
# Supporting People With Type 2 Diabetes in the Effective Use of Their Medicine Through Mobile Health Technology Integrated With Clinical Care to Reduce Cardiovascular Risk

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# Abstract

## Background

Type 2 diabetes is a common lifelong condition, affecting over 400 million people worldwide. Use of effective medications and active self-management can reduce the risk of serious complications. However, people often have concerns when starting new medications, and face difficulties in taking their medications regularly. Support provided by using brief messages delivered through mobile phone-based text messages can be effective in some long-term conditions. We have identified promising behaviour change techniques (BCTs) to promote medication adherence in this population via systematic reviewing, and developed text messages that target these BCTs. Feasibility work has shown that these messages have fidelity to intended BCTs, are acceptable to patients, and are successful at changing the intended determinants of medication adherence. We now plan to test this intervention at a larger scale in a clinical trial.

## Objectives

The aim of this trial is to determine the effectiveness and cost-effectiveness of this intervention for people in reducing cardiovascular risk for people with type 2 diabetes compared to usual care.

## Methods

The trial will be a 12-month, multi-centre individually randomised, controlled trial in primary care recruiting adults (≥ 35 years) with type 2 diabetes in England. Consenting participants will be randomised to receive short text messages intended to effect a change in medication adherence three to four times a week in addition to usual care, or to usual care. The aim is to test the effectiveness and cost-effectiveness of the intervention when added to usual care. The primary clinical outcome will be a composite cardiovascular risk measure. Data including patient-reported measures will be collected at baseline, 13-, and 26-weeks, and at the end of the 12-month follow-up period. With 958 participants (479 in each group) the trial is powered at 92.5% to detect a 4 percentage point difference in cardiovascular risk. The analysis will follow a pre-specified plan. A nested quantitative and qualitative process analysis will examine putative mechanisms of behaviour change, and wider contextual influences. A health economic analysis will assess the cost-effectiveness of the intervention.

## Results

The trial has fully recruited and is in follow up. Publication of results is anticipated in 2024.

## Conclusions

This trial will provide evidence about the effectiveness and cost-effectiveness of this intervention for people with type 2 diabetes.

## Ethics and dissemination

Ethics approval was obtained from the West of Scotland Research Ethics Committee 05. The results will be disseminated through conference presentations, peer-reviewed journals and will be published on the SUMMIT-D (SUpport through Mobile Messaging and digital health Technology for Diabetes) trial website: www.summit-d.org.

## Trial registration

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Keywords: diabetes; SMS text-messages; cardiovascular risk prevention; medication adherence; digital health; randomised controlled trial

# Introduction

## Type 2 diabetes and medication adherence

Type 2 diabetes is a lifelong condition that can cause serious long-term health problems.[1] It is one of the most common long-term conditions affecting 422 million people worldwide [2] and 4.7 million people in the UK.[3] It can lead to major complications including cardiovascular disease, renal failure and neuropathy.[1] The global economic burden of diabetes is projected to reach up to 2.2% of global gross domestic product,[4] and many of these costs are due to preventable complications. Treatments to reduce risks of complications from type 2 diabetes are effective if taken as intended.[5, 6] However, concerns about medicines and difficulties in taking them regularly, whether intentional or unintentional, are common.[7] The cost of non-adherence to diabetes medication in the UK has been estimated at £100 million per year in avoidable treatment costs alone.[8]

Some services, such as pharmacy medication checks, use of blister packaging, written reminders and routine education are available to support people in taking their medication regularly, but evidence of their effectiveness and cost-effectiveness is not strong.[9] These services may not be right for everyone and often targeted at particular groups or designed as “one-off” services. Understanding and improving this situation could make a major contribution to health.

## Digital health interventions and brief messaging

Systematic reviews of text-messaging to support adherence to treatment and of mobile health interventions in diabetes have identified some effective interventions. [10, 11] There are a few trials testing the impact of brief messaging in type 2 diabetes, but they do not all test systematically developed interventions, and many are at risk of bias or have short-term follow-up. However, despite variation in response in different settings and differences in trial design, studies to date have not resolved continuing uncertainty about implementation in routine health care.[10, 11] Trials of Short Message Service (SMS) text-messaging for cardiovascular risk prevention and blood pressure lowering have shown clinically relevant changes in outcomes compared with usual care.[12, 13]

There is substantial evidence that personalised interventions are more effective than generic interventions.[14] Tailored interventions may be seen by recipients as more personally relevant, so they will be more likely to attend to, read, understand, and act on them. In addition, tailored interventions are designed to change determinants of the target behaviour that are relevant to individuals or to small subgroups of individuals; they therefore more precisely target the determinants of the individual’s behaviour.

