# Protocol

## Title

SMARTscreen: A cluster randomised controlled trial of a narrative SMS sent to patients from their general practice to increase participation in the National Bowel Cancer Screening Program in Victoria.

## Project summary

The study will measure whether there is an increase in the uptake of the National Bowel Cancer Screening Program (NBCSP) test among 50 to 60-year-old patients who are sent an SMS bundle prior to receiving their NBCSP kit compared to a usual care. The SMS bundle will include; 1. a message from their general practice endorsing the free home test kit; 2. a link to a narrative video of someone describing their positive experience of testing; 3. a link to information about bowel cancer; and 4. an animation showing how to do the test. We will also determine the feasibility of sending the SMS bundle by evaluating how well the intervention is integrated into general practice. The intervention will be evidence-based and the final bundle with be co-designed by stakeholders. If effective, this will have an impact on increasing the early detection of colorectal cancer, which is a major health burden in Australia**.**

## Lay statement

The Australian government posts a free bowel cancer screening test to every person aged 50 years - 74 years. However, only 41% of people complete this test. We know that people are more likely to do the test if encouraged by their General Practitioner (GP). Similarly, if people can relate to stories about doing the test, they are more likely to. This research will test the use of a SMS sent from the patient’s general practice endorsing bowel cancer screening and includes links to simple instructions on how to do the test and a video of someone describing their positive experience of having the test. This SMS intervention is evidence-based and simple and if effective will have an impact on increasing the early detection of colorectal cancer, when it can be easily treated.

## Research question

Can the use of an SMS which includes a narrative story and instructions about how to do a home-based bowel cancer screening test, sent from general practice to patients between 50 and 60 years old just prior to them receiving a National Bowel Cancer Screening Program kit increase their participation in the program?

## Objectives

1. To **measure the effect of narrative videos** sent directly to people due for a screening test from their GP just prior to their 50th, 52nd, 54th, 56th, 58th, or 60th birthdays on participation in the National Bowel Cancer Screening Program.
2. 2. To conduct a **process evaluation** using an SMS delivered narrative from a general practice to evaluate how well the intervention is integrated with PenCS in the general practice software, recording if patients open SMS delivered information, as well as ensuring the fidelity of the intervention is maintained.

## Hypotheses

**Primary Hypothesis:** The use of a simple narrative message delivered as a SMS from a patient’s GP just before receiving the NBCSP will increase the proportion of patients aged 50 to 60 years who complete the test compared to patients who do not receive the message.

## Literature review

### Background

Australia and New Zealand have the highest colorectal cancer rates in the world (1) In 2019, an estimated 16,400 people were diagnosed with colorectal cancer and an estimated 5,600 people died from colorectal cancer, making it the second most common cause of cancer death after lung cancer (2). Colorectal cancer is largely preventable mainly because screening is a simple and effective way to detect colorectal cancer when in a pre-cancerous or early stage disease, so it can be treated prior to becoming an invasive malignancy (3). The Australian Government National Bowel Cancer Screening Program (NBSCP) sends a free screening test to every Australian every two years from the age of 50 years up to 74 years old (50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72 and 74) (4). The screening test – an immunochemical faecal occult blood test (iFOBT) – has a sensitivity of 53-100% and specificity of 93%, can be self-completed at home, and is safe (5). Despite this, screening with iFOBT is low with only 41% of people completing the NBCSP test (2). Furthermore, only 28% of 50-54 year olds and 36% of 55-59 year olds return the kit, compared with to 53% in the 70 to 74 year old age group, but it is known that 76% of those who participate in the NBCSP are more likely to do it again (6).

Screening at the current participation rate of 41% is estimated to reduce colorectal cancer incidence by 23% and mortality by 36%. Therefore, increasing the screening rate to 60% would decrease colorectal cancer incidence by 33% (37,300 cases) and mortality by 52% (24,800 deaths) (5). The NBCSP is also very cost effective due to the reduction in costly cancer treatments necessary for treating later stage disease and these cost benefits increase as the screening rate goes up. Changing participation in the NBCSP from 40% to 60% is estimated to reduce annual expenditure associated with colorectal cancer by 2030, by a cumulative AU$1.7 billion and AU$2.1 billion between 2030 and 2040 (5). Therefore, targeting people in the 50 to 60 years age group to increase testing uptake makes sense.

