)
1. When you are busy at home			
2. When there is no one to remind you			
3. When they cause some side effects			
4. When they cost a lot of money			
5. When you are with family members			
6. When you afraid they may affect your sexual performance			
7. When the time to take them is between your meals			
8. When you feel you do not need them			
9. When you are traveling			
10. When you take them more than once a day			
11. If they sometimes make you tired			
12. If they sometimes make you get nauseated and vomit			
13. When you have other medications to take			
14. When you feel well			
15. Get refills for your medications before you run out			
16. Fill your prescriptions whatever they cost			
17. Make taking your medications part of your routine			
18. Always remember to take your cancer therapy medications			
19. Take your cancer therapy medications for the specified time			

Échelle d'auto-efficacité de l'adhésion aux médicaments (MASES) (Ogedge et al., 2003)

Dans quelle mesure êtes-vous confiant dans la prise de vos médicaments de chimiothérapie par voie orale :

	Extrêmement sûr (3)	Un peu (2)	Pas sûr (1)
1. Quand vous êtes occupé à la maison			
2. Lorsque vous êtes au travail/lorsque vous êtes occupé avec votre routine quotidienne			
3. Quand il n'y a personne pour vous le rappeler			
4. Quand les médicaments provoquent des effets secondaires			
5. Quand les médicaments coûtent cher			
6. Lorsque vous êtes avec des membres de votre famille			
7. Quand vous craignez que les médicaments affectent vos performances sexuelles			
8. Quand le temps de prendre vos médicaments est entre vos repas			
9. Quand vous sentez que vous n'en avez pas besoin			
10. Lorsque vous voyagez			
11. Lorsque vous les prenez plus d'une fois par jour			
12. Si les médicaments vous fatiguent parfois			
13. Si les médicaments vous donnent parfois la nausée et vous font vomir			
14. Lorsque vous avez d'autres médicaments à prendre			
15. Quand vous vous sentez bien			
16. Faites renouveler vos médicaments avant d'en manquer			
17. Faites remplir vos ordonnances quel qu'en soit le prix			
18. Intégrez la prise de vos médicaments à votre routine			
19. Rappelez-vous toujours de prendre vos médicaments pour le traitement du cancer			
20. Prenez vos médicaments pour le traitement du cancer pendant la durée spécifiée			

Appendix L

Medication Adherence Rating Scale (MARS-5) (Professor Rob Horne; Chan et al., 2020)

	Always (5)	Often (4)	Sometimes (3)	Rarely (2)	Never (1)
I forget to take it					
I alter the dose					
I stop taking it for a while					
I decide to miss out a dose					
I take less than instructed					

Medication Adherence Rating Scale (MARS-5) (Professor Rob Horne; Chan et al., 2020)

Lorsqu'il s'agit de prendre vos médicaments de chimiothérapie par voie orale au cours des deux dernières semaines

	Toujours (5)	Souvent (4)	Parfois (3)	Rarement (2)	Jamais (1)
J’ai oublié de les prendre					
J’ai modifié la dose					
J’ai arrêté de les prendre pendant un moment (autre qu'à la fin du cycle/entre les cycles selon les instructions du médecin ou du pharmacien)					
J’ai décidé de manquer une dose					
J’ai pris moins que demandé					

Appendix M

Edmonton Symptom Assessment System Revised (ESAS-r) (Watanabe et al., 2011)
Please indicate the number that best describes how you feel now:

