Pilot Randomized Controlled Trial Study Protocol
Version 1.0 – 2 May 2023, Amendment 1 dated 26 June 2023

S3. Study protocol

Swinburne University of Technology (SUT)

In partnership with:

Peter MacCallum Cancer Centre (Peter Mac)

and

Digital Health Cooperative Research Centre (DHCRC)

Title:	Pilot randomized controlled trial (RCT) to test the acceptability, feasibility and potential efficacy of the SAMSON (Safety and Adherence to Medications and Self-care advice in Oncology) intervention solution
Short Title:	SAMSON pilot RCT
Principle Investigator:	(name withheld from review)
Protocol Version:	1.0 – Amendment 1
Date:	26 June 2023
Funding:	DHCRC, Peter Mac and SUT

FOREWORD

Information in this protocol should not be disclosed without written authorisation, other than to those involved in the execution or ethical review of the study.

This document is intended to describe the methodology of the SAMSON pilot RCT. It is not intended that this Protocol be used as a guide for the development of resources outside the scope of this study. Data will not be collected for analysis unless the Human Research Ethics Committee (HREC) of each participating study site has approved this trial for clinician recruitment and participation.

Amendments to the document will be circulated to participating study sites. If in doubt regarding which version is current, please contact the Research Coordinator of the SAMSON pilot RCT.

PROTOCOL APPROVAL

Version No	Date	Name of the person approving	Approval signature
1.0	02/05/2023	(name withheld from review)	Yes
Amendment 1	26/05/2023	(name withheld from review)	

PRINCIPAL INVESTIGATOR SIGNATURE

I have read and approved this protocol. My signature, in conjunction with the signature of the sponsor, confirms the agreement of both parties that the clinical study will be conducted in accordance with the protocol and all applicable local laws and regulations.

Nothing in this document limits the authority of a physician to provide emergency medical care under applicable regulations.

PRINCIPAL INVESTIGATOR SIGNATURE DATE

2 May 2023

PRINCIPAL INVESTIGATOR *(print)*

(name withheld from review)

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2 Abbreviations

Digital Health Cooperative Research Centre	DHCRC
Functional Assessment of Cancer Therapy–General	FACT-G
Human Research Ethics Committee	HREC
Medication Adherence	MA
Mobile Health Applications	APP
Motivational Interviewing	MI
Motivational Interviewing Training Platform	MITP
Patient Activation Measure-Short Form	PAM-SF
Participant Information and Consent Form	PICF
Peter MacCallum Cancer Centre	Peter Mac
Principal Investigator	PI
Patient-Reported Outcomes Measurement Information System	PROMIS
Randomized Controlled Trial	RCT
Research Coordinator	RC
Safety and Adherence to Medications and Self-care advice in Oncology	SAMSON
Statistical Package for the Social Sciences	SPSS
Swinburne University of Technology	SUT

3 Protocol synopsis

Note: This is a synopsis. The body of the protocol must be referred to for the complete study information.

Title	Pilot randomized controlled trial (RCT) to test the acceptability, feasibility and potential efficacy of the SAMSON (Safety and Adherence to Medications and Self-care advice in Oncology) intervention solution
Short title	SAMSON pilot RCT
Rational	Optimal medication adherence (MA) is critical to treatment success and survival of patients with cancer. However, adherence rates to some anti-cancer regiments could be as low as 16% and often worsens overtime. Barriers to adherence are multi-faceted and require multi-dimensional interventions. Digital solutions can support complex interventions effectively and efficiently and are increasingly accepted by patients. SAMSON is a novel patient-centred, comprehensive digital solution to improve MA in cancer. The solution consists of two synergistically operating elements: 1. SAMSON mobile platform, including smartphone-based app to remotely prompt MA, monitor patient side-effects and deliver self-care advice; and computer-based app to enable adherence and side-effect reporting 2. Health professional tele-consultations, using motivational interviewing (MI) skills being trained via the motivational interviewing training platform (MITP) to promote patient's adherence and side-effect self-management. The SAMSON mobile app was tested on 30 people with haematological cancer at Peter Mac in 2021. The MITP was developed in 2022 and is being tested by healthcare professionals at Peter Mac.
Objectives	To evaluate the acceptability, feasibility (recruitment, randomisation, retention, intervention adherence and assessment processes) and potential efficacy of the SAMSON intervention solution among 30 to 50 patients with haematological, lung or melanoma cancer newly administered oral anti-cancer medicines.
Study design	This is a pilot two-arm RCT. Recruitment will be undertaken over a period of six months and the intervention is expected to be completed in nine months from the recruitment commencement. After completion of baseline questionnaires, participants will be randomised separately to either intervention or control groups (1:1 ratio), using a computer-generated randomisation chart. Participants in the intervention group will receive the SAMSON intervention solution, while those in the control group will receive usual care, for 12 weeks immediately following the randomisation.

	Primary outcomes, including: 1. Acceptability (UTAUT) 2. Feasibility Secondary outcomes, including: 1. Medication Adherence (MA) 2. Self-report adherence (ASK-12) 3. Toxicity self-management (PAM-SF) 4. Anxiety, depression and symptoms (PROMIS) 5. Quality of life (FACT-G) 6. Optimal intervention strategy See section 7.7 for more details on outcome assessments. Data collection and results reporting will be in line with the Consolidated Standards of Reporting Trials (CONSORT) criteria for pilot RCTs (Schulz et al., 2010).
Number of participants	30-50 patients
Sample size	Sample size for this trial is pragmatic and based on both funds available and expected patient numbers in the study period.
Duration of individual's participation	16 weeks
Recruiting period	Approximately 6 months
Study duration and critical time-points	The study will run for approximately ten months. Critical timepoints include: - Baseline (or study commencement) - Week 1 - Week 4 - Week 8 - Week 12 (intervention end) - Week 16 (endpoint assessment)
Intervention	The intervention consists of two synergistically operating elements: - SAMSON mobile platform, including smartphone-based app to remotely prompt MA, monitor patient side-effects and deliver self-care advice; and computer-based app to enable adherence and side-effect reporting. - Health professional tele-consultations, using MI skills being trained via the MITP to promote patient's adherence and side-effect self-management by: o Medication reconciliation, o MA education,