A television advertising campaign conducted by the Cancer Council of Victoria (CCV) demonstrated the effectiveness of using narrative communication to increase colorectal cancer screening. This resulted in an increased uptake of testing by 11% with the highest impact among people who had never been screened or were not up to date with screening (7). There is extensive evidence supporting the use of narrative or ‘storytelling’ communication to promote health behaviour change (8, 9), and the positive effect of GP endorsement (1); a practice recommended by the NBCSP to positively influence patient behaviour (4). Furthermore, the use of SMS to remind and/or prompt patients to do the test was found to be affective among patients aged 50 receiving the NBCSP kit for first time (10). This study brings together GP endorsement and positive narrative messaging to test the impact on the NBCSP uptake.

### Research plan

The SMARTscreen trial will measure whether there is an increase in the uptake of the NBCSP test among patients who are sent a SMS endorsing the free home test kit and links to a narrative video of someone describing their positive experience of testing along with information about bowel cancer and an animation video of how to do the test compared to a control group who receive usual care. This SMS intervention is general practice-based so we will also determine the feasibility of sending the SMS bundle by evaluating how well the intervention is integrated into general practice routine.

Our trial will be conducted in the Western Victorian Primary Health Network (WVPHN) region. The WVPHN region has a population of 618,000 people, of which 190,934 (30.4%) are between 50 and 74 years old, the age targeted by the NBCSP (11, 12). There are 962 GPs and 172 general practices in the catchment area which includes regional cities and regional areas (11). NBCSP participation rates in Victoria are similar to overall Australian rates (43% compared with 41%) (2) making Victoria a suitable pilot site for testing this intervention.

Our intervention will target people who are about to receive their NBCSP kit at 50, 52, 54, 56, 58 and 60 years of age as this is when participation is lowest and can have the greatest impact. Our evidence-based intervention is simple and utilises technology already used by general practice to communicate with patients. Patients are sent an automated SMS from their general practice encouraging them to complete the test kit, a video recording of a person telling their positive story of doing the test and an animated video on how to do the test. Using an SMS message is also likely to be more effective in the 50 - 60 year age group as most (82%) use smartphones regularly (13). Besides having a broad reach, an SMS is delivered in real time, accessed at a patient’s convenience on multiple occasions and is private and discreet (14). In one UK study, SMS also overcame the ability to connect with remote and socioeconomically disadvantaged and low health literacy groups who may otherwise not have reliable links to healthcare and was shown to improve medication adherence (15). It also makes sense to trial the intervention at a time when the impact will be greater, which will be when they are receiving the NBCSP kit for the first time at aged 50 years (10).

We have a unique opportunity to undertake this cluster RCT, the most powerful and efficient method to investigate the impact of our intervention on general practice patient behaviour. The results of this trial will inform the effectiveness, feasibility and acceptability of this intervention with a view to undertaking a larger RCT after 2022.

We have brought together a team with many years of experience in quality improvement (QI) initiatives, colorectal cancer prevention, the development of narrative communication tools for general practice and the implementation and management of general practice-based research. We have a strong reputation for conducting research in general practice with minimal disruption to the general practice routine which increases our likelihood of success. We have included two consumers as co investigators for the study who will be intrinsic to the development of the intervention, and we will be guided by their advice for reducing barriers to the process.

## Conceptual Framework

This is a phase 2 efficacy trial to provide preliminary data for a larger phase 3 effectiveness RCT. Our methods are informed by the UK Medical Research Council Framework for the Development and Evaluation of Complex Interventions guidelines to optimise the development of the intervention (16).

## Methods

### Design

A cluster randomised controlled trial to examine the effect of narrative communication and GP endorsement on increasing participation in the NBCSP compared to general practice patients who do not receive the communication and GP endorsement. General practices will be the unit of randomisation and outcome measured at the individual level. General practices operate with one collective computer operating system, so it is impractical to individually randomise.