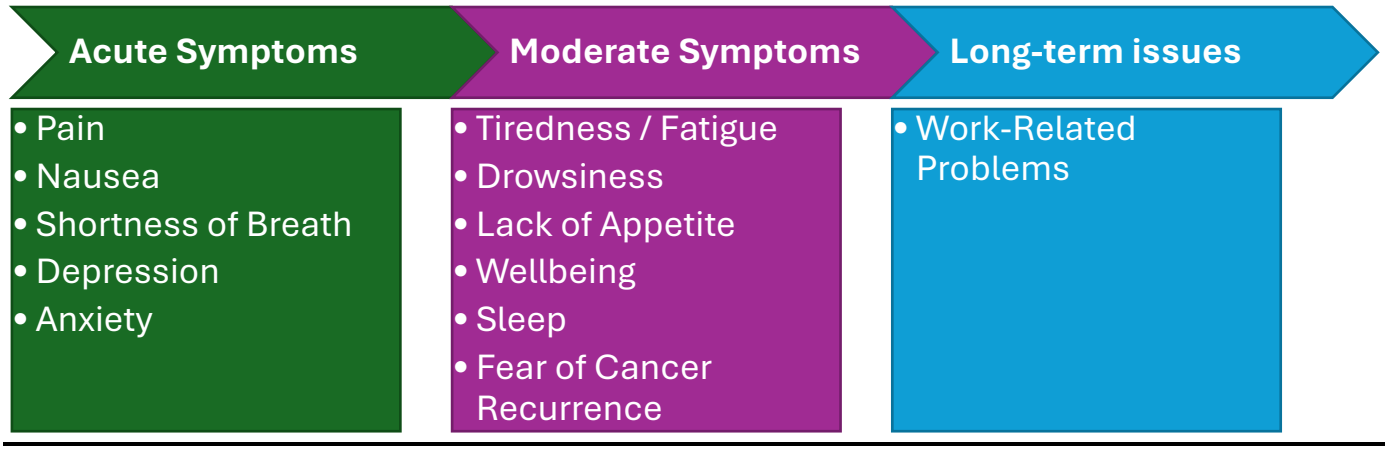
No Pain	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Pain
No Tiredness (Fatigue)	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Tiredness (Fatigue)
No Drowsiness	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Drowsiness
No Nausea	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Nausea
No Lack of Appetite	0 1 2 3 4 5 6 7 8 9 10	Worst Lack of Appetite
No Shortness of Breath	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Shortness of Breath
No Depression	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Depression
No Anxiety	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Anxiety
Best Wellbeing	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Wellbeing
Best Sleep	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Sleep
No Fear Cancer Will Come Back in the Future	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Fear Come Back in the Future
No Work-Related Problems	0 1 2 3 4 5 6 7 8 9 10	Worst Possible Work-Related Problems

Échelle d'évaluation des symptômes d'Edmonton – Révisé (ESAS-r) (Watanabe et al., 2011)
Choisissez le chiffre qui correspond le mieux à ce que vous ressentez présentement

Aucune douleur	0 1 2 3 4 5 6 7 8 9 10	La pire douleur possible
Aucune fatigue	0 1 2 3 4 5 6 7 8 9 10	La pire fatigue possible
Aucune somnolence	0 1 2 3 4 5 6 7 8 9 10	La pire somnolence possible
Aucune nausée	0 1 2 3 4 5 6 7 8 9 10	La pire nausée possible
Aucun manque d'appétit	0 1 2 3 4 5 6 7 8 9 10	Le pire manque d'appétit possible
Aucune essoufflement	0 1 2 3 4 5 6 7 8 9 10	Le pire essoufflement possible
Aucune dépression	0 1 2 3 4 5 6 7 8 9 10	La pire dépression possible
Aucune anxiété	0 1 2 3 4 5 6 7 8 9 10	La pire anxiété possible
Meilleure sensation de bien-être	0 1 2 3 4 5 6 7 8 9 10	Aucune sensation de bien-être
Meilleur sommeil	0 1 2 3 4 5 6 7 8 9 10	Le pire sommeil possible
Aucune peur de récidive	0 1 2 3 4 5 6 7 8 9 10	La pire peur de récidive possible
Aucun(s) problème(s) lié(s) au travail	0 1 2 3 4 5 6 7 8 9 10	Le(s) pire problème(s) lié(s) au travail possible

Appendix N

Protocol for acute, moderate, and long-term symptoms.



