A Digital Solution to Support Medication Adherence and Self-Management in Patients with Cancer: SAMSON Pilot Randomized Controlled Trial

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Abstract

Background: Medication non-adherence is a serious problem in cancer with potential impact on patients' health outcomes and healthcare costs. Technology-based medication adherence (MA) interventions are increasingly introduced, yet their evidence of quality and effectiveness is poor.

Objective: This study aimed to test the acceptability, feasibility, and potential effects of SAMSON, a digital solution designed to support MA and self-management in cancer.

Methods: This was a two-arm, unblinded, 12-week, pragmatic pilot randomized controlled trial (RCT). Adults who started oral cancer medicines for haematological malignancies within the last 12 months were recruited from a metropolitan specialised hospital. Participants were randomized 1:1 to either the SAMSON solution or the control arm to receive usual care. The SAMSON solution included a smartphone app which allows prompting individually tailored phone alerts and real-time self-care advice, a web-based dashboard for healthcare professionals (HCPs) to monitor patients' adherence and symptoms, alongside motivational interviewing (MI) teleconsultations delivered by oncology nurses and pharmacists scheduled after recruitment and at weeks 1, 4, 8 and 12, to support patient adherence and side-effect self-management. Primary outcomes were the patients'

acceptance of SAMSON, measured by the Unified Theory of Acceptance and Use of Technology at 12 weeks, and study feasibility, measured by predefined rates of recruitment, randomization, retention, intervention adherence and outcome assessment completion. Secondary outcomes were comparison of MA and clinical self-assessments through online questionnaires, including adherence, toxicity self-management, anxiety-depression-and symptoms, and quality of life, measured at baseline and 12 weeks between the two arms. Data retrieved from the SAMSON app on the tasks completed by patients were used for analysis.

Results: Thirty-three patients (78.6% of those who were approached) consented to participate in the trial. Of those, 31 (93.7%) completed baseline surveys and were randomised to SAMSON (n=15) and control arms (n=16). Twenty-eight patients (90.3%) completed week-12 surveys (12 SAMSON and 16 control). Overall, patients rated SAMSON solution as highly acceptable (13/15; 86.7% app usage and 14/15; 93.3% MI teleconsultation delivery). They reported that SAMSON was easy-to-use (10/12; 83.3%) and helpful in improving their MA (6/12; 50%). All study HCPs reported the SAMSON solution was helpful in supporting patients' MA. Patients completed an average of 99 tasks over the 12-week study period (70.7% of scheduled tasks). Most patients (10/12; 83.3%) completed all five scheduled consultations. All study feasibility measures were higher than the predefined upper thresholds, except the rate of patients' responses to medication reminders.

Conclusions: The results demonstrated that the SAMSON solution is acceptable, usable, and useful for oncology HCPs and patients with cancer. The SAMSON solution is feasible in real-life oncology settings. Our next steps involve refining SAMSON solution based on participants' feedback, conducting a large-scale RCT to evaluate its clinical and economic effectiveness, and exploring potential commercialisation. Clinical Trial: ACTRN12623000472673

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This study aimed to test the acceptability, feasibility, and potential effects of SAMSON, a digital solution designed to support MA and self-management in cancer.

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This was a two-arm, unblinded, 12-week, pragmatic pilot randomized controlled trial (RCT). Adults who started oral cancer medicines for haematological malignancies within the last 12 months were recruited from a metropolitan specialised hospital. Participants were randomized 1:1 to either the SAMSON solution or the control arm to receive usual care. The SAMSON solution included a smartphone app which allows prompting individually tailored phone alerts and real-time self-care advice, a web-based dashboard for healthcare professionals (HCPs) to monitor patients' adherence and symptoms, alongside motivational interviewing (MI) teleconsultations delivered by oncology nurses and pharmacists scheduled after recruitment and at weeks 1, 4, 8 and 12, to support patient adherence and side-effect self-management. Primary outcomes were the patients' acceptance of SAMSON, measured by the Unified Theory of Acceptance and Use of Technology at 12 weeks, and study feasibility, measured by predefined rates of recruitment, randomization, retention, intervention adherence and outcome assessment completion. Secondary outcomes were comparison of MA and clinical self-assessments through online questionnaires, including adherence, toxicity self-

management, anxiety-depression-and symptoms, and quality of life, measured at baseline and 12 weeks between the two arms. Data retrieved from the SAMSON app on the tasks completed by patients were used for analysis.

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Thirty-three patients (78.6% of those who were approached) consented to participate in the trial. Of those, 31 (93.7%) completed baseline surveys and were randomised to SAMSON (n=15) and control arms (n=16). Twenty-eight patients (90.3%) completed week-12 surveys (12 SAMSON and 16 control). Overall, patients rated SAMSON solution as highly acceptable (13/15; 86.7% app usage and 14/15; 93.3% MI teleconsultation delivery). They reported that SAMSON was easy-to-use (10/12; 83.3%) and helpful in improving their MA (6/12; 50%). All study HCPs reported the SAMSON solution was helpful in supporting patients' MA. Patients completed an average of 99 tasks over the 12-week study period (70.7% of scheduled tasks). Most patients (10/12; 83.3%) completed all five scheduled consultations. All study feasibility measures were higher than the predefined upper thresholds, except the rate of patients' responses to medication reminders.