	○ Medication administration, missed dose and side-effect education, including side-effect management strategies, ○ Assessment of barriers and concerns ○ The structured counselling sessions will be either in person or online at baseline, week 1, 4, 8 and 12. The length of consultations will be tailored to each patient's need and adherence status, assessed by the healthcare professional who delivers the counselling sessions.
Usual care	The usual care often includes: - An initial pharmacist consultation for medication reconciliation and medication dispensary consultation, contraindications, adverse drug reactions, administration instructions for each medication schedule, and address any patient concerns. - A consultation with the clinic clinician, to provide education about medication, and patient-focused management of side-effects. The clinic nurse will be the patient's ongoing contact for the management of any side-effects related to their treatment medication. - Telephone follow-up, provided by the oncology nurse, within 1-2-week time if no risk/need for earlier support is required. If the oncology nurse identifies there might be a need of extra support, the patient will be followed up with a telephone call within a few days. If a patient displays a high level of competence and no concerns during their education session, they will not be followed up. Instead, they will be asked to call or email the oncology nurse if required.
Measures	Patient-reported outcome measures will be administered via REDCap, a secure online data collection tool, via email or in hard copies. All study measures administered are reliable and valid (see section 7.3 for more details). ***Primary 1- Acceptability*** will be measured by a questionnaire, guided by the Unified Theory of Acceptance and Use of Technology (UTAUT) at week 12 ***Primary 2- Feasibility*** will be measured both quantitatively and qualitatively throughout the study, including recruitment, randomisation, retention, intervention adherence, and assessment processes. For intervention patients, responses to weekly side effects surveys and daily medication reminders will also be measured. ***Secondary 1- Medication adherence*** will be measured by medication refill adherence (MRA) at week 16. ***Secondary 2- Self-report adherence*** will be measured by ASK-12 at weeks 1 and 12 ***Secondary 3- Toxicity Self-management*** will be measured by the Patient Activation Measure-Short Form (PAM-SF) at weeks 1 and 12 ***Secondary 4- Anxiety, Depression and Symptoms*** will be measured by PROMIS scales at weeks 1 and 12

	Secondary 5- Quality of Life will be measured by the Functional Assessment of Cancer Therapy–General (FACT-G) at weeks 1 and 12. ***Secondary* 6- *Optimal intervention strategy*** will be measure by qualitative questions in the UTAUT survey at week 12 to identify the optimal dose of delivering MI tele-consultations. See section 7.7 for more details on outcome measurements and thresholds.
Data collection	Data collection will be either in person or online. **Screening** <u>All patients:</u> • Participant Information Consent Form (PICF) • Demographics form **Week 1 to 12** <u>All patients:</u> • Feasibility data <u>Intervention patients:</u> • Side effects monitoring • Self-responses to medication reminders **Week 1 and 12** <u>All patients:</u> • ASK-12 • PAM-SF • PROMIS • FACT-G **Week 12** <u>Intervention patients:</u> • UTAUT **Week 16** <u>All patients:</u> • MA
Inclusion criteria	1) A confirmed diagnosis of any-stage haematological, lung or melanoma cancer; 2) Scheduled to commence oral anti-cancer medicine(s) as part of routine care or commencing treatment/currently treated with the medication for less than 12 months; 3) Willing to have oral anti-cancer medicine(s) dispensed at Peter Mac; 4) Over 18 years old; 5) Proficient in English; and 6) Accessibility to the internet, a smartphone (and computer), and/or telehealth.
Exclusion criteria	1) Too unwell to participate in the study as determined by the patient's treatment team. 2) Remaining indication treatment period of oral medications for cancer therapy is less than 12 weeks.

	3) Demonstrated cognitive or psychological difficulties that would preclude study participation as defined by the treatment team's cognitive and/or psychiatric assessment or patient's disclosed medical history.
Statistical considerations	**Quantitative data**: Given the relatively small sample size, and that this is a feasibility and acceptability study, analysis of outcome data will be mainly descriptive (e.g. counts/ percentages, means/ standard deviations or medians/ inter-quartile ranges, etc.) These measures will be used to summarise the information in order to describe: 1/ sample demographics; 2/ participants' acceptability and intention to use the SAMSON (performance expectancy, effort expectancy, social influence, facilitating conditions and behavioural intention), and 3/ patients' adherence, side-effect monitoring, toxicity self-management, anxiety, depression and symptoms and quality of life. Between- and within-group comparisons on the outcomes of interest will be conducted, using chi squared t-tests and linear regression. Statistics and data software (STATA) version 17 (STATaCorp, 2021) will be used to analyse the quantitative data. **Qualitative data from the UTAUT questionnaire**: will be analysed for themes in NVivo 12. Results from this pilot RCT can be used to inform the design of a full RCT to evaluate the efficacy of SAMSON later.
Project timeline	It is anticipated that the study will run for approximately 12 months. Key activities during the study timeline are: ***January – February 2023*** Protocol development Establish project team ***March – May 2023*** Acquire Peter Mac's and Swinburne's Ethics approvals Refine SAMSON app and MITP ***June – November 2023*** Participant recruitment ***June 2023 – March 2024*** Data collection ***April - June 2024*** Analyse data and prepare study report

Study and assessment schedule

Protocol Activity	**Baseline (study commencement)**	**Week 1**	**Week 4**	**Week 8**	**Week 12 (intervention end)**	**Week 16 (last data collection)**	**Will be done by**
Inclusion/Exclusion criteria	x						RC (Referred by doctors/nurs/pharms)
Consent	x						Pts & RC
Demographics	x						Pts & RC
SAMSON app	x	x	x	x	x		Intervention pts & RC
Initial MI consultation: • Provide patient education on oral anti-cancer medicines. • Identify past, present, and potential future barriers to MA. • Resolve any barriers to MA, using MI techniques and document identified risks and barriers within the SAMSON web portal, for the next follow-up teleconsultation.	x						Pharm & intervention pts
First MI teleconsultation • Check the participant's understanding of their diagnosis, current symptoms, self-care strategies and medication regimen, and how they are managing now. • Explore what helps facilitate adherence for the individual patient, and any barriers to treatment adherence. • Use MI techniques to assist the patient to identify reasons why adherence is important for them and to develop problem-solving strategies to combat identified barriers. • Once strategies have been identified, guide the patient toward action and assist with self-care strategy rehearsal. • Provide evidence-based information/resources and remind patients		x					Nurs/Pharm & intervention pts