Acute Symptoms

If participants report higher distress (7 or above on a 0 to 10-point scale) when completing the ESAS-r questionnaire for the following symptoms: pain, nausea, shortness of breath, depression, and/or anxiety; then they will receive the following instructions – simultaneously displayed on the screen while completing the questionnaire and sent as an email notification:

Our records indicate that you reported a score of 7 or higher for (pain/ nausea/ shortness of breath/ depression/ anxiety). If you are still experiencing this level of discomfort, you can call the Symptom Management Hotline at the Jewish General Hospital at (514) 340-8222 extension 25529, Monday to Friday anytime from 8am to 4pm. If you feel worse than what you reported on the questionnaire, you can go to the Emergency Room and tell the triage nurse that you have cancer, provide the name of your oncologist, and bring a list of your medication – including the type of oral chemotherapy you are receiving.

Nos dossiers indiquent que vous avez signalé un 7 ou plus pour (douleur/ nausée/ essouflement/ anxiété/ depression). Votre infirmière pivot en oncologie et votre oncologue seront informés et votre infirmière pivot en oncologie vous contactera dans les prochaines 48 heures (hors week-end et jours fériés). Si vous n'avez pas d'infirmière pivot assignée, un membre de l'équipe d'étude vous contactera dans les prochaines 48 heures (hors week-end et jours fériés) et vous dirigera vers la ligne info-onco. En attendant, si vous vous sentez moins bien, vous pouvez vous rendre à l'urgence. Dites à l'infirmière de triage que vous avez un diagnostic de cancer, le nom de votre oncologue et apporter une liste de vos médicaments, y compris le type de chimiothérapie orale que vous recevez.

An email notification will also be sent to a member of the study team (Saima Ahmed) at the time of questionnaire completion. 24-48 hours after reporting significant distress, this member of the

study team (Saima Ahmed) will follow-up by email with the participant. If the participant does not respond to this email within 24 hours, then they will contact the participant by phone to verify that the participant has contacted the Symptom Management Hotline at the Jewish General Hospital.

Moderate Symptoms

If participants report higher distress (7 or above on a 0 to 10-point scale) while completing the ESAS-r questionnaire for the following symptoms: tiredness/fatigue, drowsiness, lack of appetite, wellbeing, sleep, and/or fear of cancer recurrence: then they will receive the following instructions – simultaneously displayed on the screen while completing the questionnaire and sent as an email notification:

Our records indicate that you reported a score of 7 or higher for (fatigue/ drowsiness/ lack of appetite/ wellbeing/ sleep/ fear of cancer recurrence). If you are still experiencing this level of discomfort, you can call your oncologist or oncology nurse and let them know how you are feeling.

Nos dossiers indiquent que vous avez signalé un 7 ou plus pour (fatigue/ somnolence/ manque d'appétit/ bien-être/ sommeil/ peur de récidive). Si vous ressentez toujours ce niveau d'inconfort, vous pouvez contacter votre oncologue ou votre infirmière en oncologie pendant les heures de la clinique (lundi au vendredi, 8h à 17h) et leur faire savoir comment vous vous sentez.

Long-term Issues

If participants report a score above 5 (on a 0 to 10-point scale) while completing the ESAS-r questionnaire for work-related problems: then they will receive the following instructions – simultaneously displayed on screen while completing the questionnaire and sent as an email notification:

Our records indicate that you reported a score of 5 or higher for work-related problems. If you are still experiencing this issue, you can visit the following site to learn more about benefits and financial programs you may want to access, if you continue to work during your oral chemo treatment, returning to work afterwards, as well as information about changing jobs and looking for work: https://www.cancerandwork.ca/survivors/

Nos dossiers indiquent que vous avez signalé un 5 ou plus pour des problèmes liés au travail. Si vous rencontrez toujours ce problème, vous pouvez visiter le site suivant pour en savoir plus sur les avantages et les programmes financiers auxquels vous pourriez avoir accès, si vous continuez à travailler pendant votre traitement de chimiothérapie orale, si vous reprenez le travail par la suite, ainsi que des informations sur le changement emplois et recherche d'emploi : https://www.cancerandwork.ca/fr/survivants/

Appendix O

Questions at every follow-up

Over the past 1-2 weeks, have you sought or receive cancer information from: (Check all that apply)

