Neuropsychiatric Disease and Treatment

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ORIGINAL RESEARCH

A Novel Digital Intervention to Facilitate Diabetes Self-Management Among People with Schizophrenia and Related Disorders: Development and Acceptability Testing of SMART

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Introduction: Compared with the general population, people with schizophrenia and schizophrenia-related disorders (SSD) have a higher prevalence of type 2 diabetes (T2D) and T2D risk factors such as poor diet and sedentary lifestyle. Antipsychotic drugs significantly contribute to this risk through metabolic adverse effects, including weight gain and insulin resistance. Prevention and self-management of T2D is challenging in this population due to inherent motivational and cognitive challenges associated with schizophrenia. The objective of this study was to describe the co-design and test the feasibility, acceptability, and usability of a novel digital health intervention, Schizophrenia and diabetes Mobile-Assisted Remote Trainer (SMART), for prevention and self-management of T2D in people with SSD.

Methods: SMART was developed through an iterative process including review of relevant literature (eg, disease-specific guidelines), stakeholder involvement, and user testing. A pre-post mixed-methods design was used to assess the acceptability and feasibility of SMART over 4 weeks among five outpatients with schizophrenia/schizoaffective disorder and pre-diabetes/T2D.

Results: The co-design process resulted in a digital intervention, which consisted of personalised, interactive text messages, providing psychoeducation and strengthening motivation for self-care behaviours that promote effective diabetes self-management (ie, nutrition, physical activity, weight management, and stress coping). The pilot study demonstrated good acceptability of SMART (response rates 75–95%). Trends towards improved clinical outcomes were observed in well-being, depression, anxiety, and mental health recovery. Barriers to usability included lack of mobile/internet data, precluding the ability to reply to text messages, and a preference for more hyperlinks and additional interactive features.

Conclusion: The comprehensive co-design process resulted in the development of a novel digital intervention for prevention and self-management of T2D tailored to unique needs and preferences of people with SSD. The pilot study findings indicate that SMART is acceptable and potentially usable for this population. Results will inform further adaptation and a future feasibility study to examine preliminary effectiveness of SMART.

Keywords: eHealth, mHealth, psychosis, SMS, mobile phone, metabolic syndrome, mental health interventions, diabetes, self-management

Received: 6 January 2025
Accepted: 4 June 2025
Published: 26 June 2025

Introduction

Compared with the general population, people with schizophrenia and schizophrenia-related disorders (SSD) are 1.85-times more likely to develop Type 2 Diabetes (T2D).[1] This inequality is due to a higher prevalence of risk factors like obesity,[2] sub-optimal diet, and sedentary lifestyle,[3] which is further compounded by socio-economic factors that impede healthy lifestyle choices.[4] Antipsychotic drugs significantly contribute to higher T2D risk through severe metabolic adverse effects, including weight gain, dyslipidaemia, and insulin resistance.[5] Second-generation antipsychotics such as clozapine, which is one of the most effective ones and used for treatment-resistant schizophrenia, are associated with the greatest metabolic disturbance and have a particularly strong propensity for weight gain,[6] prompting the use of add-on medications to attenuate this gain.[7] Despite the prevalence and burden of T2D in this population, it remains vastly undertreated. This is due to lack of patient education, limited access to general healthcare, inadequate referral to specialist care,[8] multimorbidity and less opportunity for cardiovascular risk screening and prevention.[9]

Self-management education is crucial for the prevention of secondary, short- and long-term micro- and macro-vascular complications associated with T2D. While effective self-management support interventions are vital in provision of high-quality care for long-term conditions like T2D,[10] they are not offered routinely within mental health settings.[10] Further, traditional self-management support has been provided in person, which may not be convenient for people experiencing motivational and cognitive challenges associated with severe mental illnesses (SMI) such as schizophrenia.[11] The rare existing digital self-management interventions, however, are aimed at reducing psychosis symptoms and have low engagement in real-world settings.[12] Low engagement likely indicates poor alignment with user preferences, highlighting the need for early engagement of consumers when developing novel health technologies.[13] Despite low engagement, recent systematic reviews demonstrate that the use of mobile phone technologies is feasible and acceptable for people with SMI.[14,15]

Mobile health (mHealth)—delivered via mobile phone technologies, including smartphone apps and Short Message Service (SMS) text messages—is a cost-effective and highly accessible approach to improving consumer experiences and health outcomes,[16] and has been associated with improved illness self-management among people with T2D,[17] those with SMI,[18] and schizophrenia specifically.[14,15] External prompts and behavioural nudges through apps and text messages can provide useful reminders for people with SSD[19] who experience challenges relating to executive functioning[20] which can impact glucose monitoring, remembering to take medications, and making healthy lifestyle choices, and consequentially, undermine effective glycaemic control. Texting interventions delivered among people with SSD have been found to improve medication adherence immediately post-intervention[21,22] and at follow-up,[21] with electronic monitors used to improve medication adherence as well.[23] Further, smartphone apps have also been used with people with SSD to target more complex outcomes, such as relapse prevention,[24] social functioning,[25] and psychosis symptoms.[26,27] Despite these technological advances and mHealth being an acceptable delivery format for people with SSD,[28] there are limited prevention and treatment options targeting metabolic health in this population. As such, this study aimed to co-design a digital intervention titled Schizophrenia and diabetes Mobile-Assisted Remote Trainer (SMART). SMART presents a simplified, SMS-enabled solution of a Mobile Diabetes Management System[29,30] which was found effective for improving diabetes self-management in the general population.[30] While the Mobile Diabetes Management System is a complex, cloud-based monitoring system, the co-design process of the SMART intervention indicated that a delivery via automated, interactive and tailored text messages to be implemented as an add-on to usual care was preferred for this unique population. This paper outlines the development of SMART through four stages: (Stage 1) review of relevant empirical, clinical, theoretical evidence and guidelines; (Stage 2) stakeholder involvement; (Stage 3) user testing; and (Stage 4) 4-week pilot testing of the SMART intervention using uncontrolled, mixed-method design.