Protocol Activity	**Baseline (study commencement)**	**Week 1**	**Week 4**	**Week 8**	**Week 12 (intervention end)**	**Week 16 (last data collection)**	**Will be done by**
the SAMSON app provides self-care strategies for relevant side-effects.							
Follow-up MI teleconsultations • Review adherence rates and symptom survey and any issues from the previous teleconsultation. • Assess adherence to oral anti-cancer medication. • Explore barriers to treatment adherence. • Discuss benefits and coach re adherence. • Discuss symptoms / side effects. • Coaching re evidence-based self-care strategies. • Summarise the session + assess understanding. • Discuss follow-up consultations – check convenient time. • Complete checklist + patient summary.			x	x			Nurs/Pharm & intervention pts
Final MI teleconsultation • Review adherence rates and symptom survey and any issues from the previous session. • Assess adherence to oral anti-cancer medication. • Explore barriers to treatment adherence. • Discuss benefits and coach re adherence. • Discuss symptoms / side effects. • Guidance re evidence-based self-care strategies. • Summarise the session + assess understanding. • Discuss support network and self-management. • Discuss final session • Complete checklist + patient summary.					x		Nurs/Pharm & intervention pts
Outcomes measurements							
Acceptability (UTAUT)					x		Intervention pts

Protocol Activity	**Baseline (study commencement)**	**Week 1**	**Week 4**	**Week 8**	**Week 12 (intervention end)**	**Week 16 (last data collection)**	**Will be done by**
Feasibility	x	x	x	x	x	x	RC
Medication adherence rate (medication refill adherence-MRA)						x	Pharmacy & RC
Self-report adherence (ASK-12)		x			x		Pts & RC
Side effects monitoring	x	x	x	x	x		Pts & RC
Toxicity self-management (PAM-SF)		x			x		Pts & RC
Anxiety, depression and symptoms (PROMIS)		x			x		Pts & RC
Quality of life (FACT-G)		x			x		Pts & RC
Optimal intervention strategy					x		RC

Note: MI: motivational interviewing, Nurs: nurses, Pharm: pharmacists, Pts: participants, RC: research coordinator

4 List of study documents

Attachment number	Document title	Purpose
1	Participant Information and Consent Form	Provide a detailed summary of the study and participant requirements. Obtain participant's consent to participate in the study. The last section is used for participants to request withdrawal from the study
2	Survey booklet	Obtain participant's information and feedback, including: - demographic information - status of anxiety, depression and other symptoms - quality of life - knowledge, skills and confidence in condition and symptom self-management - barriers to MA and adherence-related behaviour - acceptability and intention to use SAMSON
3a	SAMSON app and website user manual – for patients	Provide information on how to install and use the SAMSON mobile app and website
3b	SAMSON website user manual – for health professionals	Provide information on how to use the SAMSON web page
4a	Intervention manual – for pharmacists	Provide brief information on the study and protocol for pharmacists involving in the intervention to deliver consultations
4b	Intervention manual – for nurses	Provide brief information on the study and protocol for nurses involving in the intervention to deliver consultations
5	Participant spreadsheets	Obtain participants' contact information
6	Recruitment flyer	Provide brief information to patients about the study
	Appendix 1	Medicine information provided in the SAMSON app
	Appendix 2	Self-care advice on common drug side effects
	Appendix 3	Examples of side effects information and self-care advice in the SAMSON app

5 Background information and study rationale

5.1. Medication non-adherence and its burden

Medication Adherence (MA) is defined as "the extent to which a person's behaviour- taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (Sabate, 2003b, p. 3). Research has consistently shown adherence rates are typically lower among patients with chronic conditions (about 50% in developed countries and much lower in developing countries), as compared to those with acute conditions (Carter et al., 2003; Col et al., 1990; Cramer et al., 2003; Haynes et al., 2002; Sabate, 2003a; World Health Organization, 2003). Among patients with cancers, this rate varies between 16 to 100% (Bouwman et al., 2017) and often worsens overtime (Hershman et al., 2009). There is no single standard threshold for acceptable adherence, however, patients can be considered as suboptimal-adherent if their adherence rate is less than 80% (Banning, 2012; Geynisman & Wickersham, 2013; Spoelstra & Given, 2011).

Suboptimal medication adherence is often associated with poorer health outcomes and increased healthcare costs (Col et al., 1990; Kane & Shaya, 2008). Studies have shown that poor adherence to prescribed regimens can significantly impact survival rates (Makubate et al., 2013), and result in patients' disease progression, reduced functional ability, increased risk of hospitalisation, and lower quality of life (Col et al., 1990; Fuso et al., 1995; Garcia-Aymerich et al., 2000). Annually, in Australia, it is estimated that 250,000 Australians experience medication-related hospital admissions, which costs Australian taxpayers $1.4 billion (Lim et al., 2019). MA and error management are essential for tackling chronic conditions effectively and play critical roles in improving healthcare today (Sabate, 2003a).

5.2. Medication adherence interventions

Despite the problem of non-adherence being discussed, it is not consistently part of routine care, and efforts to address the problem have been fragmented (Sabate, 2003a). According to the results from our recently published systematic review, single strategies to promote adherence (e.g. education, reminders, or monitoring) are not sufficient to improve adherence (Dang et al., 2022). Multi-component interventions that involve collective adherence strategies (patient education, reminders, self-monitoring, reinforcement, and supportive counselling), especially if they were tailored to patients, were most effective to improve adherence to oral anti-cancer medicines (Dang et al., 2022).

Furthermore, the review revealed that digital solutions can enhance multi-component interventions effectively and efficiently (Dang et al., 2022; Gambalunga et al., 2020; Odeh et al., 2015), given the already-scarce resources in the health system (Phanareth et al., 2017). With the digital boom, technological advances, such as smartphones with powerful capabilities and features, have become one of the most important innovations in healthcare as they provide many advantages, including improving clinical outcomes and cost efficiency, and increased acceptability by patients (Gambalunga et al., 2020; World Health Organization, 2011). These technologies have been increasingly used to assist treatment management through enabling therapeutic education and monitoring of patient self-management (Hamine et al., 2015). Results from a systematic review of 188 studies on mobile health applications have shown that digital technology is appropriate and helpful in increasing treatment adherence (Perez-Jover et al., 2019).