	Websites
	Social Media
	Online videos (Youtube, etc.)
	Television
	Radio
	Books
	Brochures
	Newspapers or magazines
	Public lectures on cancer
	Scientific medical journals
	Other (please describe below):

Au cours de la/ des deux dernière(s) semaine(s), avez-vous recherché ou reçu des informations sur le cancer d'un des médiums suivants : (Cochez tout ce qui s'applique) :

	Sites internet
	Médias sociaux
	Vidéos en ligne (Youtube, etc.)
	Télévision
	Radio
	Livres
	Brochures
	Journaux ou magazines
	Conférences publiques sur le cancer
	Revues médicales scientifiques
	Autre (veuillez décrire ci-dessous):

Appendix P

Retrospective Acceptability E-Scale (Tariman et al., 2011)

1. How easy was the oral chemotherapy program for you to access and use?
   1 - Very difficult
   2 - Difficult
   3 - Neither easy nor difficult
   4 - Easy
   5 - Very easy

2. How understandable was the information in the e-handouts?
   1 - Very difficult to understand
   2 - Difficult to understand
   3 - Neither easy nor difficult to understand
   4 - Easy to understand
   5 - Very easy to understand

3. How understandable was the information in the videos?
   1 - Very difficult to understand
   2 - Difficult to understand
   3 - Neither easy nor difficult to understand
   4 - Easy to understand
   5 - Very easy to understand

4. How helpful was the oral chemotherapy program in managing your treatment?
   1 - Very unhelpful
   2 – Unhelpful
   3 - Neither helpful nor unhelpful
   4 – Helpful
   5 - Very helpful

5. How helpful was the oral chemotherapy program in reminding you to take your medication as recommended by your healthcare provider?
   1 - Very unhelpful
   2 – Unhelpful
   3 - Neither helpful nor unhelpful
   4 – Helpful
   5 - Very helpful

6. Was the amount of time you spent reading the information on the e-handouts acceptable?
   1 - Very unacceptable
   2 – Unacceptable
   3 - Neither acceptable nor unacceptable
   4 – Acceptable
   5 - Very acceptable

7. Was the amount of time you spent watching the video(s) acceptable?
   1 - Very unacceptable
   2 – Unacceptable
   3 - Neither acceptable nor unacceptable
   4 – Acceptable
   5 - Very acceptable

8. How would you rate your overall satisfaction with the oral chemotherapy program?
   1 - Very dissatisfied
   2 – Dissatisfied
   3 – Unsure
   4 – Satisfied
   5 - Very satisfied

Acceptabilité rétrospective (Tariman et al., 2011)

1. À quel point a-t-il été facile pour vous d'accéder et d'utiliser les informations et le soutien offert dans l'étude ?
   1- Très difficile
   2- Difficile
   3- Ni facile ni difficile
   4- Facile
   5- Très facile

2. À quel point les informations contenues dans les documents électroniques étaient-elles compréhensibles ?
   1- Très difficile à comprendre
   2- Difficile à comprendre
   3- Ni facile ni difficile à comprendre
   4- Facile à comprendre
   5- Très facile à comprendre

3. À quel point les informations contenues dans les vidéos étaient-elles compréhensibles ?
   1- Très difficile à comprendre
   2- Difficile à comprendre
   3- Ni facile ni difficile à comprendre
   4- Facile à comprendre
   5- Très facile à comprendre

4. À quel point les informations et le soutien offerts dans cette étude ont été utiles pour vous aider à gérer votre traitement ?
   1- Très inutile
   2- Inutile
   3- Ni utile ni inutile
   4- Utile
   5- Très utile

5. À quel point les informations et le soutien offerts dans cette étude ont été utiles pour vous aider à vous rappeler de prendre vos médicaments ?
   1- Très inutile
   2- Inutile
   3- Ni utile ni inutile
   4- Utile
   5- Très utile

6. Pensez-vous que le temps que vous avez passé à lire les informations inscrites sur les documents électroniques était acceptable ?