Methods

The development process of SMART (depicted in Figure 1) was informed by recommendations on developing mHealth programs[31] and the Medical Research Council Framework for the development and evaluation of complex health interventions,[32–35] as per our previous self-management intervention development work among people with SMI.[33,36]

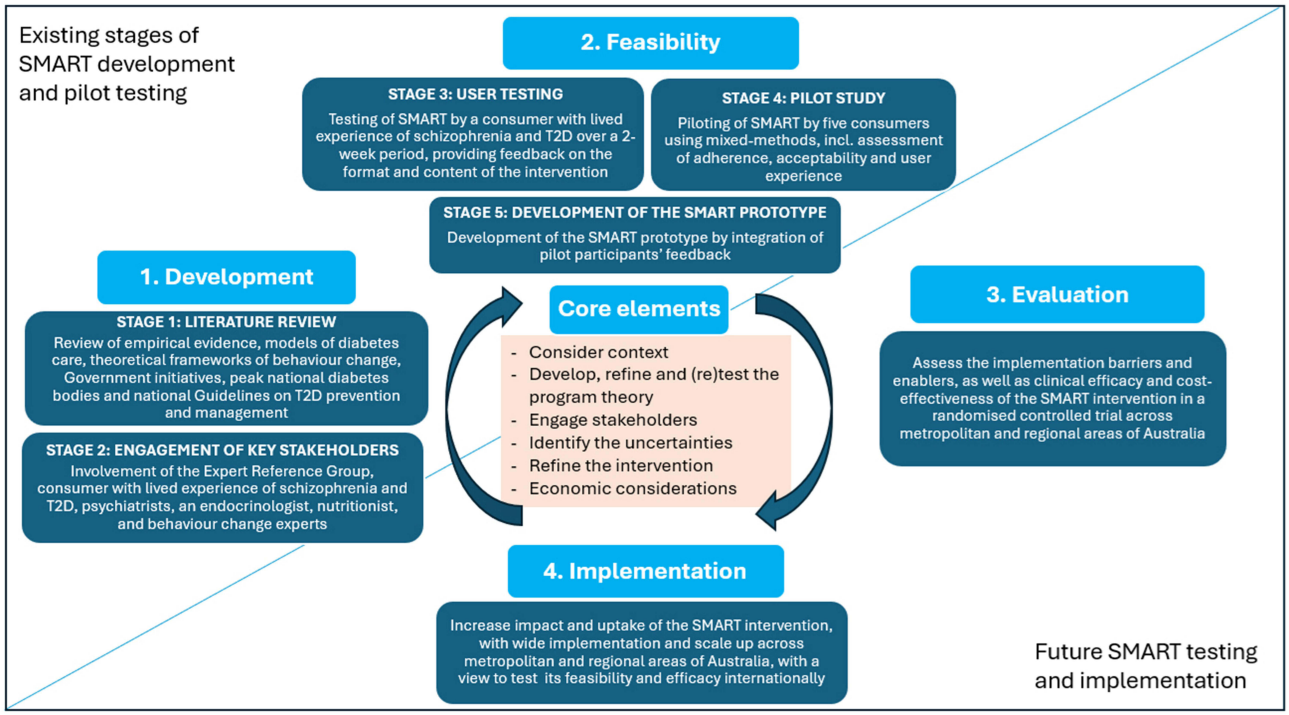

Figure 1 Stages of SMART Development and pilot testing.

Stage 1: Review of the Literature

Scoping Review: Empirical Research

The review of empirical literature of digital interventions for behaviour change among people with SSD was conducted in September 2023 and identified six studies that assessed the efficacy of interventions delivered via text messages on various health behaviours.[21,37–41] The findings of these studies showed that text messaging was able to improve medication adherence,[21] clinical symptoms,[37] and appointment adherence,[40] however, no identified studies targeted improvement of metabolic health, including diabetes self-management, in people with SSD. We, therefore, looked for studies that used text messaging to improve health in the general population, including for management of diabetes type 1,[42] T2D,[42,43] and cardiovascular risk factors (eg, physical activity and smoking) in people with coronary heart disease.[44] Combined, these studies informed the delivery of the SMART text messages, including the length, language, and frequency of text messages, as well as their interactive and personalisation features.

Behaviour Change Techniques and Theoretical Underpinnings

We used the behaviour change technique (BCT) taxonomy (V1)[45] which defines 93 distinct BCTs as the smallest active intervention ingredients to select and embed relevant techniques, which incorporated mechanisms of change within the text messages. Embedding specific mechanisms of change within the text messages was based on several reviews which identified BCTs that are effective in managing diabetes[46,47] and promoting health behaviour change, specifically smoking cessation,[48] physical activity,[49] and healthy eating,[49] in the general population. Other reviews provided suggestions for effective BCTs for health behaviour in individuals with chronic health conditions[50] and SMI.[51] A synthesis of these studies' findings informed the selection of a variety of BCTs (eg, goal setting, action planning, social support) included in each text message of the SMART intervention.