## Preliminary studies

Support through Mobile Messaging and digital health Technology for Diabetes (SuMMiT-D) is a programme of work composed of three phases: formative work, a feasibility trial and a large-scale, pragmatic randomised controlled trial of a mobile phone-based system. The programme is intended to develop and evaluate brief, tailored, behaviour change messages for people with type 2 diabetes intending to encourage regular use of diabetes medication and persistance, and modify risk factors including glucose, blood pressure and cholesterol levels, and thus risk of adverse outcomes including cardiovascular disease. The intervention is intended to focus on a broad range of individuals with type 2 diabetes, but those with younger onset diabetes and using insulin alone were not included, as these features often require different care pathways.

In the formative work for this trial, we identified theoretical constructs and features of intervention content found to be associated with medication adherence in patients with type 2 diabetes [15] and mapped these onto a standard taxonomy of behaviour change techniques (BCT), that is, active components of interventions used to promote behavioural change.[16, 17] Development work aimed to ensure that the overall approach was acceptable to people with type 2 diabetes.[15] We then developed a large set of messages to target each BCT,[18] through an expert consensus process and surveys with experts and patients to select messages that had fidelity to the intended BCTs and were acceptable to patients. We carried out a feasibility study and further qualitative work [18, 19] and confirmed that the intervention and trial processes were acceptable and feasible,[20, 21] and that the responses to specific messages matched the response observed in the formative work [awaiting doi]. [*]

## Aims

The primary objectives of the main SuMMiT-D trial are to determine the effectiveness and cost-effectiveness of this intervention in reducing cardiovascular risk for people with type 2 diabetes compared to usual care. Alongside the effectiveness and cost-effectiveness aims, a process evaluation will provide information to further develop and refine the intervention, to explore how it can achieve a wide reach and how it can be incorporated and embedded in health care pathways. It will also further identify the precise psychological mechanisms of action through which the intervention might change behaviour.

[*] YK Bartlett, AJ Farmer, & DP French. Does a text message intervention to support medication adherence in type 2 diabetes produce changes in hypothesised mediating variables, and what does change in these variables mean for medication adherence? Accepted for publication in *JMIR Formative Research*)

# Methods and Analysis

The SuMMiT-D trial protocol is reported according to Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) and the ESPACOMP Medication Adherence Reporting Guidelines (EMERGE) recommendations.[22, 23]

## Patient and Public Involvement (PPI)

Patient members of the public are integral to this trial. A panel of 11 PPI members with type 2 diabetes was set up for the formative stage of this programme of work and continues to inform our work, reviewing all patient documentation and research findings, and supporting the development and refinement of the intervention.

All patient facing documents for the SuMMiT-D trial, including the participant information sheet, informed consent form, posters, user guides and website, were reviewed by PPI panel members. The results of the study will be made available to trial participants, PPI panel members and participating general practices on the trial website (www.summit-d.org).

## Research design

The SuMMiT-D main trial is a primary-care-based, two-arm, individually randomised controlled, parallel group trial with a health economic analysis and an embedded process evaluation. The trial aims to recruit 958 participants from up to 100 general practice sites in England. Consenting participants with type 2 diabetes will be randomly allocated to receive individually tailored mobile device-based messages alongside usual care (intervention) or to usual care alone (usual care).

A process evaluation will be carried out in line with the MRC guidance on process evaluations, [24] and will focus on (a) mechanisms (or theory) of change of the intervention, that is, how the intervention produces change in participants and (b) the impact of context on how the intervention works.

An economic analysis will be conducted from the perspective of the National Health Service and Personal Social Services. The analysis will be informed by routine and self-report data and will estimate the incremental cost-effectiveness ratio expressed as the cost per Quality-Adjusted Life-Year (QALY) gained.

## Setting

The trial will be conducted in general practices in England. Recruitment of practice sites will be monitored to ensure geographical spread, to include a range of sites with levels of deprivation matching the wider distribution, and to align recruitment with burden of diabetes in the community.