1- Très inacceptable
2- Inacceptable
3- Ni acceptable ni inacceptable
4- Acceptable
5- Très acceptable

7. Pensez-vous que le temps que vous avez passé à regarder les vidéos était-acceptable ?

1- Très inacceptable
2- Inacceptable
3- Ni acceptable ni inacceptable
4- Acceptable
5- Très acceptable

8. Comment évalueriez-vous votre satisfaction globale avec l'information et le soutien offert dans cette étude ?

1- Très insatisfait
2- Insatisfait
3- Incertain
4- Satisfait
5- Très satisfait

Appendix Q

Debriefing Form
Research Title: Feasibility, acceptability, and potential effects of a comprehensive oral anticancer agent intervention on medication adherence self-efficacy, medication adherence, and symptom distress: A pilot randomized control trial
Short Title: Oncology – Bolstering Oral Agent Reporting related to Distress (ON-BOARD Study)

The researcher in charge of the study: Dr. Carmen G. Loiselle
Co-Director (Academic) of the Segal Cancer Centre, Scientific Director of Hope & Cope at the Jewish General Hospital, and Professor at McGill University's Department of Oncology and Ingram School of Nursing

Thank you for your participation in the Oncology Bolstering Oral Agent Reporting of Distress (ON BOARD) study! The goal of the study was to test a remote way of helping individuals with cancer receiving oral chemotherapy treatment.

We wanted to test whether an information and support program made a difference in the cancer journey while on oral chemotherapy. Some of you participating in the study were chosen at random (flip of a coin) to be re-contacted and offered the program.

This means there were 2 groups, both groups were asked to complete online questionnaires for 5 months. Group 1 was offered additional support, while Group 2 continued to receive the usual care offered to all patients.

You were in Group 2**,** so you continued to receive your usual care. Your group is the standard to which Group 1 will be compared to determine whether the program offered made a difference in the cancer journey. The reason we did not let you know earlier is because just being aware of the additional support may have impacted your cancer journey and your answers to the online questionnaires during the study.

You will now be offered the information and support program. It will all be available in a mobile app called *BELONG – Beating Cancer Together* that you will download on your smartphone or tablet. Once you have set up the app, you can choose to receive as much or as little information or support as you wish. This means you can choose to receive all or none of the information and support offered.

1. Tip sheets on common oral chemotherapy related-topics: these handouts will provide knowledge, facts, tips, and additional online or telephone resources.
2. Oral chemotherapy informational videos: general information on oral chemotherapy, side effects, support, fertility & work, and symptoms.
3. Reminders: receive reminder notifications to take your OC medication.

You will be able to access it by downloading the application BELONG – Beating Cancer Together on your smartphone and/or tablet and entering the code *ONBOARD*.
Your questionnaire responses will be useful information to clinicians and researchers on how patients typically respond to oral chemotherapy treatment and standard supportive care. All study results will be presented as grouped data. This means that no one person's results will be shared.

Your participation is completely voluntary and if you wish for us to delete the questionnaire data that we collected while you were participating in the study, please inform us.

If you have any questions about the research study, you can contact the researcher in charge of the study, Dr. Carmen G. Loiselle, or the study coordinator, Saima Ahmed.

Carmen G. Loiselle, R.N., Ph.D.
E-mail: Loiselle-research@mcgill.ca
Phone: 514-398-8977.

Saima Ahmed
E-mail: saima.ahmed2@mail.mcgill.ca
Phone: 514-690-7860

For all questions concerning your rights during your participation in this study, or if you have any complaints or comments regarding your experience in taking part in this research study, you can contact the Local Commissioner of Complaints and Quality of Service of the CIUSSS Centre-Ouest-de-l-Île-de-Montréal or the ombudsman of the institution at (514) 340-8222, ex. 24222.

Would you like to speak to a member of the research team to know more about the study? If yes, we can give you a phone call.