Additionally, wording of the messages was grounded in two theoretical models: The Social Cognitive Theory (SCT)[52] and Self-Determination Theory (SDT).[53] The SCT was chosen because of its utility in guiding prevention of various health behaviours, and particularly its focus on increasing an individual's autonomy and capacity for behaviour change through key concepts such as self-efficacy, behavioural capability, and reinforcements (promotion of incentives and benefits of behaviour change). The SDT, on the other hand, was embedded in the messages to strengthen an individual's intrinsic

motivation for behaviour change, based on prior evidence demonstrating that autonomous forms of motivation are associated with positive health outcomes in people with SMI[54] and may be particularly instrumental in people with SSD.[11]

Models of Diabetes Care

The content of text messages was also informed by ADCES7 Self-Care Behaviors™ (ADCES7), a model of diabetes care and education developed by the Association of Diabetes Care and Education Specialists.[55] ADCES7 is an evidence-based framework for self-management of diabetes and other related conditions (eg, prediabetes and cardiometabolic diseases) and achieving behaviour change that can lead to effective self-management through improved behaviour and clinical outcome measures. The self-care behaviours within the ADCES7 include problem solving, reducing risks, monitoring, taking medication, healthy eating, being active and healthy coping. The inner-ring (core) behaviours of healthy stress coping, healthy eating, and being active, directly informed three of the core module topics of the SMART intervention. The middle-ring behaviour of monitoring was incorporated into one of the optional modules of SMART, blood glucose monitoring, and was also utilised more generally, across other modules (eg, monitoring of weekly physical activity). The remaining three outer-ring ADCES7 behaviours (ie, taking medication, problem solving, and reducing risks associated with T2D complications), however, were not considered critical to people with SSD as confirmed through a consultation process with a consumer living with schizophrenia and T2D and our Consumer Reference Group.

National Guidelines and Other Clinical Recommendations

The content of the SMART text messages was further informed by educational resources developed by the diabetes consumer organisation body, Diabetes Australia,[56,57] and the recommendations of the Australian National Diabetes Strategy, which is aligned with the international policy, including the Global Action Plan for the Prevention and Control of Non-Communicable Diseases and the Global Monitoring Framework for Non-Communicable Diseases, developed by the World Health Organization (WHO), and the WHO Global Diabetes Compact. Clinical recommendations for management of T2D,[58] the national or state guidelines for healthy eating,[59] physical activity,[60,61] and smoking cessation[62–64] were also incorporated.

Outcomes of Stage 1

Stage 1 informed both the content and the general structure of the text messages. As such, the messages consisted of: (1) information on diabetes self-management; followed by (2) a question relating to the text message topic; with (3) text message respond options being "yes", "no", and "unsure" ("yes" most often indicated a positive stand or confidence towards behaviour change and "no"/"unsure" an absence of health behaviour or uncertainty about implementing behaviour change); and (4) an autoreply text message specific to "yes" and "no"/"unsure" responses.

Stage 2: Stakeholder Involvement

Stage 2 of SMART development integrated input through a multi-phase iterative process. Input and feedback were sought from an Expert Reference Group consisting of psychiatry (n = 3), endocrinology (n = 3), psychology (n = 4), indigenous primary healthcare (n = 1), dietetics (n = 1), software engineering (n = 2) and clinical trials nursing (n = 1). Additional feedback was sought through two face-to-face consultations with a consumer with lived experience of schizophrenia and T2D, two clinicians with extensive experience treating individuals with SSD (DS and NK), and two researchers with expertise in behaviour change, particularly the BCT taxonomy (KM and SH). Two behaviour change experts were provided with a working version of the text messages and asked to identify in each message the BCTs that, in their view, were the intended drivers of behaviour change used in a text message. As such, both experts were blinded to the specific BCTs incorporated within each text message and were consulted individually. The feedback on the intended BCTs was first provided by one expert; the overall agreement rate in the BCTs between the intended and the identified text messages across all modules was 80%. Subsequently, the updated text messages were sent to the second expert; this time, the overall agreement rate in the BCTs was 77%. Any discrepancy between the intended BCT and the BCT identified by the experts were discussed to reach a consensus. Example text messages with the underlying BCTs are outlined in Table 1.

Table 1 Example Text Messages and Underlying Behaviour Change Techniques (BCTs) of the SMART Intervention

Module	Text Message Example	Underlying BCT
Physical Activity	Many people find that when they plan exercise into their day, they feel more motivated to do it. Do you plan your workouts in advance?	1.4 Action planning
Nutrition	Had enough water today? Keep a water bottle handy and sip on it throughout the day.	1.2 Problem solving
Weight Management	I am sure you have been told before that limiting junk food like potato chips and soft drinks is an important tip for managing your weight long-term. Can you set a goal to remove these foods at your next meal?	1.1 Goal setting (behaviour)
Stress Coping	Over the last 2 weeks or so, have you felt down, sad, or unhappy, or lost interest in things you used to enjoy?	5.6 Information about emotional consequences
Blood Glucose Monitoring	Do you feel confident you have support around you to help with keeping track of your blood sugar?	3.1 Social support (unspecified)
Smoking Cessation	There are lots of different ways to quit smoking or vaping like going cold turkey or gradually cutting down. Do you know what quitting method would work for you?	11.1 Pharmacological support

Outcomes of Stage 2

After stakeholder consultation, a bank of 97 text messages was finalised. Particular attention was given to addressing consistent feedback provided by the Expert Reference Group ensuring that the text messages are informal (use of emojis and casual language), brief (links to more information if interested), and simple (only one action/question per message). Readability level was checked to ensure that all text messages received a Flesch Reading Ease score ≤70. This was to confirm that the language used had a readability equivalent to grade VI level (in Australia, this is completed at 11–12 years of age) which is consistent with the recommended level for all health communication.[65] Further, based on the discussions with a lived experience representative, the intervention was modified to increase its usefulness for this population (feedback and actions taken in response to the consumer sessions are outlined in Supplementary Table 1).

Technical systems held by the Australian Commonwealth Scientific and Industrial Research Organisation (CSIRO) enabled the storage of the text messages and the collection of user responses and engagement data. The software for the distribution of text messages was built specifically for the purposes of this study by a software engineer (DI), with the SMS solution being deployed within a project-specific AWS VPC managed by CSIRO, designed to maximise security of operational and collected data. As per the Australian Privacy Principals, only the minimum data set required (first name and mobile number), were collected, stored and will be destroyed in accordance with the CSIRO destruction policy at completion of the study. In addition, privacy and Cyber Security assessments will also be performed.