#### Population and location

We will recruit 20 general practices (10 intervention / 10 control) from a range of regional cities and regional towns in the WVPHN region. From these intervention group general practices, we will send the SMS prompt to at least 70 patients eligible to receive the NBCSP kit and 70 patients eligible to receive the NBCSP kit and usual care in the control group general practices.

#### Recruitment strategy and eligibility criteria

General practices located in the WVPHN are eligible to participate if they have:

1. Compactible EMR software (Zedmed or Best Practice) with Pen CS CAT4 clinical audit tool,
2. Use the GoShare Plus SMS reminder tool,
3. Have at least two fulltime equivalent GPs,
4. Size of practice (based on a minimum of 70 active patients aged 50 to 60 years old)
5. Have a staff member (practice manager) available to send out the SMS messages.

We will recruit each general practice to this trial by direct approach made by the project manager. The trial will be explained, and all aspects of the research will be detailed using Electronic Meeting System (EMS) such as the zoom platform. GPs in a general practice must agree for their eligible patients to receive the SMS a month prior to their birthdays. Meetings with GPs and general practice staff either face to face or via zoom will be undertaken to demonstrate the SMS bundle, and detail the trial and gain a general practice consent. All participating general practices will be reimbursed $500 to participate regardless of whether they are randomised to the control or intervention arm/group. There will be rolling recruitment with general practices randomised after recruitment. The intervention for each practice will commence after randomisation.

### Randomisation, allocation, concealment and blinding

Once consented and baseline data collected, general practices will be randomly allocated with a 1:1 ratio to either the intervention or control arms. The statistician will computer-generate the allocation sequence, stratified by geographical remoteness using the Modified Monash Model (17) (metropolitan/regional centres vs Rural town/Remote communities) and practice size (that is, the number of active patients aged 50-60 years old), with random permuted block sizes within stratum.

Baseline data will be collected prior to randomisation ensuring allocation concealment. Although patient and general practitioners cannot be blinded to study arm allocation due to the nature of the intervention, outcome data will be extracted from the EMR using the Pen CS CAT4 clinical audit tool, providing an objective measure of the primary outcome. The data manager, statistician and investigators not involved in the delivery of the intervention will remain blinded to study arm status using a code for study arm status. The key to the code will be kept by the study co-ordinator, password protected and securely stored. The study arm status code will only be revealed after all the primary outcome data have been collected and the results presented to the investigators and the findings interpreted.

The project manager will be blinded to the allocation sequence but not to the intervention. General practices will be notified of their randomisation outcome by the project manager both in writing and by direct contact.

### Intervention group

The intervention period will be six months long. Therefore, there will be six rounds of SMS sent to patients aged 50 -60 years due to receive their NBCSP kit. The research team will work with the general practices in the intervention group to generate the lists of patients (identified by their birthdates and date of last FOBT result) using the Pen SC CAT4 software.

The intervention will be co-designed and include the following components: an SMS via the Healthily / GoShare Plus platform one month prior to their 50th, 52nd, 54th, 56th, 58th and 60th birthdays or one month before their NBCSP kit is due. The SMS will contain: 1) a personalised message from their general practice; 2) a link to a video of a person telling a story about their positive experience of doing the NBCSP test; 3) a link to an animation demonstrating how to complete the test and; 4) links to information about the NBCSP. The researcher will visit or be in direct contact with the general practices monthly to support the generation of the patient lists and sending the SMS.

#### The SMS (link to an example ONLY)

<https://protect-au.mimecast.com/s/o3CvCNLwzjF0ZQ47wimHKcp?domain=goshare.realtimehealth.com>

### Control group

Control general practice patients will not have any change in their ‘usual care’ from their GP.

## Outcomes to be measured

The primary outcome will be the proportion of patients who complete the NBCSP after six months from the participants’ 50th, 52nd, 54th, 56th, 58th and 60th birthdays.

## Baseline Variables

Baseline variables are the age in years, gender, general practice attended, general practice location and NBCSP participation by Local Government Area.

## Process evaluation

Process measures will include the successful integration and distribution of the Healthily/GoShare SMS in the intervention group, the participants’ use of the SMS including; 1) if the SMS is opened; 2) which content is viewed; 3) number of times the content is viewed, 4) time of the day the content is viewed, and 5) the number of SMS not successfully sent or where patients have opted out of receiving the SMS.