5.3. SAMSON intervention solution

Harnessing the potential of technologies, we developed SAMSON - a novel patient-centred, comprehensive digital solution to improve MA in cancer. The solution comprises two components:

1) SAMSON mobile app involving individually tailored smartphone alerts and real-time advice for side-effect self-management. The beta-version of SAMSON mobile app was tested by 30 people with haematological cancer at Peter Mac in 2021 (HREC/74134/PMCC).
2) Health professional tele-consultations, using MI skills being trained via the MITP to promote patient's adherence and side-effect self-management. The MITP is a digital training platform, which was created to provide general training on motivational interviewing, communication skills with focus on medication adherence aspects for oncology clinicians. The MITP was co-designed with healthcare professionals, stakeholders and consumer representatives, and developed in 2022. It is available on Peter Mac's learning management system and being tested by healthcare professionals at the hospital. The data collection is expected to complete in March 2023 the latest.

6 Objectives

The objective of this work is to evaluate the acceptability, feasibility (recruitment, randomisation, retention, intervention adherence and assessment processes) and potential efficacy of the SAMSON intervention solution among 30 to 50 patients with haematological, lung or melanoma cancer newly administered oral anti-cancer medicines.

7 Methods

7.1. Study design

This is a pilot two-arm RCT.

After completion of baseline questionnaires, participants will be remotely randomised to either intervention or control groups (1:1 ratio), using a computer-generated randomisation chart. Participants of the intervention group will receive the SAMSON intervention solution, while those in the control group will receive usual care, for 12 weeks immediately following the randomisation.

Primary outcomes:

- Intervention group: acceptability will be assessed at week 12.
- Both groups: Feasibility will be assessed throughout the study.

Secondary outcomes: adherence will be assessed at week 16. side-effect monitoring; toxicity self-management; anxiety, depression and symptoms; quality of life will be assessed at weeks 1 and 12; and optimal intervention strategy will be assessed at week 12.

Data collection and results reporting will be in line with the Consolidated Standards of Reporting Trials (CONSORT) criteria for pilot RCTs (Schulz et al., 2010).

7.2. Number of participants and study duration

Thirty to fifty patients will be recruited into the pilot RCT. The study will run for 16 weeks. During this 16-week, the patient in the intervention arm will:

- have access to the SAMSON mobile app (the first component of the intervention solution) throughout the study period, and
- receive initial pharmacist consultation and tele-consultations provided by their care team at Peter Mac, i.e nurses or pharmacists, in weeks 1, 4, 8 and 12.

All randomisations will be done by the study statistician.

Recruitment will be undertaken over a period of 6 months and the intervention is expected to be completed in ten months from recruitment commencement.

The patient in the controlled arm will receive usual care at the hospital (see details in section 7.9.2).

7.3. Study setting

The recruitment of, and data collection from, patients with cancer will take place at Peter Mac Parkville.

The questionnaire will be completed either in person or online.

7.4. Recruitment

7.4.1. Screening and recruitment

- Potentially eligible patients will be identified by site nurse/pharmacist, treating consultants, clinic lists and pharmacy dispensing records. Healthcare staff will be provided with an

information flyer (Attachment 6) to introduce the study to patients who may be eligible and ask if they would like their details passed on for contact by the research team. If the patient is interested, the healthcare provider can refer their name and contact details to the study RC (Thu Ha Dang) for follow-up. The RC will meet the potential participant either in person outside the clinic or online to discuss the study.

- Through a comprehensive informed consent process, provided by the RC, patients will be informed that:
    - Participation in this research project is voluntary. Patients' decision about whether or not to take part, or to take part and then withdraw from this research project, will not affect their standard of care. Nor will it negatively affect their relationship with the treating team or any hospital services they receive now or in the future. If they withdraw, they will have the option to withdraw all their data from the study prior to publication.
    - Participants will be asked if they provide consent for their adherence data to be accessed by the treating clinician.
    - They will also be provided with Peter Mac's brochure "What happens to information about you?", because their medical record will be accessed as a part of this study.
    - Participants will receive a gift voucher of $50 for their time spent to complete all surveys (control-arm participants: ASK-12, PAM-SF, PROMIS and FACT-G; intervention-arm participants: these four surveys and UTAUT). Participants may find the information and support that SAMSON provides to be useful. The findings of this research project will be used to improve the care of patients with cancers, or any other type of medical condition that requires the patient to take long-term medication.
- If the patient meets the inclusion criteria and agrees to participate, they will then sign the Participant Information and Consent Form (PICF) (see Attachment 1). Patients will also select the mode to complete surveys, i.e. either face-to-face, via mail or online. They will then be invited to complete the demographic survey (Attachment 2).
    - If the patient would like some time to consider taking part in the study, the RC will provide the patient with her email, should the patient wish to contact the RC to ask further questions, or if they wish to express their interest in taking part in the study. The RC will arrange to contact the patient in approximately 3-5 working days if no contact has been made by the patient during this time, to confirm whether or not the patient would like to take part in the study. After this time, if the patient contacts the RC to express interest in taking part, then consent procedures may be re-commenced as per the above. Otherwise, it will be interpreted that the patient has declined participation.
    - Reasons for declining participation will be recorded within a secure potential participant spreadsheet.

7.4.2. Participant withdrawal

The following are considered justified reasons for terminating participation of a participant in the study. Participants who meet any of these criteria will be defined as 'withdrawals'.

- Death
- Withdrawal of patient consent (Attachment 1)
- Stopping oral anti-cancer medicine under direction of the treating clinician. At point of consent, participants will be requested to inform the study team if this occurs. The RC will confirm this with the treating clinician before the patient is removed from the study.

- The reason for study removal and the date the patient was removed will be documented in the participant spreadsheet.

7.5. Randomisation and allocation procedures

- Following consent, the study statistician (CI Quinn), located at Swinburne University, will randomise participants 1:1 in blocks of 4 to intervention or usual care arms and send by email to the RC who will arrange participants to the arm specified in the email.

- All participants will be asked to provide their contact details for communication during the study and be provided with a unique identifying number and link to the online questionnaires to be completed within three days of consenting to participate in the trial. This set of questionnaires include: PAM-SF, PROMIS, FACT-G, and ASK-12 (Attachment 2). Participants can select the questionnaires in hard copy if they wish to.

- The RC will follow-up with participants to ensure questionnaires are completed. Following completion of the above questionnaires, the research assistant will advise the participant which study arm they were randomised to.

- If randomised to the intervention, participant patients will:

  - Be provided with the SAMSON mobile app user manual (Attachment 3a) to install the SAMSON mobile app onto their smartphone. They will also be given a password and username to access the SAMSON system. The RC will assist to download the APP and train them in how to use the SAMSON APP and webpage.