Stage 3: User Testing (SMART Prototype)

In Stage 3, a consumer with lived experienced of SMI and T2D trialled the text messages for 2 weeks to further refine the SMART intervention prior to the pilot study. Overall, the feedback provided by the consumer was positive, and they felt that the messages increased their awareness about healthy lifestyle changes, but that it was too early to say whether there were any specific changes (no assessments were conducted at this stage). For details of this feedback see Supplementary Table 2.

Stage 4: Pilot Study

Study Design

We used a mixed method, pre-post, uncontrolled study design to pilot test the acceptability of the SMART intervention over 4 weeks.

Eligibility Criteria

Eligibility criteria included: aged 18 years or older; diagnosis of schizophrenia or schizoaffective disorder, diagnosis of T2D, pre-diabetes, or metabolic syndrome; able to use a mobile phone; and to provide consent and read/understand

English. The study was conducted in accordance with the principles outlined in the Declaration of Helsinki, with ethical approval obtained by the Metro South Human Research Ethics Committee (HREC/2023/QMS/100469).

Recruitment

Participants were recruited from an outpatient endocrinology clinic embedded in the Metro South Addiction and Mental Health Services (MSAMHS) through referrals from their treating MSAMHS endocrinologist (PJ) who identified potential participants based on the study inclusion criteria. Following the receipt of a referral, research staff contacted the potential participant to gauge their verbal consent and organise a face-to-face meeting, where individuals were provided with detailed information regarding the study and conducted the screening/eligibility assessment and provided written consent. Participants were reimbursed for their time with two $50 gift vouchers (one for baseline and one for endpoint assessment).

Measures

The primary outcome was acceptability, assessed via: (1) attrition (number of participants who completed the study vs those who dropped out); (2) adherence (number (%) of response text messages/week); and (3) user experience (System Usability Scale [SUS]; a 10-item questionnaire used to measure the perceived usability of a system or product with a 5-point response scale).[66] Based on the average SUS score across 500 previous studies,[67] the following grading of raw SUS scores was developed and also applied in the current study: Grade A (score >80.3; meaning above average); Grade B (score 74–80.2, higher perceived usability than 70% of all other products tested); and Grade C (score 68–73; average usability). Further, based on cut-offs used in previous studies using digital interventions in people with SSD,[68,69] "good adherence" was defined as responding to at least 50% of all text messages over the study period, whilst "acceptable adherence" described a minimum of 33% response rate.[70]

Several additional outcome measures (see Supplementary Table 3) were also assessed at baseline and 4-week endpoint, including: physical health variables (ie, blood pressure; waist circumference; weight; height; body mass index; blood glucose monitoring), diabetes Skills, Confidence and Preparedness Index (SCPI);[71] Patient Activation Measure (PAM-13);[72,73] Simple Physical Activity Questionnaire (SIMPAQ);[74] Five-a-day Community Evaluation Tool (FACET);[75] and Pittsburgh Sleep Quality Index (PSQI);[76] mental health symptoms (Positive and Negative Syndrome Scale; PANSS);[77] Global Assessment of Functioning (GAF);[78] and Depression Anxiety Stress Scales (DASS-21);[79,80] Health Literacy Questionnaire (HLQ);[81] quality of life (Short Form Survey-36; SF-36[82]); mental health recovery (Recovery Assessment Scale–Domain and Stages; RAS-DS[83,84]); stage of behaviour change; and nutrition and physical activity self-efficacy.[85]

For the purposes of describing the characteristics of sample participants, we also gathered demographic data and screened the following cognitive capacities: (1) visual attention and task switching, using the Trail Making Test (TMT);[86] (2) episodic verbal learning and memory, using the California Verbal Learning Test Brief Form (CVLT3);[87] (3) visuospatial constructional ability, using the Rey Complex Figure Test (RCFT);[88] and (4) visuospatial planning using the Tower of London (ToL) from the Brief Assessment of Cognition in Schizophrenia (BACS).[89]

After using SMART for four weeks, qualitative semi-structured interviews were conducted with participants face-to-face to explore experiences of the intervention, specifically, their perceived usefulness of the text messages and any suggestions for intervention improvement. This interview included an adapted, short version of three measures evaluating the implementation of the intervention, including Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM).[90]

Intervention and Procedure

The piloted SMART intervention, delivered via text messages, incorporated four core modules, targeting nutrition, weight management, physical activity, and stress coping, and two optional modules that targeted smoking/vaping cessation and blood glucose level monitoring. The text messages were stored and distributed through a purposefully built software, held by CSIRO, which also collected user responses and engagement data. The content of the messages was informed by SCT and SDT, as described in previous section, with the BCTs embedded in each message based on the BCT Taxonomy (V1).[45] More detailed information about the intervention is provided in previous section, describing its development.

Following consumer preferences, the SMART intervention was designed to accommodate for personal preferences through personalisation, support an individual's autonomy, and use non-judgemental and motivating language (an example of a text message depicting these features is provided in Figure 2).

Personalisation

Each person was offered the option to select a preferred time of day to receive the message and the text-messages included the recipient's preferred name. At baseline, participants were also asked to rank the four core modules in order of importance for their health. The ranking informed the number of the text messages they would have received; modules ranked 1st and 2nd were allocated two text messages and modules ranked 3rd and 4th were allocated one text message per week (total six per week). An extra text message was sent each week for any of the two additional modules if these were chosen. Further, at week 2, the research staff phoned each participant to enquire if they experienced any technical issues and whether they would like to change their rankings.