## Expected benefits

This study design will allow us to investigate the impact of the SMARTscreen intervention on the uptake of NBSCP test kits. We will also look at the cost of implementation and acceptability of the trial with a view to upscaling to a larger RCT. Increasing NPSCP testing rates nationally to 50% will prevent 24,000 bowel cancer cases 16,800 bowel cancer deaths (5).

## Duration

SMARTscreen will run for two years and be completed by 2022. The details are displayed in the timeline attached.

## Data collected

Both quantitative and qualitative data will be collected.

### Quantitative

1. Number of patients at each timepoint (50th, 52nd, 54th, 56th, 58th, 60th birthday) who are sent an SMS. Number of iFOBT results received by the general practice during the intervention period and up to six months after completion of the intervention. This data will be collected at the general practice level and through Pen SC CAT4 linked to the EMR.
2. Demographic data will be limited to date of birth, gender and general practice attended (postcode). CAT4 extracts deidentified data (not collecting names, addresses, dates of birth).
3. Number of times and which links within the SMS and the components of the bundle are opened. These data will be collected from Healthily through the Go/Share Plus application. The data will be collected as aggregated numbers. No identifying data will be collected.

### General practice specific data

Baseline data specific to the size and location of the general practice will be collected at recruitment, prior to randomisation.

### Qualitative

Field notes will be collected detailing implementation of the trial, technical issues and any problems in implementation encountered by practice staff. This will inform feasibility and scalability (Aim 2).

Interviews with practice champions and GPs to explore the acceptability and feasibility of sending an SMS from the general practice prior to eligible patient’s scheduled dates to receive a NBCSP kit. Participants will be reimbursed for their time ($50 -$100 gift voucher). GPs will be asked to invite patients who have received the SMS if they would be happy to participate in an interview (Consent forms and Plain Language Statement to follow in an Ethics amendment). The use of different sources of information (practice manager, GP, patient) is consistent with best practice qualitative research, ie. triangulation methods. (18). This strengthens the rigour, validity and comprehensiveness of the analysis. Our interviews will cover views on acceptability of receiving the SMS, views on disseminating preventive care information using SMS and nudging (19), plus the impact of the trial on the general practice routine and staff workload.

## Sample size

Sample size was based on the primary hypothesis. In total we require 1400 patients (70 per practice) from 20 general practices to provide 80% power with two-sided 5% significance level to detect a 10% increase in In total, we require 1400 eligible patients (70 per practice) from 20 general practices to provide 80% power with two-sided 5% significance level to detect a 10% increase in bowel screening uptake in the intervention arm compared to the control arm (50% vs 40%). The estimates are based on average general practice population size, assuming an intra-cluster correlation of 0.008 based on previous studies in general practice.We have not allowed for attrition as the primary outcome data will be collected from the EMR.

We anticipate no loss to follow-up given the design of the trial and the minimal requirement of general practice staff input.

## Statistical analysis

Descriptive statistics will be used to compare the baseline characteristics of general practices, clinicians and patients between the two study arms. Intention-to-treat analysis will be used, where all patients enrolled in the study and randomly allocated to the study arms will be included and analysed in the arm they were assigned too. Logistic regression using generalised estimating equations with robust standard errors to allow for clustering by practice and adjusted for stratification factors (geographical remoteness and practice size) will be used to test for differences in the proportion of patients who complete iFOBT after six months between the intervention and control arm. Estimates of the intervention effect will be reported as an odds ratio with respective 95% confidence interval and p-value. The intra-practice correlation, which quantifies the proportion of the total variation in the outcome attributable to between-cluster variation in the outcome, will also be estimated and reported with 95% confidence intervals. It will be used to inform the sample size of large multisite, cluster randomised controlled trial to test the cost-effectiveness of the intervention.

Similar regression analysis appropriate for the data type will be performed for secondary outcomes (e.g. linear regression for continuous outcomes and logistic regression for binary outcomes).The full statistical plan will be developed describing the analysis of secondary outcomes, sensitivity analysis, including the handling of missing data.