Conclusions

The results demonstrated that the SAMSON solution is acceptable, usable, and useful for oncology HCPs and patients with cancer. The SAMSON solution is feasible in real-life oncology settings. Our next steps involve refining SAMSON solution based on participants' feedback, conducting a large-scale RCT to evaluate its clinical and economic effectiveness, and exploring potential commercialisation.

Trial Registration

ACTRN12623000472673

Keywords: home-based cancer treatment; smartphone app; oral chemotherapy; patient safety; SAMSON

Introduction

Increasingly, cancer is being treated with self-administered medications [1, 2], often involving long and complex treatment regimens [2-4]. A patient's ability to adhere to medications throughout the treatment period is central to the successful delivery of self-administered anti-cancer regimens [5, 6]. However, medication adherence (MA) in cancer is low [7] and often decreases overtime [8]. For example, the MA rate in haematological cancers is varied between 6% [9] to 53% [10]. Improving MA in patients with cancer is crucial, as evidence shows that non-adherence is associated with low survival rates, disease progression, as well as increased healthcare utilisation and costs [6, 11, 12].

Given the importance of MA in cancer, there has been an increase in the number of MA interventions in recent times, especially digital interventions [13, 14]. With the boom of technology, for instance smartphones [15], digital health solutions promise more advantages in terms of improved clinical outcomes, cost efficiency, and they are increasingly accepted by patients [16]. However, evidence on the quality and effectiveness of available MA interventions in cancer survivors remains sparse [17, 18]. Our most recent systematic review showed that MA interventions that have multi-components, are theory- and evidence-based, rigorously designed and evaluated will more likely be effective [18].

Based on findings from literature review and the need to address medication non-adherence problem in cancer, we developed SAMSON (Safety and Adherence to Medications and Self-care advice in ONcology) – a multi-component digital solution to improve MA. The solution comprises two components: (1) a smartphone application (SAMSON app), involving individually tailored phone alerts and real-time advice for side-effect self-management [19] and an web-based interactive dashboard where patients can track their adherence performance and healthcare professionals (HCPs) can manage patients' profile, view their adherence performance and survey responses, manage their medication schedules and related

side-effects; to be used alongside with (2) a motivational interviewing training platform (MITP) to train healthcare professionals (HCPs) in motivational interviewing (MI) techniques to support patient adherence and side-effect self-management (manuscript under review). Individual components of the SAMSON solution were co-designed, rigorously developed based on evidence and largely informed by behavioural science research (BSR) and design science research methodology (DSRM), and then were tested on end-users, i.e. patients and HCPs [19]. We hypothesised that the combination of these two components, i.e. SAMSON solution, would be broadly acceptable to patients, practically feasible in a busy clinical practice, and potentially effective in improving MA for patients with cancer.

Methods

The CONSORT-eHealth checklist V1.6.1 [20] was used to report the present study (Multimedia Appendix 1).

Study Design

We aimed to test the acceptability, feasibility, and potential effects of the SAMSON solution on 30-50 patients with haematological cancer through a two-armed, unblinded, 12-week, pragmatic pilot randomized controlled trial (RCT) [21]. After providing written consent (Multimedia Appendix 2) and completing baseline questionnaires (Multimedia Appendix 3), participants were randomized to either intervention group (SAMSON solution) or control group (usual care) at 1:1 ratio. After 12 weeks, they completed end-of-study surveys (Multimedia Appendix 3).

Randomization

Using a computer-generated randomization chart, a permuted block randomization of size 4 was used to ensure an even balance of patients in each group throughout the study period. The allocation schedule was generated by a statistician who was blinded to the participants to

prevent any predictability when randomizing participants to intervention or control [22].

Trial registration, ethics, and oversight

The trial protocol was registered on the Australian New Zealand Clinical Trials Registry (ANZCTR) (#ACTRN12623000472673). A Steering Committee, including Chief Investigators, experts in the fields of digital health, information technology, nursing, pharmacy, psychology, and oncology, and a patients' representative, was formed to provide support for the study. This study was approved by the Human Research Ethics Committees (HREC) of Peter MacCallum Cancer Centre's (PMCC) (#HREC/95332/PMCC) and Swinburne University of Technology's (Swinburne) (#20237273-15836) (see Multimedia Appendix 4a and 4b). Patients reviewed study details and indicated their consent using e-consent forms. Patients were encouraged to contact the study team if they had any questions or concerns. Patients' personal and health information in the SAMSON app was encrypted in transit and is stored in a secure server at Swinburne. Study team access to patient's data on SAMSON web-based dashboard was password protected and limited to the research co-ordinator (RC) and four study nurses and pharmacists. All data analyses were conducted on de-identified data. Patients received a A$50 gift voucher if they completed all surveys in the study.

Patients and Eligibility

Patients were recruited from a metropolitan specialised cancer hospital in Melbourne, Australia, between August 2023 and February 2024. Eligible patients were adults (over 18 years old), diagnosed with haematological cancer, scheduled to commence oral anti-cancer medicines (OAMs) or commenced the medication for less than 12 months, willing to have OAMs dispensed at hospital for the duration of the trial, able to communicate in English, and had access to the internet, a smartphone/computer and/or telehealth.

Recruitment

Patients were identified by study site nurses, pharmacists or treating consultants, who were informed about the study and eligible criteria, then referred to the study RC for screening and comprehensive informed consent process, either in person or online, if they were interested in participating.