Two-way interactive nature: Participants could reply to text messages with either YES, NO, or UNSURE, with their response prompting an automatic reply, which was distinct for "Yes" and "No/Unsure". Most of the response text messages included a hyperlink to a website relevant to the message content (eg, recipes for healthy diet). In case of no reply, an automatic response was sent after 3 hours encouraging the participant to respond. If a participant did not respond to any of the text messages for three consecutive days, an automated alarm message was sent via Email to the researchers who would then call the participant to enquire about the reasons for non-responding.[91]

Statistical Analysis

For the quantitative data, total scale and subscale scores were aggregated at a group level, and their characteristics depicted through descriptive statistics. No inferential statistical tests were conducted due to lack of power to show a significant difference. Descriptive statistics for all assessments across measurement points are reported in Table 2. The qualitative data obtained through recorded interviews was transcribed verbatim and thematically analysed (by RS) using an inductive approach[92] in collaboration

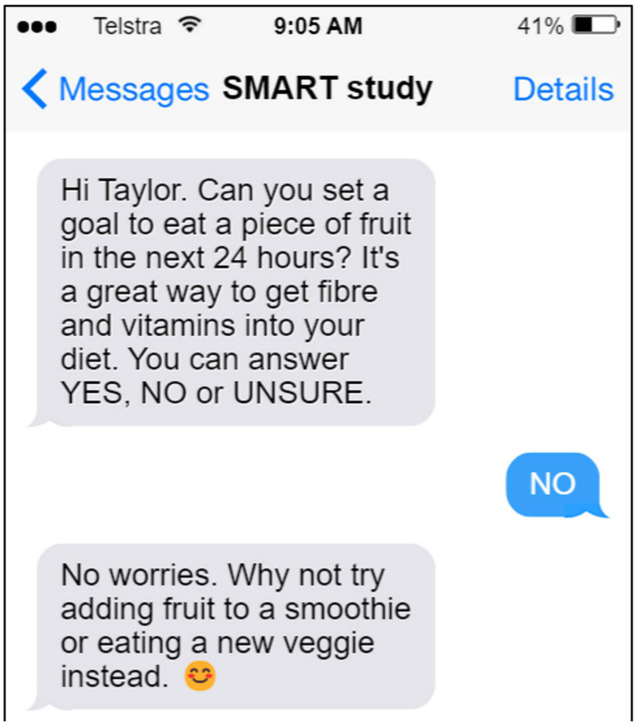

Figure 2 An example of a text message with a reply option "No" and an automatic response of the SMART intervention.

https://doi.org/10.2147/NDT.S513272

Table 2 SMART Pilot Physical Health and Clinical Characteristics at Baseline and 4-week Endpoint (n = 5)

Variables Related to Physical and Mental Health	Baseline		4-Week Endpoint	
	M	SD	M	SD
Physical health indicators				
Weight (kg)	99.34	27.29	99.34	28.36
BMI	33.28	7.06	33.28	7.42
Waist circumference (cm)	116.40	18.84	116.00	19.58
Hip measurement	117.40	21.66	115.40	19.01
Hip waist ratio	1.00	0.03	1.00	0.01
Blood Pressure - Sitting Systolic	124.00	11.94	122.00	13.04
Blood Pressure - Sitting Diastolic	77.60	5.60	77.60	10.90
Cigarettes per day	10.00	14.14	10.00	14.14
Mental health indicators				
PANSS				
Total PANSS score	55.60	12.34	55.60	8.08
Positive subscale	15.00	7.71	13.60	5.86
Negative subscale	13.00	1.73	14.40	2.30
General Psychopathology subscale	27.60	4.51	27.60	2.70
GAF				
Total score (past 2 weeks)	55.00	9.33	55.00	8.66
SIMPAQ				
Sedentary time (hours) per day	8.00	3.08	9.80	2.49
Total MVPA (hours) per week	322.00	331.39	264.00	288.84
FACET				
Total fruit and vegetable intake	4.80	2.78	4.20	1.92
Total fruit intake	3.00	1.87	2.40	1.95
Total vegetable intake	1.80	1.64	1.80	1.79
SF-36 component scores and subscales				
Physical component score	66.50	18.20	72.88	21.57
Mental component score	58.45	9.46	67.88	18.10
Physical functioning	76.00	20.74	78.00	27.52
Role limit. due to physical health	70.00	32.60	80.00	32.60
Role limit. due to emotional problems	40.00	14.91	73.33	27.89
Energy/Fatigue	54.00	10.25	54.00	12.94
Emotional well-being	72.80	13.39	71.20	23.73
Social functioning	67.00	24.33	73.00	30.99
Pain	69.00	22.26	74.50	26.01
General health	51.00	10.84	59.00	7.42
PSQI				
Subjective Sleep Quality Total score	0.60	0.55	1.00	0.71
Daytime Dysfunction Total score	1.20	0.84	0.80	0.45
DASS-21				
Total Depression score	10.40	10.43	8.00	8.83
Total Anxiety score	7.20	7.82	6.40	6.54
Total Stress score	10.80	9.12	10.40	9.94
SCPI				
Skills subscale*	5.70	0.57	5.90	0.71
Confidence subscale*	5.60	0.42	5.90	0.28
Preparedness subscale*	6.35	0.21	6.65	0.50
Total score*	5.90	0.28	6.15	0.07

(*Continued*)

Table 2 (Continued).

Variables Related to Physical and Mental Health	Baseline		4-Week Endpoint	
	M	SD	M	SD
Health literacy				
HLQ domain 3 score	2.80	0.49	2.64	0.70
Self-efficacy				
Nutrition Total score	16.00	2.00	15.20	1.64
Physical Activity Total score	12.80	2.95	11.60	2.88
PAM-13				
Total Raw score	40.20	4.97	39.80	4.21
Total Calibrated score	58.90	11.67	57.84	9.84
RAS-DS				
Domain 1 score**	17.00	4.69	17.40	2.97
Domain 3 score**	16.60	4.62	20.20	4.38

Notes: *SCPI was only administered among participants with diagnosed T2DM (n = 2). **Domain 1 referred to Doing things one enjoys, while Domain 3 referred to Mastering own illness.