## Intervention

### Intervention arm: condition-specific tailored text messaging system and usual care.

Participants assigned to the intervention group will receive brief health-related text messages, based on a systematic review of the evidence identifying determinants of medication-taking behaviour.[17] Messages were developed based on a systematic review of the evidence by experts, [17] and refined in an iterative process of ensuring acceptability based on patient feedback and demonstration of fidelity to intended behaviour change determinants, as rated by an independent group of experts.[18] A more detailed description of the intervention is given in the template for intervention description and replication (TIDieR) checklist,[25] included in the online supplementary file (see online supplementary material). Examples of messages are given in the supplementary file along with the corresponding BCT that the message is intended to target based on the formative work for the trial.[18]

The intervention is a digital health system with the following components:

i. Participants will be sent up to four automated text messages per week with an average frequency of three per week relating to diabetes management and use of medicine.

ii. The library of text messages uses different groups of BCTs (see supplementary material) to target health-related behaviour change relating to use of medicines, as well as messages targeting other aspects of diabetes care (including diet and exercise).

iii. The frequency of messages received using a particular group of BCTs can be modified based on a participant's response to individual messages by sending a text message in response to a particular message asking for that type of message to be sent more or less often. Participants may incur a cost for sending messages in response depending on their network plan.

iv. The style of messages is patient-centred and encourage patients to seek further relevant information (including the use of links where possible to selected external websites, e.g., Diabetes UK).

## Outcomes

The primary outcome will be a composite cardiovascular outcome adapted from the equations used for the UKPDS risk engine.[26] We will evaluate the effect of changes in metabolic outcomes (glucose, blood pressure and cholesterol levels) on the estimated risk of CVD. We will calculate CVD risk at baseline and at follow-up using the UKPDS risk engine.[26] The UKPDS risk engine is type 2 diabetes-specific and based on 4540 patients from the UKPDS trial (1977 to 1991). It includes HbA1c as a continuous variable and calculates the risk of developing a new coronary heart disease (CHD) event.

Secondary outcomes will include glycaemic control (HbA1c), blood pressure, total and HDL cholesterol (mean and clinically relevant change), self-reported smoking status, resource use and EQ-5D-5L. Participants will be assessed at 13, 26 and 52 weeks (not all measures at all time points), with all measurements and data being collected directly from the participants or via their medical records.

Medication adherence outcomes for anti-diabetic medication will be pre-specified as a proportion of participants with ≥80% medication available over one year, a continuous measure of the proportion of medication available over one year defined as the medication possession ratio (MPR) and persistence with a medication, calculated from routine electronic health data.[27, 28] We will also measure MPR for statins and blood pressure lowering medication.

## Procedures and assessments

Potential participants who express interest in taking part in the trial will be screened by the trial team and will consent and submit their baseline questionnaires either online or on paper according to their preference. Participants will be randomised by the trial team and will receive messages for 52 weeks from randomisation to final follow-up. All participants will be asked to complete questionnaires at baseline, 13, 26- weeks and at the end of their 52-week follow-up period. Medical notes reviews will be conducted at baseline, and 12months from randomisation.

## Recruitment

Potential participants will be identified through general practices across the United Kingdom. A short information leaflet will be provided to potential participants using a variety of methods including post, displayed in waiting areas at participating general practices, and given to patients by a practice team member.

Healthcare professionals will screen their type 2 diabetes clinic lists for potentially eligible patients and invite them to take part in the study. Searches and screening may be done periodically

to enable newly potentially eligible patients to be invited. Potentially eligible patients may be contacted up to three times (including by phone, letter, email or text-message).

## Expressions of Interest

People interested in taking part in the trial can send their full name by SMS text-message to the trial team to register their interest. If potential participants have any difficulties in registering their interest in the trial in this way, they will be able to call a trial telephone number and will receive support in registering as required.

## Screening assessment

Following an expression of interest, a member of the trial team will contact the potential participant by phone to provide further information about the trial and conduct screening and eligibility.

## Inclusion criteria

Eligible participants:

- are ≥35 years of age,
- are taking oral glucose lowering treatment, blood pressure-lowering treatment or lipid-lowering treatment either alone or in combination.
- have access to a mobile phone and are able, if necessary, with help (e.g., relative, friend, neighbour), to send, understand and retrieve brief SMS text messages in the English language.