Intervention

SAMSON solution

Patients allocated to the intervention group received SAMSON solution in addition to their usual care at PMCC. They were instructed by the RC on how to install the SAMSON app on their smartphone and received log in details with protected password as well as SAMSON app user manual. Patients' personal and clinical information, such as diagnosis and treatment, extracted from the hospital's electronic medical record system (EMR), was entered in the SAMSON web-based dashboard by the RC and made available in the smartphone app.

In the first three days after enrolling in the study, patients received the initial structured tele-consultation (either via phone or telehealth) from a hospital clinical pharmacist previously trained in MI using the developed MITP. The initial consultation took 30-60 minutes, aiming to provide education on the OAM(s) that the patient received and the importance of adherence, support the patient in making decision on their medication taking schedule, and identify and document possible risks and barriers to MA.

Based on the agreed medication taking schedule, individualised daily medication reminders and weekly side-effects surveys were set up in SAMSON backend platform using the web-based dashboard user interface, so patients can receive them in the installed smartphone app. Medicine information and side-effects self-care advice, developed by experienced oncology pharmacists based on available reliable resources, clinician review and approved by PMCC's

HREC, were populated in the SAMSON backend platform using the web-based dashboard. Patients were asked to respond to daily medication reminders and weekly side-effects surveys, as well as review self-care advice in the smartphone app. Data on patients' adherence and drug toxicity collected through SAMSON solution were stored centrally on a secured server, then aggregated, analysed and uploaded onto the web-based dashboard, so that study nurses and pharmacist could monitor patients' adherence and symptoms. This data was also used by HCPs to tailor their tele-consultations with patients. Patients used the SAMSON app throughout the 12-week period of the study.

Patients also received maximum four follow-up structured tele-consultations (15-30 minute-length) with a clinical nurse previously trained in MI using the developed MITP, scheduled at weeks 1, 4, 8 and 12. The follow-up consultations aimed to check the patient's understanding of diagnosis, symptoms, self-care strategy and medications; further explore patient's facilitators and barriers to MA; motivate patient's adherence, strengthen their medication self-management skills, and change patient's non-adherence behaviour by using MI skills. The quantity and length of these consultations were tailored to the individual patient's need and adherence status.

Intervention nurses and pharmacists had more than five years of clinical experience in providing oncology care and successfully completed MI training via the MITP. They were also equipped with instruction manuals on how to conduct tele-consultation and use SAMSON web-based dashboard. Brief notes were produced and recorded in hospital electronic medical records, as well as sent to the patient at the end of consultation session.

Usual care

Patients who were allocated to the control group received usual care. The usual care at the hospital consisted of a clinician consultation, an initial in-person pharmacist consultation (often 5-10 minute-length), and a phone-call follow-up from a clinical nurse within 1-2 weeks

after commencing medication.

Measures

Overview

Demographic was completed at baseline (t_0). Patients' personal and clinical information were collected from the hospital EMR. The study's primary outcomes included the patients' acceptance of SAMSON, measured by the Unified Theory of Acceptance and Use of Technology (UTAUT) [23, 24] at 12 weeks (t_1), and study feasibility, measured by predefined rates of recruitment, randomization, retention, intervention adherence and outcome assessment completion [25, 26]. Secondary outcomes included MA, self-reported adherence, toxicity self-management, anxiety, depression and symptoms, and quality of life. Outcomes were assessed at baseline (t_0) and at the end of week 12 (t_1), except MA measured in week 16. All survey data collection (see Multimedia Appendix 3) was done through REDCap [27].

Primary outcome measures

Acceptability

The UTAUT questionnaire was adapted to assess determinants of HCPs' and patients' acceptance and use of the SAMSON solution, including five dimensions: performance expectancy, effort expectancy, social influence, facilitating conditions and behavioural intention [24]. Patients were asked to rate their satisfaction with SAMSON solution on a 5-point Likert scale. Participants were also invited to provide free-text feedback and suggestions on the solution.

Feasibility

A traffic light approach [28] (Table 1) was used to determine the feasibility success at three levels: feasible (above the upper threshold), infeasible (below the lower threshold), and protocol revision (between the two thresholds). The thresholds were defined in consultation

with the Steering Committee and based on literature of similar studies. Informal discussions with study personnel were attempted to obtain feedback on the feasibility.

[Table 1. Thresholds for traffic light approach to feasibility]

Secondary outcome measures

MA was measured by medication refill adherence (MRA) [29] collected from pharmacy dispensing data. MRA was defined as a percentage calculated from the total days' supply divided by the number of days of study participation and multiplied by 100. In this study, the patient was considered as optimal adherence if their MRA was ≥ 90%.

Self-report adherence was measured by Self-report Adherence (ASK-12) [30], which includes 12 items in three sub-scales: adherence behaviour, health beliefs and inconvenience or forgetfulness.

Toxicity Self-management was measured by Patient Activation Measure-Short Form (PAM-SF) [31, 32] - a 13-item self-report measure assessing the patient's knowledge, skills, and confidence in the self-management of their disease and related symptoms.

Anxiety, Depression and Symptoms were measured by Patient-Reported Outcomes Measurement Information System (PROMIS) [33] to assess depression, anxiety, pain interference, fatigue, sleep disturbance and physical function.

Quality of Life was measured by Functional Assessment of Cancer Therapy–General (FACT-G) [34], which is a 27-item self-report scale measuring quality of life of patients currently undergoing cancer treatment.