- ☐ Yes
- ☐ No

Compte Rendu

Titre de la recherche: Faisabilité, acceptabilité et effets potentiels d'une intervention complète d' agent anticancéreux oral sur l'auto-efficacité de l'observance du traitement, l'observance du traitement et la détresse liée aux symptômes : un essai pilote randomisé de contrôle
Titre court : Oncologie – Basée sur Oral Agent Rapportant de la Détresse (ON-BOARD)

Chercheuse principale: Carmen G. Loiselle, Inf., Ph.D
Codirectrice (académique) du Centre du cancer Segal et professeure au département d'oncologie de l'Université McGill et à l'École des sciences infirmières Ingram

Merci de votre participation à l'étude Oncologie – Basée sur Oral Agent Rapportant de la Détresse (ON BOARD) ! L'objectif de l'étude était de tester un moyen à distance d'aider les personnes atteintes de cancer recevant un traitement de chimiothérapie orale.

Nous voulions tester si un programme d'information et de soutien faisait une différence dans le parcours du cancer pendant la chimiothérapie orale. Certains d'entre vous qui ont participé à l'étude ont été choisis au hasard (pile ou face) pour être recontactés et ont été offert le programme.

Cela signifie qu'il y avait 2 groupes. Les deux groupes ont été invités à remplir des questionnaires en ligne pendant 5 mois. Le groupe 1 s'est vu offert du soutien supplémentaire, tandis que le groupe 2 a continué à recevoir les soins habituels offerts à tous les patients.

Vous étiez dans le groupe 2. Vous avez donc continué à recevoir vos soins habituels. Votre groupe correspond à la norme à laquelle le groupe 1 sera comparé pour déterminer si le programme offert a engendré une différence dans le parcours du cancer. Nous ne vous avons pas informé plus tôt de ce fait, car si vous étiez conscient du soutien supplémentaire, votre parcours contre le cancer et vos réponses aux questionnaires en ligne auraient pu être affecté.

Le programme d'information et de soutien vous sera maintenant disponible. Le tout sera offert dans une application mobile appelée *BELONG – Beating Cancer Together* que vous téléchargerez sur votre téléphone intelligent ou votre tablette. Une fois que vous avez configuré l'application, vous pouvez choisir de recevoir le niveau d'informations ou de support que vous souhaitez. Cela signifie que vous pouvez choisir de recevoir toutes les options de support ou d'informations proposées, ou aucune.

1. Fiches de conseils sur des sujets courants liés à la chimiothérapie orale : ces documents fourniront des connaissances, des faits, des conseils et des ressources supplémentaires en ligne ou par téléphone.
2. Vidéos d'information sur la chimiothérapie orale : informations générales sur la chimiothérapie orale, les effets secondaires, le soutien, la fertilité et le travail, et les symptômes.
3. Rappels : recevez des notifications de rappel pour prendre vos médicaments de chimiotherapie orale OC.

Vous pourrez y accéder en téléchargeant l'application BELONG – Beating Cancer Together sur votre téléphone intelligent et/ou tablette et en saisissant le code *ONBOARD*.

Vos réponses aux questionnaires aideront les cliniciens et les chercheurs à mieux comprendre la façon dont les patients répondent généralement au traitement de chimiothérapie orale et aux soins de soutien standard. Tous les résultats de l'étude seront présentés sous forme de données regroupées. Cela signifie que les résultats d'une personne unique ne seront pas partagés.

Votre participation à l'étude est totalement volontaire. Si vous souhaitez que nous supprimions les données du questionnaire que nous avons collectées lors de votre participation à l'étude, laissez-nous le savoir.

Si vous avez des questions sur l'étude, vous pouvez contacter la chercheuse principale de l'étude, Dre Carmen G. Loiselle, ou la coordinatrice de l'étude, Saima Ahmed.

Carmen G. Loiselle, Inf., R.N., Ph.D.
Courriel : Loiselle-research@mcgill.ca
Téléphone: 514-398-8977

Saima Ahmed
Courriel : saima.ahmed2@mail.mcgill.ca
Téléphone: 514-398-8977

Pour toute question concernant vos droits lors de votre participation à cette étude, ou si vous avez des plaintes ou des commentaires à propos de votre expérience en tant que participant à cette étude, vous pouvez contacter le Commissaire local aux plaintes et à la qualité de service du CIUSSS Centre-Ouest- de l'Île-de-Montréal ou l'ombudsman de l'institution au (514) 340-8222, poste 24222.