Participants who are using insulin treatment without also concomitant use of oral glucose-lowering treatment; who are pregnant, within 3 months postpartum or planning pregnancy during the trial; have a serious medical condition that, in the opinion of the investigator, makes them ineligible; have been admitted to hospital within the last 3 months for hyperglycaemia or hypoglycaemia, or who use a pharmacist-managed monitored dosage system are ineligible.

## Informed consent

Participants will provide consent either online or on paper.

## Baseline and follow-up assessments

Questionnaires will be administered (online or by post) at the baseline assessment, 13 weeks and 26 weeks after randomisation, and at 52 weeks. The measures and the schedule are detailed in Table 1.

At the baseline assessment questionnaires will be the Medication Adherence Report Scale (MARS);[27] EQ-5D-5L,[29]; a measure to assess the hypothesised mediators of effect based on developmental work and the technology acceptance model,[30], a resource use questionnaire,[8]

and a brief measure of satisfaction with diabetes treatment. Experience of diabetes education, presence of a carer and their role in medication administration, duration of diabetes, time since last change in type 2 diabetes medication, if the pharmacy used by the participant automatically requests patient's medication from surgery, self-reported level of education, smoking, age, gender, ethnicity, postcode, NHS number, date of birth, previous use of mobile phones and computers, and details of current mobile phone including contract type, will also be recorded.

Follow-up will last for 52 weeks after randomisation. The following questionnaires will be completed at 13 and 26 weeks (± 4 weeks) following randomisation: EQ-5D-5L,[29] and a brief questionnaire based on health psychology theory and the technology acceptance model.[30]

At 52 weeks (± 4 weeks) following randomisation, the following questionnaires will be completed: MARS self-report scale,[31] the EQ-5D-5L.[29], a measure based on health psychology theory and the technology acceptance model, 26), a healthcare utilisation record,[8] and the brief measure of satisfaction with diabetes treatment. A full schedule of measures is shown in Table 1.

*Table 1: Schedule of trial outcomes and measures*

| **Procedures** | **Visits/Data collection timepoints** | | | | | |
|---|---|---|---|---|---|---|
| | **Screening**[#] | **Participant expression of interest** [##] | **13 weeks** | **26 weeks** | **52 weeks** | **Any time point** |
| Screening | X | | | | | |
| Eligibility assessment | | X | | | | |
| Informed consent | | X | | | | |
| Demographics and additional information questionnaire (to include age, gender, postcode) | | X | | | | |
| MARS self-report scale - Questionnaire | | X | | | X | |
| EQ-5D-5L Health status - Questionnaire | | X | X | X | X | |
| Healthcare Utilisation Record Questionnaire | | X | | | X | |
| Hypothesied mediators of behaviour change & Technology Acceptance Questionnaire | | X | | | X | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Brief hypothesied mediators of behaviour change & Technology Acceptance Questionnaire | | | X | X | | |
| Brief attitudes to diabetes and treatment | | X | | | X | |
| Data collection (including medical history and concomitant medication) | | X | | | X | |
| Randomisation | | X | | | | |
| Text Messaging System Registration | | X | | | | |
| Sending of Intervention or Control messages initiated | | X | | | | |
| Scheduled and Unscheduled Contacts | | X | X | X | X | |
| Adverse event assessments | | | | | | X |

# GP to screen list prior to mail out
## Day expression of interest received or as soon as possible thereafter.

Routinely collected data: Hospital Episode Statistics from NHS Digital, data from medical records for metabolic outcomes, utilisation of primary care services, and medicine costs including drug prescriptions issued.

## Additional trial procedures

All participants will receive non-health-related SMS text-messages at a frequency of approximately one every 4 weeks. These messages will be used for the purpose of maintaining contact and prompting completion of questionnaires. Sending and receipt of messages by mobile phones will be monitored throughout the trial and contact made with participants if problems identified.

## Randomisation

Participants will be randomised after consent and when all baseline assessments have been completed. Participants will be allocated in a 1:1 ratio to either intervention or usual care. Randomisation will be done using a validated secure web-based randomisation programme (Sortition) provided by the University of Oxford Primary Care Clinical Trials Unit (PC-CTU).

Allocation will be carried out with a non-deterministic minimisation algorithm to ensure groups are balanced for important baseline prognostic and other factors: study site, age (<65/≥65 years), gender (male/female), duration of diabetes (<5 years/≥5 years) and number of medications (<5/≥5).