Analysis

Descriptive statistics were used to summarise participant characteristics across study arms, and differences in baseline attributes was assessed using t-tests or chi-squared as appropriate. SAMSON acceptability was analysed thematically. The UTAUT aims to examine individual quality dimensions, which means it is a suite of scales rather than one quality measure;

therefore, adding up the overall scale of the questionnaire is not suitable. Results of UTAUT surveys were summarised for each of the five dimensions with the percentage of patients endorsing Likert scale ratings of 3 (disagree, neither agree nor disagree, and agree). Free text answers to UTAUT questionnaires were narratively summarised to gain further insight into acceptability.

Feasibility was determined based on the traffic light approach. Recruitment feasibility was assessed by the number of patients recruited (consented) divided by the number of patients were approached to join the study. Randomization feasibility was assessed by the number of patients who were randomised divided by the number of patients who consented. Retention in both arms of the study was assessed by the number of patients who remain at the end of the study divided by the total patients who consented to join the study. We also tracked intervention adherence, e.g. percentage of patients completed tasks on SAMSON smartphone app and received MI teleconsultations. Compliance data for survey completion was calculated as percentage of patients completed surveys at t_0 and t_1 out of total patients in the study at these timepoints.

Secondary outcomes were analysed using linear regression. The dependent variable was the outcome at follow-up and the independent variables were arm assignment and the outcome at baseline. Standard checks for normality and homoscedasticity of residuals were conducted for each outcome. All analyses were conducted using StataNow 18 [35].

Results

Patient Characteristics

Among 42 patients who were approached, 33 (78.6%) consented to participate, and 31 (93.7%) completed baseline (t_0) surveys. Of those who completed baseline surveys, 3 patients (all from intervention arm) withdrew from the study (9.7 %) due to burden of the disease. All the remaining 28 patients (100%) completed week-12 surveys (12 intervention and 16

control) (Figure 1). Demographics are reported for patients who completed baseline surveys and were randomised (Table 2). The mean (SD) age of participants was 58.1 (13.7) years, 10 (32.3%) were female, 20 (64.5%) were born in Australia, 28 (90.3%) spoke English as their first language, 23 (74.2%) college educated and above, 25 (80.6%) lived in the metropolitan area, and 6 (19.4%) reported annual income equal or less than AU$ 20,000. There were no significant differences in participants' demographics between the two arms.

[Figure 1. CONSORT diagram of SAMSON pilot randomized controlled trial]

[Table 2. Participant demographics by arm]

Acceptability Results (Primary Outcome 1)

Thirteen intervention arm patients (86.7%) installed SAMSON app on their phone for use (two patients withdrew). All 15 patients in the intervention arm received the initial pharmacy teleconsultation. Fourteen patients (93.3%) received at least one nurse teleconsultation and 10 of them (66.7%) completed all four scheduled nurse teleconsultations.

Data retrieved from SAMSON app showed moderate engagement among participants. Patients completed an average of 99.1 app tasks (including responses to daily medication reminders and weekly side-effects surveys) over the 12-week study period, which accounted for 70.7% of scheduled tasks. A total of 36 severe episodes of symptoms were reported.

Twelve patients (80.0%) and three study HCPs (100%) completed the UTAUT surveys. A summary of patients' and HCPs' responses to the UTAUT questionnaire is presented below, with full details in Multimedia Appendix 5 and 6. Figure 2 presents patients' and HCPs' key opinions about the SAMSON solution.

[Figure 2. Patients' and HCPs' opinions about the SAMSON solution (n=12 and n=3, respectively)]

Performance expectancy

Half of patients (n=6) in the intervention arm reported that their MA could improve with the help of SAMSON solution. Patients used different MA-supporting mechanisms provided by

SAMSON solution, including prompting reminders (n=7; 58.3%), disease and treatment education (n=10; 83.3%), improving confidence in treatment (n=6; 50.0%), and improving side-effects self-management skills (n=9; 75.0%). Despite this, three patients (25.0%) found the SAMSON app component was not that helpful. Of those, two were using another commercial MA app with greater functionality. Some patients (n=4; 33.3%) reported functional issues of the app occurring in a short period of time (1-3 days), e.g. medication reminders were not delivered or responses to reminders were not saved properly.

Of three HCPs participating in the trial, two found the SAMSON solution useful in their job. All HCPs agreed that SAMSON could enable their two-way communication with patients which would increase their ability in supporting patient treatment adherence. However, one HCP suggested that the SAMSON dashboard's visual design could be improved to be more appealing. HCPs' comments on the time required for MI teleconsultations were controversial: some suggested that the scheduled time was good, while it was reported as quite long for another, which might be a constraint in clinical practice.

Effort expectancy

The SAMSON app was found easy-to-use by most patients (n=10; 83.3%). Its presentation was clear, and content was easy-to-understand (n=11; 91.7%). Most participants could easily navigate the app (n=10; 83.3%), yet one (8.3%) struggled in responding to surveys in the app. Some issues with the app's functionality were reported, for example, the medication reminders' time was not automatically updated after the day light saving time changed, and the app was frozen sometimes, which affect patients' responses to reminders.

All HCPs reported SAMSON quite easy to use. However, some issues with SAMSON web-based dashboard were reported, for example, it did not allow more than one HCP to monitor the patient, so all study HCPs had to share one account. Two HCPs found implementing MI consultations quite challenging in practice due to time constrains.

Social influence

Five patients (41.6%) thought that their family and friends would support their use of SAMSON, while most of them (n=10; 83.3%) thought that other patients with cancer would find SAMSON valuable. Almost all patients (n=11; 91.7%) desired SAMSON to be available for use in cancer hospitals.