  - Receive an initial pharmacy consultation with the SAMSON trained pharmacist following the intervention manual (Attachment 4a). This consultation will be conducted either face-to-face, via phone or online.

  - Have their medication reminders and side effects surveys programmed into the app.

- Participants randomised to the control arm will be provided with pharmaceutical care as usual.

7.6. Study population

7.6.1. Inclusion criteria

All the following criteria must be satisfied for enrolment in the study.

1) A confirmed diagnosis of any-stage haematological, lung or melanoma cancer;
2) Scheduled to commence oral anti-cancer medicine(s) as part of routine care or commencing treatment/currently treated with the medication for less than 12 months;
3) Willing to have oral anti-cancer medicine(s) dispensed at Peter Mac;
4) Over 18 years old;
5) Proficient in English; and
6) Accessibility to the internet, a smartphone (and computer), and/or telehealth.

7.6.2. Exclusion criteria

Presence of any of the following criteria will exclude the participant from enrolment in the study.

1) Too unwell to participate in the study as determined by the patient's treatment team.

2) Remaining treatment period of oral medications for cancer therapy is less than 12 months.
3) Demonstrated cognitive or psychological difficulties that would preclude study participation as defined by the treatment team's cognitive and/or psychiatric assessment or patient's disclosed medical history.

7.6.3. Concurrent participation

If the patient is already participating in another clinical trial (identified through the screening questionnaire or by their treating healthcare team), the PI of this trial and the PI of other trial will discuss whether one trial will impact adversely on the other.

7.7. Outcome assessments

7.7.1. Primary outcomes

7.7.1.1. Acceptability

We will assess clinicians' and patients' acceptability via a questionnaire, guided by the Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al., 2003; Venkatesh et al., 2012). The questionnaire will be adapted to assess determinants of clinicians' and patients' acceptance and use of the SAMSON, including: 1) *performance expectancy* (the degree to which clinicians believe that using the SAMSON will increase their ability to support patient adherence, while patients believe that using the solution will increase their knowledge, ability and confidence in medication treatment management); 2) *effort expectancy* (the degree of ease associated with using the SAMSON); 3) *social influence* (the extent to which clinicians and patients perceive that the SAMSON is considered socially acceptable); 4) *facilitating conditions* (the degree to which the organisational resources and support are available for clinicians and patients to use the SAMSON); and 5) *behavioural intention* (the degree to which clinicians and patients plan to use SAMSON in real life). Reliability metrics and validity analysis showed that UTAUT is a useful tool to assess the likelihood of success and to understand the drivers of acceptance of a new technology intervention (Venkatesh et al., 2003; Venkatesh et al., 2012). The theory is widely adopted and empirically validated in healthcare (Nguyen et al., 2016; Zhou et al., 2019). The questionnaire also includes some open questions for participants to provide more feedback and suggestions on the intervention solution. The questionnaire is adapted separately for healthcare professionals and patients.

7.7.1.2. Feasibility

The feasibility of the SAMSON intervention will be assessed by the research team at every stage of the trial, including recruitment, randomisation, retention, intervention adherence and assessment processes (Abbott, 2014; Leon et al., 2011). The RC will collect this data throughout the study. We will assess the feasibility quantitatively, using the traffic light approach (Table 1). Any outcome above the upper threshold will be deemed feasible. Any outcome below the lower threshold will be deemed as infeasible. Outcome(s) between the two thresholds will be considered for protocol changes to raise the measure above the upper threshold. This will inform overall feasibility for the future full RCT. Furthermore, the RC will also collect information from study nurses and pharmacists on issues and challenges that might raise during the study, and feedback that healthcare professionals and patients will provide in the UTAUT survey and use them to explain the quantitative results.

Table 1. Thresholds for traffic light approach to feasibility

Measures of feasibility	**% Lower threshold**	**% Upper threshold**
Recruitment rate	30	60

Retention rate of study	70	80
Intervention adherence – patients:		
- Responding to medication reminders	70	90
- Responding to symptoms surveys	70	90
Data collection compliance:		
ASK-12	50	70
PAM-SF	50	70
PROMIS	50	70
FACT-G	50	70
UTAUT	50	70

Recruitment rate is defined as the number of patients recruited divided by the number of patients offered to join the study.
Retention rate of the study will be defined as the number of participants who remain at the end of the study divided by the total patients who consent to join the study.

7.7.2. Secondary outcomes

7.7.2.1. Medication adherence will be assessed by medication refill adherence (MRA) (Hess et al., 2006) in week 16. A systematic review of current or recently used measures of calculating adherence from administrative data recommended MRA as the preferred measure of adherence, because of its convenience while still produces equivalent results comparing with other measures (Hess et al., 2006). Pharmacy dispensing data (Merlin) will be used to determine MRA, defined as the total days' supply divided by the number of days of study participation and multiplied by 100. Data will be extracted at a single time point once the last patient has reached week 16. Data will be extracted by pharmacy as part of collaboration in this research program. Note that the total days' supply will include any deliberate break periods, e.g. if the patient is asked to take the drug for 21 days, follows by 7 days break, then the total days' supply will be 28. If the patient needs to reduce the dose for some medical reasons, e.g. side effects, the MRA formulation will be manually adjusted accordingly. In this study, the patient will be considered as optimal adherence if their MRA is ≥ 90%.
Note that MRA may be impacted if patients are given larger pack sizes and therefore not coming in at every cycle or if dose adjustments occur due to toxicity resulting in a participant using a single pack for longer. Therefore, the RC will collect this information and compare the MRA with patients' responses to drug reminders on the SAMSON mobile app and discuss with the PI case by case.

7.7.2.2. Self-report adherence will be measured by ASK-12 (Matza et al., 2009) at weeks 1 and 12. This instrument was originally designed with 20 questions to provide a practical, yet detailed, assessment of adherence behaviour as well as potential barriers to adherence (Hahn et al., 2008). The ASK-20 has been used in studies focusing on a range of treatments and settings, for example asthma and different pharmacy programs. The shorter refined version of this instrument, i.e. ASK-12 includes 12 items in three sub-scales: adherence behaviour, health beliefs and inconvenience or forgetfulness. The tool has good internal consistency reliability (Cronbach alpha = 0.75) and test-retest reliability (intraclass correlation = 0.79). This tool was found to be practical and useful for the

clinical setting for predicting risk of nonadherence as well as measuring rates of adherence (Matza et al., 2009; Spoelstra & Rittenberg, 2015). Completion of the ASK-12 is anticipated to take approximately 2-3 minutes.