### Process evaluation

We will calculate and describe the number of times content items in the SMS bundle are viewed. Extensive field notes will be used to describe additional information that might add to the feasibility of conducting the study including technical issues and problems encountered by the general practice staff. Capacity to carry out the research or potential barriers to implementing the research. One potential barrier includes unanticipated technological problems. The risk is low as the technology is well established and Healthily/GoShare is currently being used in up to 80 general practices in the WVPHN region. The WVPHN already use PenCS software to collect de-identified clinical data as part of their ongoing engagement with local general practices. We have minimised the risk by involving a highly skilled team and included some funding in the budget to ensure we have technical support throughout the study team have at least 15 years’ experience in conducting research with novel interventions in general practice to improve health outcomes and have demonstrated high recruitment and retention (>65% and >78% respectively).

### Cost-consequence analysis

A simple cost consequence analysis comparing the cost of implementing our intervention and consequences in scenarios for continuation and scalability. Cost (including researcher time, travel and payment to general practice for staff input) will be compared with the consequence (the number of patients returning the completed kit following receiving the SMS).

## Discussion

## Translation, innovation and communication

This trial involves the direct translation of evidence into clinical practice in Victoria by using already established communication and data collection applications linked to the general practice EMR to reach patients who are due to receive a NBSCP kit. This is a simple innovative method of utilising established systems to improve patient health outcomes.

The evidence says a NBSCP iFOBT kit sent to people increases early detection and treatment of colorectal cancer (5, 20). The NBCSP is cost effective and increased participation reduces the morbidity from colorectal cancer (5). We have evidence that patient narrative messages are supportive of behaviour change (8, 21) and a message from the GP will increase the likelihood that a patient will complete the colorectal cancer screening test (21).

#### Short term translation and communication

Our trial will disseminate the evidence by bringing together a GP’s endorsement written in plain language and simple, easy to follow narrative messages sent directly to patients’ due to receive the NBCSP test kit to bridge the translational gap between receiving the test kit by post and completing it, and returning the test (5). We will communicate with participating GPs and general practice staff by conducting meetings in the general practice, by zoom and by email and telephone. Training a general practice champion will also be undertaken as part of the implementation of the intervention. A waiting room poster will inform patients the research is being conducted and that should they want to, they can opt out.

#### Medium term translation and communication

If our trial is demonstrated to be effective, we will test our intervention on a larger scale to maximise the translational impact across a broader diverse population. We will use implementation science methodology (22) to explore barriers and enablers for increasing the effective components of the intervention in general practice. The larger trial will incorporate a cost effectiveness analysis and methods for upscaling the intervention and sustainability of the intervention over time.

Results of our trial will be communicated through existing academic and public networks; University of Melbourne *Pursuit*, *The Conversation*, the *ABC radio Health Report*, and other media outlets. We will disseminate results through twitter, and podcasts including the Primary Care Collaborative Cancer Clinical Trials Group (PC4) and PC4 consumer advisory group (CAG). We will present the trial and results at academic conferences (National and International) and publish in academic peer reviewed journals.

## Potential limitations and solutions

The benefits of implementing SMARTscreen outweigh the risks. There is minimal risk to patients who receive the SMS. Those who receive the SMS are eligible to receive a NBSCP within a month. Throughout the COVID19 pandemic, implementation of the NBCSP has continued in Australia and doesn’t require people to leave their homes to complete the test and do not need to visit their general practice, making SMARTscreen an optimum trial design for this period of self-isolation. Patients can call their general practice if they have any questions about the trial.

One risk with implementing SMARTscreen during a pandemic is the limitations of face to face engagement between the researcher and the general practice staff. We believe this can be overcome using technology such as electronic messaging services (EMS), telephone communication and email. We have the capacity to develop videos and presentations to be delivered in an online capacity. Support with training and data collection can also be done via webinar and EMS.

## Financial and legal agreements involving investigators and participants

There are no financial or legal conflicts of interest

## Ethics approval

## This trial has received Ethics approval from the University of Melbourne General Practice Human Research Ethics Advisory Group on the 29th June 2020. Approval ID: 2057042.1

## Timeline

SMARTscreen commenced in April 2020 and will be completed by March 2022.

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