All HCPs commented that their colleagues would find the SAMSON valuable and desire to receive hospital's support in implementing SAMSON in daily practice.

Facilitating conditions

Most participants were confident that they had adequate knowledge and resources (n=10; 83.3%) to use SAMSON and could access support when needed (n=9; 75.0%). Nevertheless, two patients (16.7%) reported their difficulties when dealing with some technical issues when using the app.

Despite all HCPs reported that they had adequate knowledge to apply MI techniques in teleconsultations, one (33.3%) wished to have more training resources on the SAMSON app.

Behavioural intention

Most patients (n=9; 75.0%) felt confident using SAMSON app. They would want to continue using SAMSON after the study finishes (n=8; 66.7%) or recommend it to their peers (n=7; 58.3%). The three patients (25.0%) who were using another commercial MA app with more functionalities would prefer to receive MI teleconsultations alone. Cost was reported as an important factor influencing the intention to use of SAMSON by majority of patients (n=8; 66.7%).

Regarding the open-ended questions in the UTAUT survey on experience and perception of SAMSON solution, patients valued the SAMSON smartphone app, because it was "*easy to use and prompted reminders*" (P31), "*placed all medication resources in one place*" (P16), "*informative and helpful*" (P25), and provided "*help quickly if [the patient has] any queries*"

(P30). The ‘side-effects’ tab within the app, providing self-care advice, was reported to make the patient “*feel more secure in managing medication regimens*” (P2), which could result in high adherence, as P7 commented “*I didn’t miss a dose*”. The number of teleconsultations, duration and quality were reported by most patients as good or “*perfect*” (P3), “*at the right length of time and allowed me [the patient] to ask all questions I need while allowing the nurse to gather all information*” (P2), except one mentioned it was “*too long*” (P31). Patients provided some helpful suggestions to improve the convenience of using SAMSON smartphone app, including fixing glitches, combining all medications scheduled at the same time in one reminder (rather than separate reminders), having more options for responding to reminders, and more attractive presentation.

Over 60% of study HCPs felt confident in delivering SAMSON to patients in the trial and would like to continue using it in the future. All of them would introduce the solution to their peers to use.

Feasibility Results (Primary Outcome 2)

The study recruitment rate was 78.6% (33/42). Most participants went through the information and consent process via phone, except four (33.3%) were recruited on site. The randomization rate was 93.9% (31/33). The retention rate was 84.8% (28/33). The RC conducted phone-call or in-person check-ups at least two times during the 12-week study. All recruitment, randomiszation and retention rates were higher than the upper threshold.

Thirteen intervention arm patients (86.7%) used the SAMSON app. The proportions of responses to medication reminders and side-effects surveys comparing to the scheduled tasks during the 12-week study period were 68.9% and 90.8%, respectively. The unmet threshold of responses to medication reminders could be due to the app’s functional issues as reported earlier. In total, 61 MI teleconsultations were delivered during August 2023 to June 2024, in which 35 (53.8%) were conducted on time as scheduled, 26 (40.0%) were later than

scheduled, and 4 (6.2%) were missed. The average length of initial pharmacy and nurse follow-up consultations were 40 and 21 minutes, respectively. Reasons for delayed and missed consultation sessions were mostly from patients: not showing up at the appointment (n= 25, 83.3%), not responding to HCP phone calls (n=4, 13.3%) or international travel (n=1, 3.3%). Only 2 sessions (6.7%) were delayed, because the HCP could not match their work schedule. Of 12 intervention arm patients who were retained until the end of the study, 10 (83.3%) received all five scheduled teleconsultations, one (8.3%) received four teleconsultations and one (8.3%) received two teleconsultations.

Baseline surveys were completed by 31 (93.7%) patients. All who stayed until the end of the study (n=28; 100%) completed week-12 surveys. Participants completed all surveys online without any need for support. An alert email was sent by RC to all participants a few days before the survey due date. However, over one-third of participants (n=10) only completed surveys after being reminded. Details of feasibility results are presented in Table 3.

[Table 3. Study feasibility results]

Preliminary Efficacy Results (Secondary Outcomes)

Medication refill adherence

Of 28 patients who completed the study, 25 (89.3%) had 100% adherence rate and 3 (10.7%) had over 95% adherence rate. There is no difference in the proportion of patients who had optimal adherence (MRA ≥90%) between the intervention and control groups (100% for both groups).

The mean and 95% confidence intervals (CI) of ASK-12, PAM-SF, PROMIS and FACT-G at baseline and week 12 are shown in Table 4.

[Table 4. Differences and change from baseline to week 12 between arms, ANCOVA test]

Discussion

In this study, we aimed to test the acceptability, feasibility, and preliminary efficacy of a multi-component MA solution, i.e. SAMSON, to help patients with cancer improve their adherence to OAMs and self-manage their physical and emotional symptoms. Overall, patients and oncology HCPs rated SAMSON as highly acceptable, usable, and useful. These high levels of user satisfaction evidence that the solution meet the various needs of support among patients with cancer to medically adhere to and manage side effects at home [36]; as well as the needs of oncology HCPs for a practical and tailored MI training, and a means to regularly monitor and provide ongoing support to patients' MA (manuscript under review). Moreover, qualitative findings suggest SAMSON has the potential to help patients in MA and symptoms' self-management, and to assist HCPs in monitoring and supporting patients' adherence. Results of the study help to address the gap of knowledge and the need in oncology practice [17, 18] by providing evidence on the high quality and potential effect of a digital multi-component MA solution.