Souhaitez-vous parler à un membre de l'équipe de recherche pour en savoir plus sur l'étude? Si oui, nous pouvons vous faire un appel téléphonique.

- ☐ Oui
- ☐ Non

Appendix R

Exit interview guide (Exp)

1. Overall, what are your general impressions of the oral chemotherapy information and support you received during the study – this includes the videos, e-handouts, and phone calls?

Dans l'ensemble, quelles sont vos impressions générales sur les informations et le soutien sur la chimiothérapie orale que vous avez reçus au cours de l'étude ? Cela inclut les vidéos, les documents électroniques et les appels téléphoniques ?

2. Tell me about the positives, what did you like about the information and support you received? Think back to specifics.

Parlez-moi des points positifs. Qu'avez-vous aimé des informations et du soutien que vous avez reçus? Repensez aux détails.

3. Tell me about the negatives, what did you not like?

Parlez-moi des points négatifs, qu'est-ce que vous n'avez pas aimé ?

4. In terms of the videos and e-handouts, what did you think of the information they provided? Was it useful or helpful to you? Do you think other individuals on oral chemotherapy (or even their families) would use them and/or find them helpful?

En ce qui concerne les vidéos et les documents électroniques, que pensez-vous des informations qu'ils ont fournies ? Cela vous a-t-il été utile? Pensez-vous que d'autres personnes qui prennent la chimiothérapie orale (ou même leurs familles) les utiliseraient et/ou les trouveraient utiles ?

5. Was the information provided easy for you to understand? Are there topics you would have liked to know more about? Are there other changes that you would like to see? In terms of content or even the look of the videos or e-handouts?

L'information fournie vous a-t-elle été facile à comprendre ? Y a-t-il des sujets sur lesquels vous auriez aimé en savoir plus ? Y a-t-il d'autres changements que vous aimeriez voir? En termes de contenu ou même d'apparence des vidéos ou des documents électroniques ?

6. Did you request a call from a nurse in oncology? If yes, were you satisfied with the help you received?

Avez-vous demandé un appel d'une infirmière en oncologie ? Si oui, avez-vous été satisfait de l'aide que vous avez reçue ?

7. In the long term, would you like to be able to request phone calls from a nurse in oncology when you need them? During later stages of your treatment? Do you think others on oral chemo would find these phone calls useful or helpful?
À long terme, aimeriez-vous pouvoir demander des appels téléphoniques à une infirmière en oncologie lorsque vous en avez besoin ? À des moments ultérieurs de votre traitement ? Pensez-vous que d'autres personnes qui prennent la chimiothérapie orale trouveraient ces appels téléphoniques utiles?

8. Between the different options available you (videos, e-handouts, and phone calls) is there one that stood out?

Parmi les différentes options qui s'offrent à vous (vidéos, documents électroniques et appels téléphoniques), en a-t-il une qui était plus essentiel?

9. What did you – yourself- get from the study? Did you feel more supported or better informed? Would you recommend the program (videos, e-handouts, and phone calls) to other individuals on oral chemo? Do you think it would positively or negatively affect their experience taking the medication?

Qu'avez-vous personnellement obtenu de votre participation à l'étude ? Est-ce que vous vous êtes senti plus soutenu ou mieux informé ? Recommanderiez-vous le programme (vidéos, documents électroniques et appels téléphoniques) à d'autres personnes prenant la chimio orale ? Pensez-vous que l'information et le soutien additionnel affecterait positivement ou négativement leur expérience de prise du médicament ?

9. Keeping in mind everything we discussed today, on a scale of 1-10, 1 being extremely poor and 10 being excellent, how would you rate the videos, e-handouts, phone calls individually and then everything as a whole?

En gardant à l'esprit tout ce dont nous avons discuté aujourd'hui, sur une échelle de 1 à 10, 1 étant extrêmement médiocre et 10 étant excellent, comment évalueriez-vous les vidéos, les documents électroniques, les appels téléphoniques – individuellement, puis le tout dans son ensemble ?