Abbreviations: BMI, Body Mass Index; SD, standard deviation; SF-36, Medical Outcomes Scale Short Form-36; PANSS, Positive and Negative Syndrome Scale; GAF, Global Assessment of Functioning; MVPA, moderate-to-vigorous physical activity; PSQI, Pittsburgh Sleep Quality Index; SIMPAQ, Simple Physical Activity Questionnaire; FACET, Five-a-day Community Evaluation Tool; DASS-21, Depression Anxiety Stress Scales; SCPI, Skills Confidence and Preparedness Index; HLQ, Health Literacy Questionnaire; PAM-13, Patient Activation Measure; RAS-DS, Recovery Assessment Scale Domain and Stages.

with the interviewers (UA and GR) through an iterative process. Data management and coding were conducted in NVivo (Version 14),[93] following these steps: transcription of audio files; data familiarisation through initial transcript readings; preliminary code identification; analysis into overarching themes; and final deliberation on theme definitions.

Results

Participants Description and SMART Preferences

The mean age of five pilot participants was 45 years (range: 43–48). Their primary diagnosis was schizophrenia or schizoaffective disorder. Two had T2D and three had metabolic syndrome as diagnosed by their treating endocrinologist. Two participants were smokers at the time of the study, while the remaining were former smokers or had never smoked. Cognitive assessments (see Supplementary Table 4) revealed variability in participants' strengths and weaknesses, in keeping with the range, pattern, and extent of deficits typically seen in individuals with schizophrenia, albeit with slightly less pronounced executive dysfunction than expected. One participant demonstrated entirely age-appropriate cognitive performance, while others exhibited at least one area of impairment. Verbal learning and memory were moderately-to-severely impaired immediately after presentation, with the most common pattern reflecting difficulties in retrieving information rather than in encoding and retention. Two participants exhibited severely deficient task-switching abilities.

Out of the four SMS modules, Nutrition and Weight management were the most frequently ranked as the 1st (n = 2) or 2nd (n = 2). The physical activity module was most often ranked as 3rd (n = 3) and Healthy stress coping as 4th (n = 4). One participant chose Quitting smoking as an additional module, one chose Monitoring blood glucose levels, and one chose both additional modules. Three participants chose to receive text messages between 8 and 11am and two between 11am-2pm.

Usability of the SMART Intervention

Responses, reflecting participants' perceptions of the SMART intervention, were coded into 12, more granular themes, which were further categorised into the following three overarching themes: Acceptability of the SMART intervention, Feasibility of the SMART intervention, and Support of behaviour change.

Acceptability of the SMART Intervention

The personalised nature of the text messages (ie, use of participants' names, emojis and supportive, non-judgemental language) fostered a sense of connection and care, enhancing the overall participant experience. As one participant noted, "I found the messages to be like from an actual person…they sounded caring". The check-in phone call from research staff further reinforced this sense of support, with participants feeling reassured by knowing there was "an actual person out there who wants to help you and cares for your health and your well-being". Additionally, participants appreciated the option to prioritise the content of the text messages, as this enabled them "to be able to target it [the intervention] towards what I feel is needed".

Language used within the text messages also contributed to the participants' evaluations of the SMART acceptability, with text messages frequently described as "easy to read" and "not complicated". Logistical design elements, such as frequency and length of the text messages were not perceived as burdensome, with the ability to customise the timing of text message delivery to accommodate individual preferences noted particularly favourably. While the three response options (ie, Yes, No, and Unsure) were generally acceptable, some participants say that they would "like to have not just yes or no answer. [but rather] more interaction with it" (eg, option to engage in a longer exchange of text messages), as well as including more hyperlinks to further information on the topic. High acceptability of SMART was also supported by participants' ratings on the 5-point AIM (M = 4.4, *SD* = 0.6).

Appropriateness of Intervention

The importance of focusing on diabetes self-care for individuals with SSD was highlighted by a participant who remarked, "Type 2 diabetes, it's a pandemic for, you know, Australia". The relevance of the lifestyle-focused content, aligned with participants' personal health goals was emphasised with statements like, "it's just like positive, and it's about being healthy and that's what I want as well. And that's one of my goals... to be more healthy for my eating and my exercise... so it was in line with what I value". The need for a holistic approach that integrates mental and physical health was also highlighted: "I think it makes a big difference... with mental health or even any health condition, there's a holistic approach. So it's not this [points to the box with the medication on the table]. The medication helps. But then you've got all the other factors, your lifestyle, you know, and all that".

However, the content was less relevant for one participant who, while having metabolic syndrome, did not have the T2D diagnosis: "I understand it's about diabetes, but I didn't have diabetes. So yeah, I thought... it's not useful to me".

Despite this, the usefulness of lifestyle-focused content was generally valued. Participants reported the practical tips for diabetes self-care as beneficial, with one stating, "it was like really encouraging... it helped me... reminding me to make healthier choices and about what I was eating... there's a lot of good advice on there. I really enjoyed it".

Others found the recipe ideas and mindful eating techniques helpful, with one participant saying, "I like it when they said that only eat till you're full, you're satisfied... when I did have a full meal, I snacked less". Of note, perceived usefulness was influenced by prior knowledge however, as reflected by one participant who said, "mostly just it mentioned pretty much what I already knew kind of thing". Appropriateness of SMART was reflected also in the IAM mean score which was 4.4 (*SD* = 0.6).

Feasibility of the SMART Intervention

Participants were enthusiastically receptive to the idea of receiving similar text messages on diabetes self-management in the future, emphasising the value of reiterating key concepts to reinforce learning. One participant noted, "consistency's good, but also introducing new things as well would be good". They also expressed that the duration of receiving these messages should be personalised, continuing until they feel confident in making and sustaining lifestyle changes. One barrier identified by a participant was inconsistent internet access and lack of mobile data. This participant noted difficulties in responding to messages, stating, "I've missed a few days in between because I didn't have credit", which impacted their ability to remain consistently engaged with the intervention. Considering these berries, the FIM ratings were slightly lower (M = 4.0) and more variable (*SD* = 1.2).