Regarding SAMSON's feasibility, we noted a high level of engagement with the SAMSON solution by the overall tasks completed by patients on SAMSON smartphone app, and the MI teleconsultations completed by both HCPs and patients. The high acceptability and feasibility of SAMSON is a result of several factors. First, co-design and rigorous design framework were applied to develop SAMSON [21]. By involving end-users and stakeholders throughout all design stages of the intervention, co-designing helped to improve the solution's acceptability, desirability, and usability [37, 38]. The use of design frameworks, e.g. DSRM in this study, could enhance the artifact's design, which is crucial in digital intervention development, and improve its acceptance, usage and efficacy [39]. Furthermore, the design framework usage can improve the rigor and translatability of research, which is currently limited or poorly reported in the development of available MA interventions in cancer [18].

Second, after development, individual components of SAMSON were successfully tested by end-users on their acceptability, usability and usefulness [19] (manuscript under review). To the best of our knowledge, SAMSON is the first comprehensive digital MA solution in cancer that is co-designed, theory-based, evidence-based, and rigorously developed and tested.

Although overall acceptance and feasibility were relatively high, some HCPs and patients in the trial reported several technical issues with the SAMSON app and desired better visualisation, more functionality, and further instructions/training. This feedback will be used to further improve the solution in the future. A couple of study HCPs were concerned about the time required for MI consultations. Time constraint has been reported as one of the barriers to MI implementation in clinical practice [40]. It is noted that in this study, SAMSON was delivered as an add-on service on top of hospital's usual care, which required extra time and effort from already-busy HCPs. In addition, delivering MI consultations to promote adherence was a newly acquired skill by the study HCPs, thus, required more time to master this approach. A holistic approach, including hospital's mechanisms to provide continuous MI monitoring and training, as well as supports, both in terms of skills and resources, to facilitate and maintain HCPs' confidence and motivation in using this skill set can be a solution to tackle MI implementation barriers [40, 41].

The overall recruitment, randomization, retention, and data collection compliance rates were higher than the preset upper thresholds. High attrition rate is generally one of major concerns in digital health RCTs when comparing to RCTs testing more 'traditional' interventions [42]. However, the high recruitment rate and the low rate of loss to follow-up in this trial indicate that the SAMSON solution and online pragmatic RCT design are feasible in busy oncology clinical settings, as long as appropriate methodological strategies are applied. Specifically, in this study, clinical nurses and pharmacists from the Haematology department were recruited and funded to support study recruitment and deliver teleconsultations. The RC dedicated

additional time to build rapport with participants and consistently worked them through all processes of the trial (consenting, baseline assessment, randomization, app installation, technical training and support, and outcome assessments). In addition, different channels of communication, e.g. emails, phone calls, and SMSs were used to follow-up and motivate participants throughout the study. The importance of check-ups and follow-ups post randomization in trials of digital interventions, where participants are required to have certain levels of digital literacy to perform tasks of the intervention [43], have been emphasised in several studies [44]. Future digital trials may benefit from these recruitment and retention strategies.

In this trial, a combination of techniques was used to measure MA, including self-report measures and prescription refill reports. Although triangulation of measurements could improve the accuracy of adherence [45], its interpretation needs to be cautious. The MRA using pharmacy computer records, which is objective [46], does not guarantee that all dispensed medications were consumed by patients. The self-reported adherence (ASK-12) survey is simple, but often subjective and more about barriers to adherence than actual adherence status [30]. Future studies should consider to use high accuracy methods, such as Medication Event Monitoring System [5] to measure MA.

This study has some limitations. Like many digital health studies, our sample was predominantly Caucasian and highly educated [47, 48]. Consequently, the findings may not be representative of patients who are non-Caucasian or have lower socioeconomic status, who might face higher barriers to adherence and could potentially benefit more from the SAMSON solution than their Caucasian or higher socioeconomic status peers [49, 50]. Participants were recruited from the Haematology department at PMCC, one of Australia's leading oncology hospitals, and were prescribed only one oral anti-cancer regiment. Therefore, the results may not be generalisable to those who use multiple anti-cancer

medications or receive care in low-resource oncology settings. A more targeted recruitment strategy focusing on underserved cancer patient populations with other types of cancer in various levels of oncology care institutions is warranted.

Conclusion

Before undertaking this pilot trial, both components of the SAMSON solution were co-designed and developed based on evidence and theory, then individually tested on target users. The results of this study confirmed that SAMSON is acceptable, usable, and useful for both HCPs and patients with cancer. Both the SAMSON solution and the pragmatic RCT design are feasible in real-life oncology settings. These findings are very encouraging, given numerous challenges in applying RCT as an evaluation design for digital health interventions [51]. Our next steps will involve refining SAMSON solution based on participants' feedback from this study and conducting a full RCT to evaluate its clinical and economic effectiveness.

Author Contributions

(name withheld from review) is submitting and corresponding author. (name withheld from review) conceived of the study, its design, coordination and implementation, and drafted the manuscript. (name withheld from review) were involved in study design and protocol development. (name withheld from review) were involved in literature review and developing study instruments and materials. (name withheld from review) supported patient recruitment and delivered motivational interviewing tele-consultations. (name withheld from review) assisted collecting medication refill data. (name withheld from review) contributed to the design of the statistical analysis approach. (name withheld from review) analysed the data in consultation with (name withheld from review). All authors involved in providing a critical review of the manuscript. All authors read and approved the final manuscript.