10. What would make it a 10 (if it is not)?
Qu'est-ce qui en ferait un 10 (si ce n'est pas le cas) ?

11. Is there anything else you would like to add to our discussion today?
Other suggestions? Questions?

Y a-t-il autre chose que vous aimeriez ajouter à notre discussion d'aujourd'hui ?
D'autres suggestions? Des questions?

Exit interview guide (control)

1. Overall, what are your general impressions of the information and support you received during your oral chemotherapy treatment?

Dans l'ensemble, quelles sont vos impressions générales sur les informations et le soutien sur la chimiothérapie orale que vous avez reçus au cours de votre traitement?

2. Tell me about the positives, what did you like about the information and support you received? Think back to specifics.

Parlez-moi des points positifs. Qu'avez-vous aimé des informations et du soutien que vous avez reçus? Repensez aux détails.

3. Tell me about the negatives, what did you not like?

Parlez-moi des points négatifs, qu'est-ce que vous n'avez pas aimé ?

4. What did you think of the information you received? Was it useful or helpful to you?

Que pensez-vous des informations qu'ils ont fournies ? Cela vous a-t-il été utile?

5. Are there topics you would have liked to know more about?

Y a-t-il des sujets sur lesquels vous auriez aimé en savoir plus ?

6. In the long term, what type of support would you like to receive for your treatment? During later stages of your treatment? What type of support do you think others on oral chemo would find useful or helpful?

À long terme, quel type de soutien souhaiteriez-vous recevoir pour votre traitement? À des moments ultérieurs de votre traitement ? Quel type de soutien pensez-vous que d'autres personnes qui prennent la chimiothérapie orale trouveraient utiles?

7. What do you think it would have helped positively affect your experience taking oral chemotherapy medication?

Pensez-vous qu'il aurait influencer positivement ou négativement votre expérience de prise du médicament ?

8. Keeping in mind everything we discussed today, on a scale of 1-10, 1 being extremely poor and 10 being excellent, how would you rate the level of support you received for your treatment?

En gardant à l'esprit tout ce dont nous avons discuté aujourd'hui, sur une échelle de 1 à 10, 1 étant extrêmement médiocre et 10 étant excellent, comment évalueriez-vous le soutien que vous avez reçus au cours de votre traitement?

10. What would make it a 10 (if it is not)?

Qu'est-ce qui en ferait un 10 (si ce n'est pas le cas) ?

11. Is there anything else you would like to add to our discussion today?
Other suggestions? Questions?

Y a-t-il autre chose que vous aimeriez ajouter à notre discussion d'aujourd'hui ? D'autres suggestions? Des questions?

Appendix S

List of hospital and community-based support resources

This information was provided to all participants at the end of every form, questionnaire, or interview.

Psychosocial Oncology Service	**Location**	**Telephone**
Jewish General Hospital (CIUSSS Centre-Ouest-de-L'Île) Segal Cancer Centre Psychosocial Oncology Service	3755 Chemin de la Côte-Sainte-Catherine, Montréal, QC H3T 1E2**,** Room E-768	(514) 340-8222 ext. 23223
Community		
Talk to an information specialist at the Canadian Cancer Society	1-888-939-3333	
Info-cancer hotline from the Quebec Cancer Foundation	1-800-363-0063	
Hope & Cope	514 340-3616 514 340-8255	

Programme d'oncologie psychosociale	**Adresse**	**Telephone**
l'Hôpital général juif (CIUSSS Centre-Ouest-de-L'Île) Centre de cancerologie segal Programme d'oncologie psychosociale	3755 Chemin de la Côte-Sainte-Catherine, Montréal, QC H3T 1E2**,** Chambre E-768	(514) 340-8222 ext. 23223
Communautaire		
Parlez à un spécialiste en information à la société canadienne du cancer	1-888-939-3333	
Ligne Info-cancer de la fondation québecoise du cancer	1-800-363-0063	
L'espoir c'est la vie	514 340-3616 514 340-8255	