The allocated intervention will be implemented directly by the platform on which the digital health system is run. Apart from the qualitative research team and the engineering team, all other trial and healthcare staff are blinded to treatment group. We determined that unblinding would not be required during the trial.

## Discontinuation of intervention or withdrawal from trial

Participants can withdraw from the trial at any time. Participants can also choose to pause or stop receipt of text messages by sending a text message or contacting the trial office by telephone or post. Serious unexpected adverse events related to the intervention are determined by the chief investigator and reported in line with local procedures.

## Statistical Analysis

### Power

A total sample size of 958 participants (479 per group) provides 92.5% power to detect a difference in cardiovascular risk of 4 percentage point change in risk (NNT=25) based on a standard deviation of 15% for cardiovascular risk derived from a primary care diabetes trial with patients with type 2 diabetes, in which reductions of between 4% and 7% in estimated 10-year CVD risk were observed with statin treatment.[32] This estimate includes 15% inflation due to clustering and 20% loss to follow up at 92.5% power and 5% 2-sided level of significance). The sample size also gives a power to detect changes in HbA1c between groups of 4 mmol/mol based on a standard deviation of 15mmol/mol for patients newly starting glucose-lowering therapy.[28] This number of participants will also give us 80% power to detect an increase in proportion of medication available from a baseline of 50% to 60.9%

### Analysis

The primary analysis population will include all randomised participants in the treatment arm to which they were assigned regardless of intervention received. Those found to be ineligible after randomisation will be excluded from the analysis. For the primary and secondary outcomes, HbA1c values will be included if between 3 and 12 months post randomisation. The other data collected via notes review (cholesterol and blood pressure) will be included if between 6 weeks and 12 months post randomisation.

Baseline variables will be presented by randomised group using frequencies (with percentages) for binary and categorical variables and means (and standard deviations) or medians (with lower and upper quartiles) for continuous variables.

The primary outcome will be analysed using a multiple linear regression model. The model will adjust for baseline score, experience of diabetes education (yes/no) and minimisation factors as fixed effects. Depending on the results of a preliminary exploration of site, a mixed-effect model will be used instead with site fitted as a random effect. The adjusted difference in means between the 2 groups will be presented, along with its associated 95% confidence interval and P-value.

Secondary continuous outcomes that are collected at 13, 26, and 52 weeks will be analysed using a mixed effect model which includes a [time x treatment] interaction so that the treatment effect can be estimated at each time point, otherwise the outcomes will be analysed in a similar way to the primary outcome.

Similarly, binary outcomes measured at multiple time points will be analysed using a generalised linear model (adjusting for the same factors as listed above).

Missing data will be reported with reasons given where available and the missing data pattern will be explored.

## Economic analysis

The health-economic analysis will be embedded in the clinical trial. The principal aim will be to assess the cost-effectiveness of the intervention as compared to usual care and will be accomplished by adopting an English National Health Service (NHS) and Personal Social Services (PSS) perspective, estimating total costs, and benefits expressed in QALYs. The intervention will be micro-costed. Trial participants' use of health care resources will be estimated from self-reported questionnaires, hospital episode statistics and EMIS data, and will be costed using current prices. Health utilities will be estimated using methods specified by NICE at the time of analysis.

