Participant Information Sheet/Consent Form
Interventional Study - Adult providing own consent

Title
A multicentre, colonoscopist-blinded, randomised controlled trial to determine the efficacy of dynamic multimedia bowel preparation instructions versus standard instructions as control on adenoma detection and patient reported measures in adults aged 45 years and older indicated for a colonoscopy.

Short Title
Digitising colonoscopy care pathways and enhancing bowel preparation quality with patient reported measures (DIGICLEAN).

Coordinating Principal Investigator/Site Principal Investigator
Dr Viraj Kariyawasam

Location

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are scheduled for a colonoscopy. The research project is testing new communication methods for bowel preparation for your colonoscopy. The new communication methods will use SMS, video, and web-based applications.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

Master - Participant Information Sheet/Consent Form Version 5 dated 02/01/2023

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You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

It is unclear if SMS technologies, videos and web-based applications can improve the quality of bowel preparation and cancer detection for patients undergoing a colonoscopy. Therefore, these technologies need to be tested to see if they can be useful.

This research has been initiated by the study doctor, Dr Viraj Kariyawasam.

This research has been funded by the investigators and the Western Sydney Local Health District Research Education Network.

Investigators from Western Sydney University are also involved in this research.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which communication pathway is best for bowel preparation for colonoscopy. To find out we need to compare different methods of communication. We put people into groups and give each group a different communication method. The quality of the bowel preparation, assessed at the time of colonoscopy, are compared to see if one method of communication is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You have a one in two chance of receiving the new SMS, video and web-based application communication technologies.

If you participate in this trial, you may be given a different bowel preparation regimen than what is normally used at your hospital. This bowel preparation regimen will be provided free of charge and may be effective in achieving adequate bowel preparation than current standard regimens. However, you may need to purchase additional Movicol sachets and Senokot tablets from your local pharmacy.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

You will have to pay for some medicines according to hospital policy. For example, you may require additional bowel preparation which you will need for your colonoscopy which you will have to pay.

4 What do I have to do?

You will need to have a smartphone which supports web browsing and be able to receive text messages. You will need to also have an email address to receive emails. You will be asked to follow bowel preparation and dietary instructions leading up to your colonoscopy as well as answer some surveys related to your care.

You will not need to buy your own bowel preparation as this will be provided free of charge if you participate in this study. This will be posted to you. However, you may need to buy additional bowel preparation to achieve adequate bowel preparation. We will instruct you if you need to do this.
If you are in the group receiving the new dynamic communication technologies, you will be regularly reminded what you need to do, what bowel preparation you need to take, and what dietary restrictions you need to follow. It is also important you answer all surveys as they relate to your care.

If you are in the group receiving written instructions, you need to follow the bowel preparation instructions and dietary restrictions emailed or posted to you. This is what would normally occur if you were not part of the study and is current routine practice. You will be asked to complete a survey after your colonoscopy.

The bowel preparation and dietary instructions that you receive participating in this study is the same as what you would normally receive. The only difference is the type of bowel preparation you receive, and the ways that we inform you about how and when to take these bowel preparations.

5 Other relevant information about the research project

Around 1300 patients are expected to be part of this study.

You have one in two chances of being in either the group receiving dynamic bowel preparation instructions or the group receiving standard instructions via post or email.

This study will occur at Blacktown and Mt Druitt Hospitals, Westmead Hospital, Concord Repatriation General Hospital, Campbelltown Hospital, St George Hospital, and Gosford Hospital.

The research will be performed by investigators at these hospital sites and from Western Sydney University.

Some participants may be additionally approached to participate in a transabdominal ultrasound substudy. In this substudy, a doctor will perform a short 2-minute ultrasound assessment of your abdomen to assess your bowel preparation. You will be asked about your perception of your bowel preparation quality. You can choose not to participate in this substudy.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with your treating hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive information about your bowel preparation at this hospital. Other options are available; these include information that we normally email or post to you. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.
8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include improved quality of bowel preparation which may facilitate more accurate examination of your colon, reducing the possibility of needing a repeat colonoscopy.

9 What are the possible risks and disadvantages of taking part?

It is possible you may become annoyed at the frequency of messages we send to you. If you become upset or distressed as a result of your participation in the research, the study doctor or nurse will be able to arrange for counselling or other appropriate support. You can withdraw from the study at any time. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

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<tr>
<th>Side Effect</th>
<th>How often is it likely to occur?</th>
<th>How severe might it be?</th>
<th>How long might it last?</th>
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<tr>
<td>Distress, inconvenience, or annoyance</td>
<td>It is possible that this may occur during the study. You may become annoyed at the frequency of messaging and notifications we send to you.</td>
<td>The distress and inconvenience you experience will vary from person to person.</td>
<td>The duration of distress you experience will vary from person to person.</td>
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10 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. The contact details are presented below. You will be asked to sign the withdrawal form. This notice will allow that person or the research supervisor to discuss any special requirements linked to withdrawing. Withdrawing from this research will not affect your care, your routine treatment, your relationship with those treating you or your relationship with your treating hospital.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

11 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The information pathways being shown not to be effective
- The information pathways being shown to work and not need further testing

12 What happens when the research project ends?

You will be contacted if the research ends earlier than expected and you will receive standard routine care at that point forward. This should not affect your colonoscopy. There will be no additional costs to you. The bowel preparation regimens and dietary restrictions will be the same. Information will be posted or emailed to you which is current routine practice.