Nevertheless, the feasibility of intervention was strongly supported by participants' quantitative accounts related to the usability of SMART. Specifically, the analysis of usability data showed good adherence, as demonstrated by a mean response rate of 60% to the text messages across all modules during the 4-week period. The response rates ranged between 75%

(Quitting smoking) and 95% (Physical activity) and exceeded the 50% pre-defined threshold of good adherence for all core and optional modules (See Table 3 for specific replies across modules). Positive ("Yes") replies, indicating positive engagement in target behaviour, were the most frequent to text messages on Nutrition (78%) and the least frequent to Physical activity (35%). Across weeks 1–4, the total response rate across all modules increased from 82% to 95% (see Table 4 for detailed responses across reply options and weeks). Further, the mean SUS total score post-intervention was 82 (SD = 12.8).

Support of Behaviour Change

Several responses pertained to the intervention serving as a valuable reminder, enhancing awareness and focus on health ("it made me more aware, like it was more in the front of my mind, like to be healthy with my eating") despite competing demands ("you get so caught up with life, like with my studies and stuff, so you sort of neglect your health and your healthy eating and exercise"). SMART text messages also provided encouragement and acknowledged progress. A participant remarked, "It's good to be reminded of the positive things you are doing as well as what you can do to change or improve what you're doing kind of thing".

Overall, participants reported several positive behavioural changes due to receiving the text messages, including better portion control, increased fruit and vegetable intake, reduced sugar consumption, more routine blood monitoring, and increased exercise. These behavioural changes also indicated self-reported improvements in well-being, with one participant noting, "You know, I had a little bit more energy, natural energy, and I just think that it's a positive change".

Preliminary Efficacy of SMART

Overall, the inspection of baseline-endpoint changes indicated no notable changes in assessment scores, including no changes in physical health indicators like weight or waist circumference, or in diabetes skills, confidence, and preparedness (for details, refer to Table 2). Positive trends, however, were detected in well-being, depression, anxiety, and self-rated recovery, specifically Mastering my illness sub-scale. Improved scores were also observed for quality of life, both on the Physical and Mental component scores and across most of the sub-scales. Regarding self-reported stages of change in physical activity engagement, healthy nutrition, and smoking cessation (Figure 3), positive changes were observed for healthy nutrition; however, this change was not reflected in the self-reported 24-hour total fruit and vegetable intake.

Table 3 Response Rates to SMART Text Message Across All Modules During the 4-week Period (n = 5)

	Core Modules				Optional Modules	
Participants' reply	**Nutrition N (%)**	**Physical Activity N (%)**	**Healthy Stress Coping N (%)**	**Weight Management N (%)**	**Quitting Smoking N (%)**	**Monitoring BGL N (%)**
Yes	28 (78)	7 (35)	16 (57)	21 (58)	5 (63)	5 (63)
No	2 (6)	10 (50)	7 (25)	5 (14)	1 (12)	2 (25)
Unsure	2 (6)	2 (10)	3 (11)	7 (20)	0 (0)	0 (0)
No reply	4 (10)	1 (5)	2 (7)	3 (8)	2 (25)	1 (12)

Table 4 Response Rates for SMART Text Message Across the 4-week Period (n = 5)

Participants' reply	**Week 1 N (%)**	**Week 2 N (%)**	**Week 3 N (%)**	**Week 4 N (%)**	**All weeks N (%)**
Yes	25 (74)	18 (53)	19 (56)	19 (56)	81 (60)
No	2 (5)	11 (32)	8 (24)	6 (18)	27 (20)
Unsure	1 (3)	4 (12)	3 (8)	7 (21)	15 (10)
No reply	6 (18)	1 (3)	4 (12)	2 (5)	13 (10)

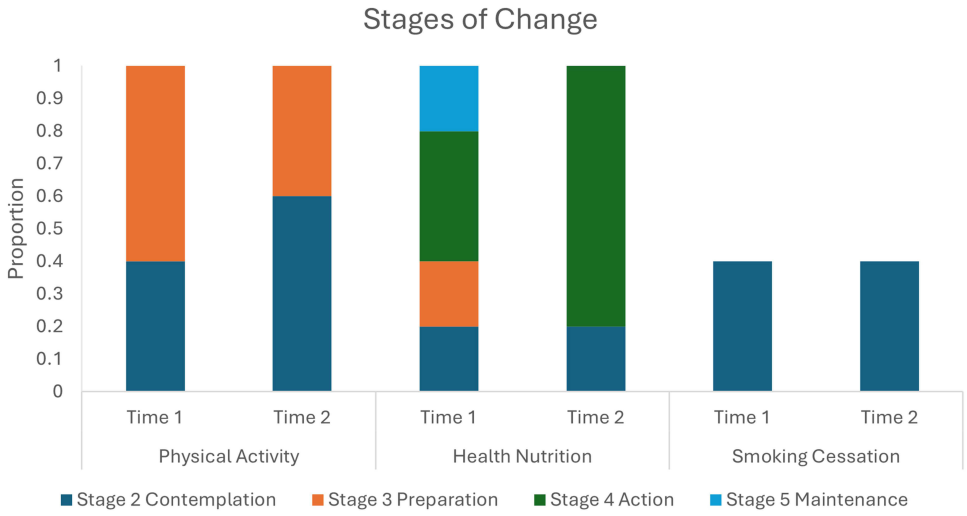

Figure 3 SMART Pilot stages of change (n = 5).
Note: Smoking cessation was only administered among participants who were current smokers (n = 2).