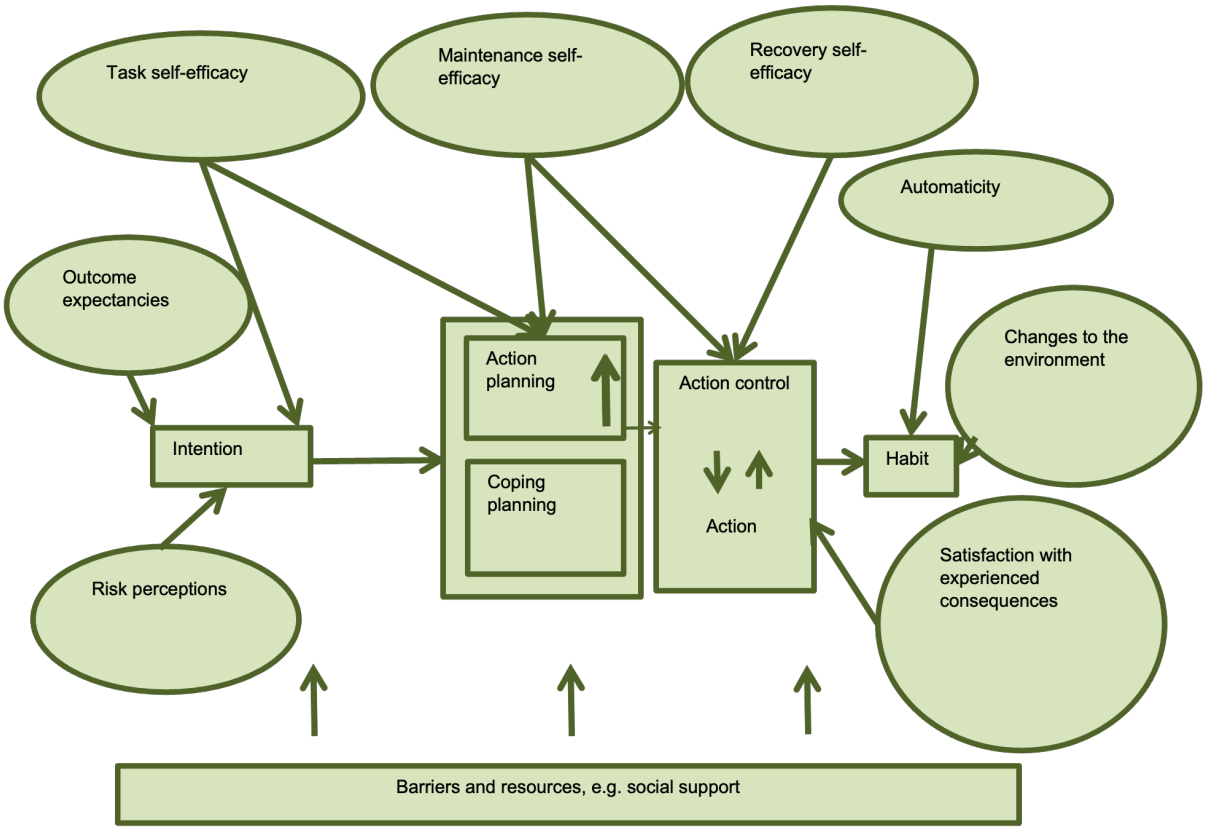
A Health Economic Analysis Plan (HEAP) will be agreed prior to the analysis, which will primarily be over the time horizon of the trial, and secondarily over a lifetime. QALYs over 1 year will be estimated directly from the clinical trial, and a trial-based incremental cost-effectiveness ratio will be calculated as the ratio of the difference in mean costs to the difference in QALYs. The joint uncertainty in costs and benefits will be considered through the application of bootstrapping and the estimation of the cost-effectiveness acceptability curve.

If the intervention is determined to be clinically effective, an extrapolation of costs and outcomes will be performed using the UKPDS model.[33] Costs and outcomes accruing after the first year will be discounted according to rate specified by NICE at the time of analysis. The modelled extrapolation will be subject to probabilistic sensitivity analysis, to characterise parameter uncertainty and present the probability of the adherence intervention being cost-effective. The health economic analysis will be reported according to the CHEERS checklist.[34]

## Process evaluation

A process evaluation will be carried out in line with the MRC guidance on process evaluations,[24] and updated MRC Framework.[35] The process evaluation will have quantitative and qualitative elements and will focus on (a) mechanisms (or theory) of change of the intervention, that is, how the intervention produces change in participants and (b) the impact of context on how the intervention works.

Figure 1: Process evaluation: Logic Model



## Participants

Participants who consent to taking part in the embedded qualitative study will be purposefully sampled by characteristics including but not limited to age, gender, duration of diabetes, medication use (duration and number), current adherence and familiarity with digital devices, with the aim of a maximum variation sample within the sampling framework of the trial.

Up to 60 participants will be recruited from the intervention group in two waves. The initial wave of up to 30 participants will be recruited for two interviews, at 1-month and 12-month follow-up to explore any change after initial exposure to the intervention, and potential longer-term change after 12 months. Up to an additional 30 participants will be recruited for interviews at 12 months following analysis of the interim measures. This will allow purposive sampling based on any changes in psychological constructs.

