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BETTER prevention and screening: Personalized clinical visits for adults

Submission date 31/08/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/12/2016	**Overall study status** Completed	
Last Edited 31/01/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Family doctors often lack the resources, tools, and time to address cancer and long-term (chronic) disease prevention and screening. Most guidelines and resources focus on specific diseases, organ systems and/ or lifestyle risks, however patients are usually at risk of developing multiple conditions. Patients often lack awareness of how lifestyle contributes to the development of cancers and chronic diseases. In addition, cancer survivors and patients living in poverty achieve fewer prevention and screening goals. In a previous study, a program (BETTER) which involved an approach that proactively targeted patients to attend individual chronic disease prevention and screening program through a visit with a Prevention Practitioner improved patient care by 37%. This study is looking at an adapted version of this program, which is tailored for general health patients and cancer survivors and takes poverty into consideration (BETTER WISE). The aim of this study is to investigate the effectiveness of the BETTER WISE program in terms of cancer surveillance and general prevention and screening outcomes.

Who can participate?

Men and women aged 40-65, including general health patients and cancer survivors (breast, colorectal, or prostate cancer), who attend participating health practices.

What does the study involve?

Family doctors are randomly allocated to one of two groups. For those in the first groups, patients are booked in for a 60 minute personalized prevention visit with the Prevention Practitioner (an allied health professional within the practice). Before the visit, participants complete the BETTER WISE health survey to capture their previous screening and prevention history. At the visit, the Prevention Practitioner educates the participant on their health status and how to improve their health. Through a process of shared decision making the Prevention Practitioner identifies the patient's health goals and tailors a prevention program to that patient. The patients then complete a follow up version of the BETTER WISE health survey and attend follow up visits with the Prevention Practitioner at 6, 12, 18 and 24 months after the initial visit. Those in the second group continue as normal but are asked to complete the surveys at the same times as those in the first group.

What are the possible benefits and risks of participating?
Patients can benefit through improving their health through improved cancer and chronic disease prevention and screening. Participating practices will develop skills and resources for cancer surveillance, and cancer and chronic disease prevention and screening. Benefits to physicians may include the ability to bill for prevention and screening activities in settings that allow billing for these activities. There are no known risks involved with participating.

Where is the study run from?
Eight primary care practices in Alberta, four in Ontario and four in Newfoundland and Labrador (Canada)

When is the study starting and how long is it expected to run for?
March 2016 to July 2022

Who is funding the study?
Alberta Innovates (Canada)

Who is the main contact?
1. Dr Donna Manca (scientific)
dpmanca@ualberta.ca
2. Ms Carolina Aguilar (public)
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Study website
http://www.better-program.ca/

Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201500833

Study information

Scientific Title
Building on Existing Tools To improvE cancer and chronic disease pRevention and screening in primary care for Wellness of cancer survIvorS and patiEnts: The BETTER WISE Project

Acronym
BETTER WISE

Study objectives
The aim of this study is to determine if patients aged 40-65, including general health patients and cancer survivors (breast, colorectal, and/or prostate), randomized to receive an individualized prevention visit with a Prevention Practitioner have improved cancer surveillance and general prevention and screening outcomes determined by a composite index as compared to standard care in a wait-list control group twelve months after the initial prevention visit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Alberta HREB, 09/11/2016, ref: Pro00067811

Study design
Pragmatic two-arm multi-centre cluster randomized controlled trial

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer and chronic disease

Interventions
Current interventions (as of 18/12/2017):
Participating primary care physicians will be randomized to have their patients in the intervention group or to a wait-list control group. The physician is defined as the “cluster” to minimize the risk of contamination in that all patients in that physician cluster will either receive the intervention or wait-list control, according to the arm to which their physician is randomly assigned.

Intervention group: Patients will be scheduled for a personalized prevention visit with the Prevention Practitioner. Before the visit, patients will be asked to complete the BETTER WISE health survey. The BETTER WISE health survey will capture the patients’ detailed prevention and screening history. The intervention, a 60-minute visit with the Prevention Practitioner, will take place at the physician’s office.
Before the initial prevention visit, the Prevention Practitioner will assess the patient’s medical history using the patient’s answers to the health survey as well as the patient’s medical chart (electronic or paper) to determine which prevention and screening actions the patient is eligible to receive and to prepare to discuss their risk for chronic diseases such as cancer, diabetes, and heart disease. During the prevention visit, the Prevention Practitioner and the patient will, through a process of shared decision-making and Brief Action Planning, develop a personalized Prevention Prescription for the patient.
All recommendations and discussions will be based on the evidence-based BETTER WISE prevention and screening actions developed by the Clinical Working Group in Phase 1 of the project. The Prevention Prescription will be written on a standardized BETTER WISE form and may include plans for screening (e.g., mammogram, blood tests) and referrals to programs (e.g., smoking cessation). A copy will be given to the patient and copies will be placed in the patient’s medical record and in the BETTER WISE patient source documentation. The patient will complete a follow-up version of the BETTER WISE health survey and Prevention Practitioner follow-up visits at 6, 12, 18 and 24 months after the initial visit. This will allow us to evaluate the impact of the intervention over a period of one year and to follow the intervention group to assess maintenance over a two-year period.

Control group: Patients will be asked to complete both the consent form and BETTER WISE health survey at baseline. Wait-list control patients will be asked to complete the BETTER WISE

health survey (follow-up version) at 12 months following baseline data collection. Additional screening and prevention data will also be obtained for wait-list control patients from the patient's medical chart (electronic or paper) at each data collection point (i.e., baseline and 12-months). A prevention appointment with the Prevention Practitioner will be made for these patients after the end of the intervention period of the study (i.e., once patients in the intervention arm complete their 12-month follow-up).