Discussion

This study is the first, to the authors' knowledge, to report on the co-design of a digital intervention for prevention and self-management of T2D for people living with schizophrenia. Through a comprehensive, theory- and evidence-informed approach, which included all key stakeholders, we were able to develop an easy-to-use SMS-delivered intervention, which provided psychoeducation and motivational prompts tailored to individual needs. The study pilot data indicated that SMART is a feasible and acceptable intervention for adult people with schizophrenia who are at risk of T2D or have T2D, as demonstrated by high retention and response rates. Further, overall satisfaction and usability of SMART was very positive, indicating above average (Grade 1) usability, compared to several other tested systems.[67]

Qualitative feedback from participants corroborated the high usability scores, with positive perceptions about the format and content of the SMART prototype reflected in participants' quotes. Specifically, the participants appreciated the motivational messages embedded within the text messages relating to health behaviour change and reported improvements in their nutrition (eg, better portion control), exercise (eg, increased frequency) and monitoring blood glucose levels. Importantly, these behavioural changes seemed to have had a flow-on positive effect on their well-being and energy levels. A common theme in the participants' feedback was friendly, caring, and easy-to-understand language of the text messages, with appreciation of the additional information provided through the hyperlinks. The interactive nature of the text messages was perceived positively, with a few participants expressing a wish for even greater interaction with the system and for more text messages including a hyperlink with relevant information. This feedback is reflected in the high response rate to text messages, with missed response being primarily due to insufficient mobile data. As such, the lack of mobile data may present a barrier to sustained implementation of digital tools in this population, which may be worth addressing at the health system level (eg, integrating digital interventions like SMART within routine mental health systems) if digital mental health interventions are, indeed, to be equitable, accessible, and ultimately effective therapeutic approaches within mental health populations.[94]

While there were no notable changes across four weeks in measures of mental and physical health, including metabolic health, or lifestyle behaviours, positive trends were observed in depression, anxiety, overall physical and mental wellbeing, and mental health recovery, in terms of mastering own illness and doing things they liked. Acknowledging that these results are based on a very small number of people, they corroborate non-significant findings of a large randomised controlled trial (RCT) of lifestyle interventions, delivered in person, among people with SSD.[95] However, while systematic reviews of interventions delivered by digital means among people with SSD have found that digital technologies are acceptable and feasible for this population,[15,96] and individual RCTs have shown improved clinical outcomes, including relapse,[24,39] psychosis symptoms,[27] and depression,[97] there is currently no other existing

RCTs of digital interventions delivered in people with SSD that would target lifestyle behaviours, or specifically T2D self-management.[15] As such, the current pilot data provide an important and promising direction in building new knowledge and empirical evidence on digital lifestyle interventions that are safe[98] and tailored to the needs of people with SSD.

From a preventative perspective, it is crucial to develop innovative approaches to help individuals with SSD more effectively manage complex physical health conditions, such as metabolic syndrome, diabetes, and hypertension, which are significantly associated with global cognitive impairment in this population.[99] Without adequate management of these physical health issues, cognitive deficits are likely to worsen, increasing the risk of functional decline and perpetuating a cycle of inequality. SMART presents a unique intervention that has the potential to address poor metabolic health of people living with SSD, and particularly of those taking antipsychotic medications likes clozapine which is associated with substantial weight gain.[6]

Strengths and Limitations

This study has several strengths and limitations that should be considered. One notable strength is that by using a mixed-methods design, this study offers rich insights into the feasibility and acceptability of the SMART intervention and will inform further development and implementation of SMART with a potential for wide scaling-up. Further, pilot data indicate high acceptability and feasibility of the simple, text message-based delivery format for this population, which provides support for further development and testing of SMART to address a pressing physical health issue in this cohort of people. This is particularly noteworthy in the context of observed cognitive profiles of pilot participants which indicated moderate-to-severely impaired performance in several cognitive domains for all, apart from one, of the pilot participants. Despite these strengths, there are a few limitations. Acknowledging this was a pilot study of the SMART prototype, it is nevertheless worth noting that the small sample of participants precludes drawing conclusions about the statistical significance of changes in the assessment included. Further, there is a question about accuracy of self-reported data and the lack of social desirability assessment. The research officers who administered the assessments and have known the lifestyle of participants for longer time (based on their engagement in previous studies) expressed doubt into some of their self-reported data, particularly around healthy eating and physical activity (at baseline and endpoint reporting these to be better than what the research officers thought they would be), and their reported stages of change. This concern highlights the need for more objective assessments of key lifestyle behaviour, such as use of Fitbits to record actual physical activity and validated 24-h recall food check-lists, to capture the food quality.

Conclusions

By ensuring that the co-design process was developed on a strong theoretical basis and each text message incorporated a mechanism of action supporting the intended behaviour change, we were able to pilot an intervention that was perceived as highly acceptable for people living with schizophrenia, with qualitative data providing support for the appropriateness and feasibility of SMART. Participants' positive feedback of SMART, combined with the observed trends in positive improvements in physical and mental well-being scores and depression, indicates a promising direction for future research. Further improvements may be beneficial to make SMART even more interactive, possibly with the use of innovative approaches such as chatbox or Artificial Intelligence while continuing to use an informal, friendly, and motivating language to facilitate positive behaviour change in key lifestyle components for prevention and management of T2D. The current study provides critical information to inform a subsequent feasibility study of SMART and potential needs to improve wide implementation and the capacity of SMART to be scaled up, to address the high burden of T2D, and more broadly of cardiovascular disease, in this population in Australia and globally.

Acknowledgments

We would like to thank all the participants who contributed to the evidence arising from this study, and the CADENCE clinical trial team for their efforts with conducting assessments with participants. This paper has been uploaded to SSRN as a preprint: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5154765.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This trial is funded from the Metro South Health Research Support Scheme (MSH RSS) Early Career Researcher Grant (RSS_2023_013), awarded to UA as a Principal Investigator and DS, AM, AM, AR, *RS* as Co-investigators. This grant has an external peer review process. DS is funded in part by an NHMRC Emerging Leadership Fellowship GNT1194635. AM is supported partially by the Australian Government through the Australian Research Council's Centre of Excellence for Children and Families over the Life Course (ID CE200100025), the Medical Research Future Fund Clinician Researchers Applied Research in Health (MRF2032279) and the NHMRC (ID 2025098).

Disclosure

The authors have no conflicts of interest to declare in this work.

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