If the research is completed, findings from the study may be published in a peer-reviewed scientific journal or presented at a scientific conference. No identifiable information will ever be released.
Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Data collected will be de-identified at the point of collection and you will be assigned an encrypted identification code for the purpose of this research. Your encrypted identification code can be re-identifiable. Identifiable data collected include your name, phone number, email address, date of birth, and date of colonoscopy procedure, will be stored on a password protected hospital computer and only accessible by the Principal Investigator, Dr Kariyawasam.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

By signing the consent form, you consent to the use of your name, date of birth, email, date of colonoscopy procedure, and your phone number to be used on a secured password protected healthcare application, The Clinician, to coordinate the dissemination of healthcare related of information to your email address and phone. At the end of the study, all data entered into The Clinician will be permanently removed and destroyed. The Clinician has ISO27001 certification (an internationally recognised standard for information security) and uses HL7 v2.x and FHIR standards. The service has been used by a range of government and non-government agencies, including Queensland Health.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained, relevant to the study during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and the institution relevant to this Participant Information Sheet, Western Sydney Local Health District, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. There are no plans for future research with this data.

Data will be entered into a REDCap (Research Electronic Data Capture) database under the Office for Health and Medical Research license. The REDCap system is an online secure capture data collection and management tool for research use. It been provided by the Office for Health and Medical Research for the use of researchers in NSW Public Health LHDs, Networks and pillars. REDCap is hosted in the eHealth AWS cloud, maintained by eHealth, supported by
Office for Health and Medical Research. It is secured, and backed up daily, with privacy and confidentiality considerations are protected. At some hospital sites, your data will remain securely stored on hospital-based servers and only your de-identified data will be entered into REDCap.

14 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

15 Who is organising and funding the research?

This research project is being conducted by Dr Viraj Kariyawasam.

The Clinician may benefit financially from this research project if, for example, the project assists The Clinician to be widely used as part of standard care for bowel preparation.

You will not benefit financially from your involvement in this research project even if, for example, your samples (or knowledge acquired from analysis of your samples) prove to be of commercial value to The Clinician.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to The Clinician, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Western Sydney Local Health District.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

The Gastroenterology and Hepatology Department at Blacktown Hospital and Concord Repatriation General Hospital have also endorsed this study.

Western Sydney University have reviewed this project and have endorsed this study as part of research learning for a medical student.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 0493 267 442 or any of the following people:
**Clinical contact person**

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<th>Name</th>
<th>Position</th>
<th>Telephone</th>
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For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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<th>Position</th>
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If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

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<tr>
<th>Reviewing HREC name</th>
<th>Western Sydney Local Health District</th>
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<tr>
<td>Executive Officer</td>
<td>Kellie Hansen</td>
</tr>
<tr>
<td>Telephone</td>
<td>(02) 8890 9007</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:wslhd-researchoffice@health.nsw.gov.au">wslhd-researchoffice@health.nsw.gov.au</a></td>
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**Site RESEARCH GOVERNANCE Office contact**

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Consent Form - Adult providing own consent

Title
A multicentre, colonoscopist-blinded, randomised controlled trial to determine the efficacy of dynamic multimedia bowel preparation instructions versus standard instructions as control on adenoma detection and patient reported measures in adults aged 45 years and older indicated for a colonoscopy.

Short Title
Digitising colonoscopy care pathways and enhancing bowel preparation quality with patient reported measures (DIGICLEAN).

Coordinating Principal Investigator/ Site Principal Investigator
Dr Viraj Kariyawasam

Location

Declaration by Participant
I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Western Sydney Local Health District concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I acknowledge that any regulatory authorities may have access to my medical records specifically related to this project to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print)

Signature __________________________ Date ____________

Name of Witness* to Participant's Signature (please print)

Signature __________________________ Date ____________

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.
**Declaration by Study Doctor/Senior Researcher**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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<th>Name of Study Doctor/Senior Researcher† (please print)</th>
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.
Form for Withdrawal of Participation - Adult providing own consent

Title
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Short Title
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Coordinating Principal Investigator/ Site Principal Investigator
Dr Viraj Kariyawasam

Declaration by Participant
I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Western Sydney Local Health District.

Name of Participant (please print)

Signature ________________ Date ________________

Declaration by Study Doctor/Senior Researcher†
I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/Senior Researcher† (please print)

Signature ________________ Date ________________

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.