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Authors' Disclosures of Potential Conflicts of Interest

None declared.

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Abbreviations

ANZCTR	Australian New Zealand Clinical Trials Registry
ASK-12	Self-report adherence
BSR	Behavioural science research
DSRM	Design science research methodology
EMR	Electronic medical record

FACT-G	Functional Assessment of Cancer Therapy–General
HCP	Healthcare professional
HREC	Human Research Ethics Committees
MA	Medication adherence
MI	Motivational interviewing
MITP	Motivational interviewing training platform
MRA	Medication refill adherence
OAM	Oral anti-cancer medicine
PAM-SF	Patient Activation Measure-Short Form
PMCC	Peter MacCallum Cancer Centre
PROMIS	Patient-Reported Outcomes Measurement Information System
RC	Research coordinator
RCT	Randomized controlled trial
SAMSON	Safety and Adherence to Medications and Self-care advice in ONcology
Swinburne	Swinburne University of Technology
UTAUT	Unified Theory of Acceptance and Use of Technology

Appendices

Multimedia Appendix 1. CONSORT-eHealth checklist V1.6.1

Multimedia Appendix 2. Participant information statement and consent form

Multimedia Appendix 3. Survey booklet

Multimedia Appendix 4. Ethics' approvals

Multimedia Appendix 5. UTAUT results of patient participants

Multimedia Appendix 6. UTAUT results of HCP participants

Data Availability

The data sets generated and analysed during this study are not publicly available but are

available from the corresponding author on reasonable request.

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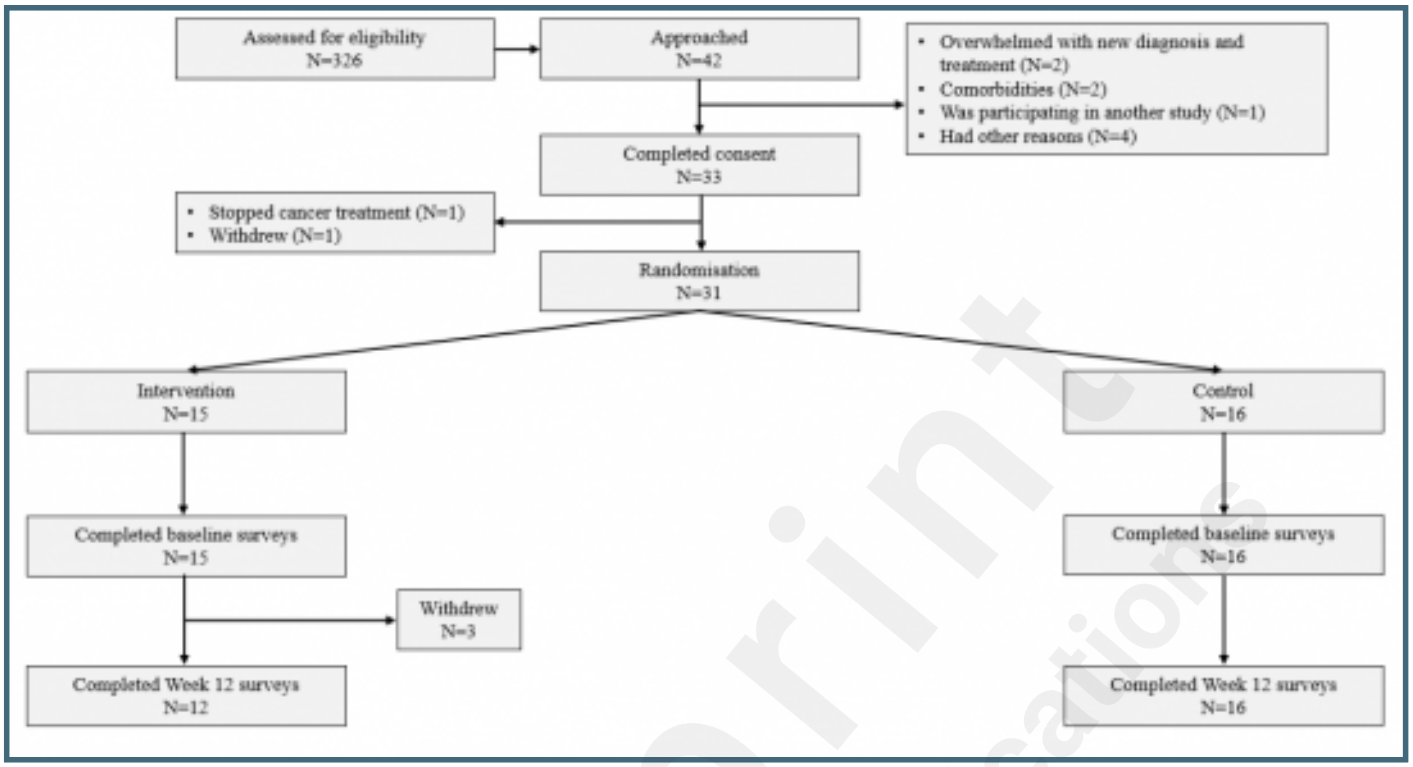
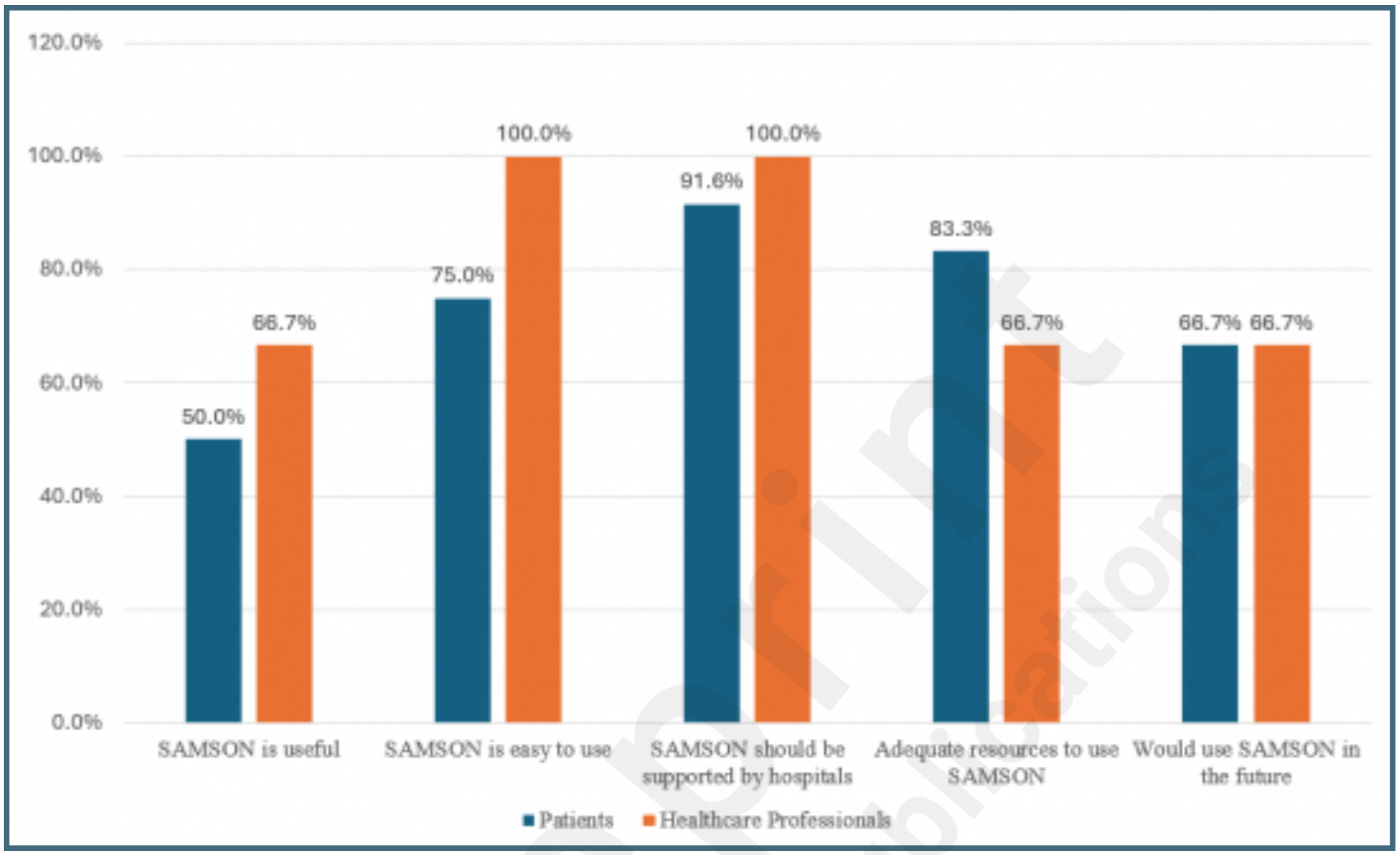
Supplementary Files