7.7.2.3. Toxicity Self-management will be assessed at week 1 and week 12: Patient Activation Measure-Short Form (PAM-SF) (Hibbard et al., 2005) is a 13-item self-report measure assessing the patient's knowledge, skills, and confidence in the self-management of their disease and related symptoms. Responses to each of the 13 items are measured using a 4-point Likert scale, with responses ranging from 1 (strongly disagree) to 4 (strongly agree), with an additional 'not applicable' option. Scores range from 0-100, which categorise patients into one of four possible groups: (1) disengaged and overwhelmed, (2) becoming aware but still struggling, (3) taking action, and (4) maintaining behaviours and pushing further. Higher scores are reflective of greater activation. This scale has good internal consistency, $\alpha = 0.81$ (Prey et al., 2016). Completion of the PAM-SF is anticipated to take approximately 5-10 minutes.

7.7.2.4. Anxiety, Depression and Symptoms will be assessed at week 1 and week 12: Patient-Reported Outcomes Measurement Information System (PROMIS) scales – adult short-form will be used to assess ***depression*** (4-items), ***anxiety*** (4-items), ***pain interference*** (4-items), ***fatigue*** (4-items), ***sleep disturbance*** (4-items) and ***physical function*** (6-items). These self-report scales have excellent test-retest reliability ($\geq .86$) and acceptable convergent and discriminative validity in people with cancer (Quach et al., 2016). PROMIS encompasses a set of person-centred measures that evaluate and screen for dysfunction in physical, mental, and social health in children and adults. PROMIS utilises a T-score metric with a mean of 50 and a standard deviation of 10 in a reference population. Higher scores on the PROMIS scales are indicative of a higher degree of the concept being measured, with a score range of 20-80. For mental health, pain, and sleep scales, higher scores indicate greater dysfunction. For the physical function scale, higher scores indicate lower dysfunction. Completion of the PROMIS scales (26 items in total) is anticipated to take approximately 5-10 minutes.

7.7.2.5. Quality of Life will be assessed at week 1 and week 12: Functional Assessment of Cancer Therapy–General (FACT-G) (Cella et al., 1993) is a 27-item self-report scale measuring quality of life of patients currently undergoing cancer treatment. Questions are categorised according to measurement domain, which are: physical wellbeing (7-items), social/family wellbeing (7-items), emotional wellbeing (6-items), and functional wellbeing (7-items). The response format for all questions is a 5-point Likert scale ranging from 0 (not at all) to 4 (very much), with higher scores indicative of a better state of health. The scale has shown internal consistency of $\alpha \geq .90$ overall and $\alpha \geq .70$ for each subscale, and acceptable convergent validity when assessed in patients with non-Hodgkin's lymphoma (Yost et al., 2013). Completion of the FACT-G is anticipated to take approximately 5-10 minutes.

7.7.2.6. Optimal intervention strategy: will be measured by qualitative questions in the UTAUT surveys for both clinicians and patients at week 12 to identify the optimal dose of delivering MI tele-consultations.

7.8. Intervention

The SAMSON (Safety and Adherence to Medications and Self-care advice in Oncology) intervention solution, is the next iteration of the REMIND intervention. REMIND was developed and assessed in 10 patients with CML. Results of the REMIND trial have been published:

Pereira-Salgado, A., Westwood, J.A., Russell, L., et al. Mobile health intervention to increase oral cancer therapy adherence in patients with chronic myeloid leukemia (The REMIND System): Clinical feasibility and acceptability assessment. Mhealth Uhealth 2017;5:e184.

SAMSON is a digital support tool used in conjunction with usual care to improve adherence, reduce administration and interaction errors, and provide evidence-based advice for effective management of medication side-effects. It includes two elements:

1) SAMSON mobile app, including smartphone-based app to remotely prompt MA, monitor patient side-effects and deliver self-care advice; and computer-based app to enable adherence and side-effect reporting. The beta-version of SAMSON mobile app has been tested on 30 people with haematology cancer at Peter Mac in 2021 (HREC/74134/PMCC). Data on patient's diagnosis and treatment will be extracted from the patient's medical record at PeterMac. Data on drug administration, indications, cautions and side-effects, and counselling have been developed by Peter Mac Pharmacy Medicines Information Service, based on approved product and consumer information resources (Appendix 1). Self-care advice information has been developed based on resources such as American Society of Clinical Oncology (ASCO), Cancer Australia, Health Direct and Peter Mac's information for patients and carers, and reviewed by the SAMSON clinical team (Appendix 2). All data will be entered into the SAMSON platform by the RC. Drugs names and dosages will be matched with the patient's prescription; thus the patient will only receive prompted reminders and feedback on medication adherence status relating to their own treatment. Examples of how this information is shown in the SAMSON app are in Appendix 3. The project team member will debrief study nurses and pharmacists on how to use the SAMSON webpage at the beginning of the study, and continue providing IT support for them if issues arise.
2) Health professional tele-consultations, using MI skills being trained via the MITP to promote patient's adherence and side-effect self-management by:
    - Medication reconciliation,
    - MA education,
    - Medication administration, missed dose and side-effect education, including side-effect management strategies,
    - Assessment of barriers and concerns
    - Addressing barriers and concerns

MITP is a digital training platform, which was created to provide general training on MI, communication skills with focus on MA aspects for oncology clinicians. The MITP consists of different eLearning adaptive, interactive and possibly personalised modules, including formative assessments, being provided online via Peter Mac's learning management system (LMS) (Learning Hub). The MITP was developed in 2022 and is being trialled by oncology clinicians at Peter Mac. After the study's completion, expected in March 2023, the MITP will be refined accordingly, and will then be delivered in conjunction with the refined SAMSON mobile app as the SAMSON intervention solution in this study.

The structured counselling sessions will be either in person or online at baseline, week 1, 4, 8 and 12. The quantity and length of consultations will be tailored to patient's need and adherence status, assessed by the consultant. The initial consultation will be delivered in person or online by a pharmacist when patients receive their medicines. The tele-counselling sessions will be delivered via phone or telehealth by clinical nurses or pharmacists of participating departments at Peter Mac. In departments where there is no allocated clinical pharmacist, nurses will deliver teleconsultations or an alternative approach will be arranged in discussion between the patient's care team.