Previous Interventions:
Participating primary care physicians will be randomized to have their patients in the intervention group or to a wait-list control group. The physician is defined as the "cluster" to minimize the risk of contamination in that all patients in that physician cluster will either receive the intervention or wait-list control, according to the arm to which their physician is randomly assigned.

Intervention group: Patients will be scheduled for a personalized prevention visit with the Prevention Practitioner. Before the visit, patients will be asked to complete the BETTER WISE health survey. The BETTER WISE health survey will capture the patients' detailed prevention and screening history. The intervention, a 60-minute visit with the Prevention Practitioner, will take place at the physician's office.
Before the initial prevention visit, the Prevention Practitioner will assess the patient's medical history using the patient's answers to the health survey as well as the patient's medical chart (electronic or paper) to determine which prevention and screening actions the patient is eligible to receive and to prepare to discuss their risk for chronic diseases such as cancer, diabetes, and heart disease. During the prevention visit, the Prevention Practitioner and the patient will, through a process of shared decision-making and Brief Action Planning, develop a personalized Prevention Prescription for the patient.
All recommendations and discussions will be based on the evidence-based BETTER WISE prevention and screening actions developed by the Clinical Working Group in Phase 1 of the project. The Prevention Prescription will be written on a standardized BETTER WISE form and may include plans for screening (e.g., mammogram, blood tests) and referrals to programs (e.g., smoking cessation). A copy will be given to the patient and copies will be placed in the patient's medical record and in the BETTER WISE patient source documentation. The patient will complete a follow-up version of the BETTER WISE health survey and Prevention Practitioner follow-up visits at 6, 12, 18 and 24 months after the initial visit. This will allow us to evaluate the impact of the intervention over a period of one year and to follow the intervention group to assess maintenance over a two-year period.

Control group: Patients will be asked to complete both the consent form and BETTER WISE health survey at baseline. Wait-list control patients will be asked to complete the BETTER WISE health survey (follow-up version) at 6-month intervals over a period of 12 months following baseline data collection. Additional screening and prevention data will also be obtained for wait-list control patients from the patient's medical chart (electronic or paper) at each data collection point (i.e., baseline, 6, and 12-months). A prevention appointment with the Prevention Practitioner will be made for these patients after the end of the intervention period of the study (i.e., once patients in the intervention arm complete their 12-month follow-up).

Intervention Type
Other

Primary outcome measure

Proportion of cancer and chronic disease prevention and screening (CCDPS) actions for which the patient was eligible at baseline that are met (according to pre-defined targets) at 12-month follow-up.

Secondary outcome measures
1. Proportion of patients meeting the evidence-based targets will be measured by tracking specific cancer and chronic disease prevention and screening actions (e.g. mammograms completed, alcohol consumption reduced, screening for poverty) longitudinally at 6, 12, 18 and 24 months
2. Number of targeted cancer and chronic disease prevention and screening actions that patients randomized to the intervention group were deemed eligible to improve at baseline that are met (according to pre-defined targets) at 24-month follow-up

Overall study start date
31/03/2016

Completion date
28/07/2022

Eligibility

Key inclusion criteria
1. 40-65 years of age
2. Men and women
3. Able to give written informed consent
4. Cancer survivors who are low risk breast and/or colorectal and/or prostate cancer survivors
5. Patients without a personal history of breast, colorectal or prostate cancer
6. Patients on whom the researchers can obtain access to their medical records for the previous three years
7. Patients who are able to attend in-person preventions visits at their primary care site
8. Patients who are not receiving active treatment (i.e., systemic and/or radiation therapy) for cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

1,280

Total final enrolment
115

Key exclusion criteria
1. Unable to give written informed consent for reasons of language, literacy, or competence
2. Unable to access their medical history for the previous three years
3. Receiving active treatment for cancer (i.e., systemic and/or radiation therapy)

*Prophylactic or hormone treatments (e.g., aromatase inhibitors) are not exclusion criteria. Physicians may request that a particular patient not be invited and the rationale for exclusion will be captured (e.g. patient too frail)

Date of first enrolment
01/01/2018

Date of final enrolment
31/08/2019

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta
Department of Family Medicine Research Program
8303 - 112 Street NW
610 University Terrace
Edmonton
Canada
T6G 2T4

Study participating centre
Discipline of Family Medicine, Memorial University
Room 426
4th Floor Janeway Hostel
Health Sciences Centre
300 Prince Philip Drive
St. John's Newfoundland
Canada
A1B 3V6

Study participating centre

Department of Family and Community Medicine, University of Toronto
500 University Avenue
Toronto
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M5G 1V7

Sponsor information

Organisation
University of Alberta

Sponsor details
University of Alberta
Department Name
Building Room and Number
Attention: Contact Person
116 St. and 85 Ave.
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T6G 2R3

Sponsor type
University/education

Website
https://www.ualberta.ca/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Research organisation

Funder Name
Alberta Innovates

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the BETTER WISE study will not be made publicly available due to planned analyses and publications, but are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2018	12/03/2021	Yes	No
Interim results article	qualitative findings	23/01/2023	24/01/2023	Yes	No
Results article	results	30/06/2023	03/07/2023	Yes	No
Results article		28/09/2023	29/09/2023	Yes	No
Results article	Qualitative results	16/03/2023	31/01/2025	Yes	No
Results article	Qualitative results	19/07/2021	31/01/2025	Yes	No
Results article	Secondary analysis	15/04/2024	31/01/2025	Yes	No