Figures

CONSORT diagram of SAMSON pilot randomized controlled trial.



Patients' and healthcare professionals' opinions about the SAMSON solution (n=12 and n=3, respectively).



Multimedia Appendixes

Table 1. Thresholds for traffic light approach to feasibility.
URL: http://asset.jmir.pub/assets/2ebb5ad6e9672c3874f19e05f31094a9.docx

Table 2. Participant demographics by arm.
URL: http://asset.jmir.pub/assets/4d807297135c722932194aa3248f833b.doc

Table 3. Study feasibility results.
URL: http://asset.jmir.pub/assets/c529dd02d790650cfee542fdf4f68df7.docx

Table 4. Differences and change from baseline to week 12 between arms, ANCOVA test.
URL: http://asset.jmir.pub/assets/270be8e3b6f7a6699ef35ec59751c280.docx

Participant information statement and consent form.
URL: http://asset.jmir.pub/assets/d04e3d7ac30a0fe0ce0e555306efcf09.docx

Survey booklet.
URL: http://asset.jmir.pub/assets/d90101a0468e1d1e3212261c0164ba60.docx

Ethics' approvals.
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Ethics' approvals.
URL: http://asset.jmir.pub/assets/330c3854bb297fb9aa3c8b369a1683ae.pdf

UTAUT results of patient participants.
URL: http://asset.jmir.pub/assets/2f3de1f693834a3af7bd1cc8e07b10d5.docx

UTAUT results of HCP participants.
URL: http://asset.jmir.pub/assets/8a931141a4dda780f94aeddbeb8674f7.docx

CONSORT (or other) checklists

Multimedia Appendix 1. CONSORT-eHealth checklist V1.6.1 .
URL: http://asset.jmir.pub/assets/daacc41856db28429763d8dd5fc3606b.pdf