Nurses and pharmacists will participate in the study depending on their availability and interest. They will need to have at least one year of clinical experience in providing oncology care and successfully complete the MITP training to conduct the structured counseling sessions with participants. Study nurses and pharmacists will be provided instruction manuals to guide them for each consultation. It is predicted that some nurses and pharmacists involved in the MITP testing study in 2022 will

participate in the trial. The UTAUT questionnaire for healthcare professionals includes a statement that by completing the survey, they provide implied consent for the research team to use the data from this questionnaire for the purposes of the research project.

The online intervention manual (Attachments 4a and 4b), summarising details of the intervention, has been developed to guide the nurses and pharmacists while delivering the intervention. Besides this, they will be provided with the SAMSON website user manual (Attachment 3b). They will also work together to schedule who deliver which sessions. After each consultation, nurses/pharmacists will need to send to the RC a consultation checklist and summary, and concurrently send a consultation summary to the patient.

7.9. Procedure outlines

7.9.1. Patients randomised to the intervention arm

- At the initial pharmacist consult, participants will undergo an initial 30-60 minutes in person/online appointment with a SAMSON trained pharmacist, which will include a medication reconciliation and contra-indication assessment, MA, administration, missed dose and side-effect education, discussion about where on the APP side-effect solutions are located, an opportunity for the participant to discuss any concerns and ask questions. The pharmacist will record identified barriers and facilitators to MA in the SAMSON web-based system under the patient consultation notes section. These will be addressed in the following consultations.
- During the first week an intervention nurse/pharmacist will consult (either via phone or telehealth) the participant to commence the intervention. The tele-counselling session will be 15-30 minutes in duration (Appendix 10). Components of the teleconsultation session are outlined below.
  - Establishing the patient's understanding of the diagnosis, current symptom experience and medication regimen, and current self-care strategies.
  - Exploring any barriers to treatment adherence of the patient; particularly side-effects or other negative consequences.
  - Providing evidence-based self-care strategies
  - Exploring patient perceived benefits associated with MA.
  - Identifying the top concerns about MA (from the initial consultation notes) for each patient and address these concerns, using MI approach
  - Then, negotiating a plan of action based on discussions and arrange the next scheduled tele-consultation.
- Daily, a smartphone reminder message will be sent to the patient for each medication and dose based on their individual dosing regimen. The patient will be asked to respond to the message for each medication reminder by clicking the 'Yes' button to confirm they took the medication or the 'No' button if they did not take the medication on that occasion.
- Once a week, participants will be sent a message to their smartphone with a link to the weekly Side-Effects Survey that assesses the presence, severity and bother levels of common medication related side-effects. Participants will complete the survey via the app. The SAMSON system will record key medication-related toxicities and this information will be stored on a secure centrally-stored server to enable clinician review, and review weekly by the nurse/pharmacist conducting the tele-consultation. The SAMSON app provides evidence-based symptom self-care information to patients for each of the common toxicities, which is available to the patient in real-time. In addition, for severe or potentially life-threatening symptoms, e.g. fever, the app will notify the participant to seek immediate medical attention and generate an alert to be sent to the participants treating clinician and the study nurse.

- The nurse/pharmacist will contact patients via phone/telehealth at an arranged time in weeks 4, 8 and 12 (Appendix 10). These consultations will take 15-30 minutes and be focused on any new issues with adherence or side-effects, as well as outstanding barriers to adherence and adherence levels that are suboptimal. The length of consultations will be tailored to patient's need and adherence status, assessed by the healthcare professional who delivers the counselling sessions. The consultation style will be one of guidance to assist the participant with development of their own strategies suitable to their lifestyle and values that enable optimisation of health behaviours. This is consistent with MI, an evidence-based method of modifying health behaviours.
- The SAMSON platform provides patient MA and side-effect reports to the treating clinician. Both the treating clinician and the patient can login to the SAMSON platform to view the patient's adherence and side-effect reports.
- At the beginning of the study, the patient will be educated that if they experience any severe or concerning symptoms, e.g. a fever equal to or above 38 degrees at any time during the 16-week intervention, they should report to the treating team by the preferred method (pager, email, phone) to alert them of this event as per standard processes, and the treating team will follow-up with the participant to ensure they received medical assistance. Symptoms reported via the SAMSON smartphone app will be actioned by the SAMSON team (clinical referral to medical/nursing as appropriate), however, this is secondary to standard care processes and referral pathways. Any urgent care enquires should follow standard care processes.
- We will 'buy out' nurses' and pharmacists' time to deliver MI consultations in the study.

7.9.2. Patients randomised to the controlled arm

- Participants in the control/usual care arm will receive usual care and will not have access to any of the intervention. Standard care will involve:
  - A consultation in the clinic with the clinic clinician, to provide education about medication, and patient-focused management of side-effects including the appropriate action to take regarding serious side-effects (e.g. when/where to seek urgent medical attention). The disease stream nurse will be the patient's ongoing contact for the management of any side-effects related to their treatment medication.
  - An initial pharmacist consultation at Peter Mac for the patient who chooses to fill their prescription at Peter Mac. In this consult, a medication reconciliation and medication dispensary consultation is conducted with a pharmacist to catalogue the patient's prescription and non-prescription medications (including new medications), identify any contraindications, adverse drug reactions, provide administration instructions for each medication schedule, confirm that administration instructions have been understood, and address any patient concerns regarding their medication or medication schedules.
  - Follow-up after commencing medication will be undertaken within 1-2-weeks by the disease stream nurse for assessment of early toxicity.
- Patients are provided with the contact details for the pharmacist and disease stream nurse, and can call or email if required, although they are advised of the limitations of this (i.e. business hours) and to seek alternative/urgent medical assistance if required outside of business hours.

7.9.3. Procedure of data collection with questionnaires

The questionnaires as described in section 7.7 will be completed by all participants. Completion time for all of these questionnaires is approximately 30 minutes. All questionnaire reminders will be scheduled on REDCap to be sent out on days 4 and 8 after the initial notification is sent. The REDCap reminder will automatically stop once the survey is completed. If these questionnaires are still not completed in 10 days after initial participant notification, the RC will email the participant to remind them to complete or may contact the participant and ask if they would like to complete over

the phone. This will be the final attempt by the research team to encourage participants to complete the questionnaires. Any participants who don't complete the questionnaire after the final attempt will be treated as lost follow-up.

7.10. Data analysis

Quantitative

All quantitative data will be analysed by the study statistician using STATA 17 (STATaCorp, 2021). Prior to formal data analysis, data cleaning will be performed to identify and correct for missing data and outliers, assess the distributional characteristics and summarise study measure completion rates and missing data points.

Given the relatively small sample size, and that this is a feasibility and acceptability study, analysis of outcome data will be mainly descriptive (e.g. counts/ percentages, means/ standard deviations or medians/ inter-quartile ranges, etc.). These measures will be used to summarise the information in order to describe: 1/ sample demographics; 2/ participants' acceptability and intention to use the SAMSON (performance expectancy, effort expectancy, social influence, facilitating conditions and behavioural intention), and 3/ patients' adherence, side-effect monitoring, toxicity self-management, anxiety, depression and symptoms and quality of life. Between- and within-group comparisons on the outcomes of interest will be conducted using chi-squared tests, t-tests and linear regression. Results will be used to inform the selection of appropriate endpoints and sample size calculations for a larger RCT.

Qualitative

Qualitative data, including a) answers to open questions on the healthcare professionals' and patients' experience and perception of the SAMSON intervention in the UTAUT questionnaire, b) feasibility data, and c) consultation checklists and summaries from the study nurses and pharmacists, will be summarised and analysed thematically by the RC. A thematic analysis (Liamputtong, 2020; Maguire & Delahunt, 2017) will be undertaken to identify the full range of experiences, expectations and perceptions that arose when participants discussed their experience in using the SAMSON. Thematic analysis is "a method for identifying, analysing and interpreting patterns of meanings (or themes) in qualitative data" (Braun & Clarke, 2016, p. 84). Themes are repeated patterns of meaning that are recognised in the data through categorisation and analysis of individual meaning (Houser, 2015). QSR NVivo Version 12 software (Bazeley, 2009; Bazeley & Jackson, 2013) will be used for qualitative data management. The RC will initially analyse the data. After that, a qualitative inter-rating process (Kitto et al., 2008) will be conducted by PI or another researcher, who has experience in qualitative analysis, to improve the quality of data analysis. Any disagreements will be discussed among researchers until reaching agreement. The researchers' inter-rating process helped to strengthen the credibility and trustworthiness of this study (Barbour, 2001; Mays & Pope, 2000).

7.11. Data management and quality assurance

All essential study-related documentation will be collected, stored, and maintained, with appropriate version control logs. These documents include (but are not limited to) Human Research Ethics Committee (HREC) approved copies of:

i. The study protocol;
ii. PICF;
iii. Participant withdrawal consent form;
iv. Survey booklet
v. SAMSON user manuals

vi. Intervention user manuals
vii.Participant spreadsheets
viii. Recruitment flyers
xii. Any communication with PeterMac's and Swinburne's HRECs.

All of the information that the study participants have provided will be de-identified. Only the research team will have access to the list that can link participants' names with their individual data. All study data will remain confidential and will be kept securely for seven years from the date of publication of the results, after which it will be destroyed as confidential waste. Paper-based study data will be stored in password-protected electronic files, as well as in locked filing cabinets at the principal trial site: PeterMac Parkville. Electronic data will be captured and stored in REDCap while the study is being undertaken, then downloaded to a secure electronic file and transferred to disk to be archived following analysis. No identifying information will be stored electronically together with questionnaire data. The study data will only be accessible by members of the research team who require access, or as required by law. In any publication, information will be provided in such a way that the participant cannot be identified. They will not, for example, be mentioned by name in any publication of the results. In accordance with relevant Australian and/or Victorian privacy and other relevant laws, the participant has the right to access their information that has been collected and stored about them by the research team. They also have the right to request that any information, with which they disagree, be corrected.

8 Risks and risk management

Participants will also be informed that any information gathered from them, including any responses to questionnaires, will remain confidential and they have the right to withdraw their data at any time prior to publication.

There are no known major risks from being involved in this research project. However, given the personal nature of the information being collected there is a very small risk of psychological discomfort. All participants will be provided with the contact details of the RC, should they experience any distress during their involvement in the study. If a participant expresses any distress to a member of the research team during their involvement in the study, they will be referred to appropriate counselling services (ie. Beyond Blue). Also, the RC will report this to the patient's care team at Peter Mac.

9 Ethics and dissemination

9.1. HREC

Ethics application will be submitted to PeterMac's HREC, an authorised reviewer. The RC will work in conjunction with the PI to submit the protocol, and other appropriate documentation to PeterMac's HREC for approval. The HREC approval/advice letter must include:

- the date of HREC approval
- the trial title
- the protocol number, date and version
- the name, date and version of all trial documents, such as the PICF
- the period of protocol approval, if applicable
- the requirements for trial progress report submissions annually.

9.2. Protocol amendments

Any change or addition of this protocol requires a written protocol amendment that must be prepared by the PI. All protocol amendments will be reviewed by the project steering committee prior to submission to PeterMac as the reviewing HREC. Significant changes affecting the safety of participants, the scope of the investigation or the scientific quality of the study cannot be implemented until approval is obtained. A copy of the written approval by the HREC must be sent to the RC.

Administrative changes of the protocol are defined as minor corrections and/or clarifications that have no effect on the way the study is to be conducted, or on the safety of participants. These administrative changes will be agreed upon by the study steering committee and the PI, and will be documented in a memorandum.

9.3. Monitoring and project governance

This study will be coordinated centrally by the research team based at Peter Mac Parkville. PI Schofield will maintain regular weekly contact with the RC to ensure that the study is running smoothly, and that recruitment is on target. Adherence to the research protocol will be monitored by the study's Steering Committee throughout the study. Protocol violations or operational issues will be discussed and resolved at project team meetings.

9.4. Access to data

All electronic data collected from this study will be stored on a computer that will be password secured. The research team who have been granted permission will have access to this data. ID codes will be used for all questionnaires and no identifying information will be made available on study reports or publications. De-identified questionnaire data will be stored for seven years after the publication of the study.

9.5. Reporting of results and dissemination policy

There are no limitations or restrictions on the publication of results by researchers. However, funders must be acknowledged on papers, presentations and posters; and a copy of the proposed publication (including, without limitation, conference abstracts, posters and papers) must be submitted to the funders in writing not less than 30 days prior to submission for publication. All publications

stemming from this research will list all study authors and acknowledge the study site (PeterMac Parkville).

The results of this study will be used to refine SAMSON and be presented at conferences and submitted for publication in peer-reviewed journals. Participants involved in this study will receive a summary of the outcomes if they indicate their interest.

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