Prompts in the interview guide will be informed by anticipated themes derived from the existing literature and our previous qualitative studies, but consistent with inductive qualitative research methodology, we will also invite participants' stories of their experience in the trial without imposing a strictly limited pre-conceived topic guide. Further areas for questioning will be added as necessary as new themes emerge from early interviews (see appendix 3 for example topic guide). Participants will be invited to share their views on how they engaged with the system, the messaging system content, and will be invited to describe how the system was implemented in daily life. This will support identification of issues around potential attrition.

All interviews will be audio-recorded (with consent), transcribed verbatim and analysed thematically.[36] We will involve people with diabetes closely in both the development of the interview guide and in testing and refining our interpretation of the data, to ensure the analysis is as relevant and credible to eventual users as possible.

## Quantitative data in the process analysis

The trial will include brief questionnaires to assess the key behaviour change constructs that the messages are targeted at changing (Table 2). An assessment will be made of the use of the system (messages received and responses) from routinely collected electronic data. In line with MRC guidance,[35] we have developed a logic model (Figure 1) that indicates how the intervention will produce changes in behaviour and thereby CV risk, based on the Health Action Process Approach,[37] and developmental work.

Three mediation analyses based on instrumental variable techniques,[38-40] will be used to explore the extent to which changes in the behaviour change constructs can explain any impact of the intervention on medication adherence measured by (i) MPR and (ii) self-reported MARS and health measured by (iii) the composite cardiovascular outcome. The constructs to be included are: intention, action planning, coping planning, action control, habit, task self-efficacy, maintenance self-efficacy, recovery self-efficacy, automaticity, changes to the environment, satisfaction with experienced consequences, risk perceptions, outcome expectancies, social support and patient activation. Relevant covariates will be included in the models including age, gender, and index of multiple deprivation.

### Qualitative data in the process analysis

Interview data will be used to further explore the psychological mechanisms by probing what actions and feelings the intervention may result in and the contextual factors that may influence how the intervention works for an individual. A content analysis of previous qualitative work has identified potential contextual factors and mechanisms that may influence how the SuMMiT-D intervention is working, or is not working. The connection between these and the effects of the intervention will be probed in these interviews (for detail of the contextual factors and mechanisms identified see appendix 2). In accordance with recent guidelines related to potential measurement reactivity within trials we have considered the effects these interviews may have on the trial outcomes and have taken steps to mitigate these.[41] All 52-week interviews will be conducted following quantitative data collection. The timing of the 4-week interviews has been chosen to allow exploration of initial changes in response to the messages while still leaving an appropriate gap between the interview and follow-up measurement (11 months). Sensitivity analyses will be considered as an option to look at the potential effects of being interviewed at the interim and final outcome point.

## Data management

All trial data will be entered on electronic case report forms. The clinical database is built on Research Electronic Data Capture, a secure, web-based application designed to support data capture for research studies.[42]

## Ethics and dissemination

The trial will be conducted according to the principles of the Declaration of Helsinki and in accordance with other relevant national guidelines, regulations, acts and using Good Clinical Practice guidelines. The University of Oxford sponsors the trial.

The role of the Trial Steering Committee is taken on by the National Institute for Health Research Programme Steering Committee. The composition of the Trial Steering Committee is set out in the

appendix. The sponsor and funder detrmined this as a trial at low risk and a DMC has not been set up, with the TSC monitoring any problems arising

The trial is sponsored by the University of Oxford, Clinical Trial and Research Governance Unit, Boundary Brook House, Headington, Oxford UK. The sponsor and funder have no role in the in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.

### Dissemination plan

The results of this trial will be submitted to a peer-reviewed journal for publication, through conference presentations, publications of process evaluation and qualitative work,. and on the SUMMIT-D trial website.

## Results

Recruitment to the SuMMiT-D trial began with the first participant randomised on 23 March 2021. General Practices across England have agreed to identify and invite participants to take part in the study Participants have been recruited from 42 general practices. Reporting of the trial is anticipated in 2024.

## Discussion

The SuMMiT-D Trial is a large scale randomised controlled trial that aims to estimate the clinical and cost-effectiveness of the text messaging intervention compared to usual care. It addresses the need to develop and better understand scalable interventions that can address the continuing challenge of sub-optimal medication adherence through the increasing capability of mobile phones and digital platforms.

The trial is pragmatic in design and can provide information about the impact of brief messaging to people with diabetes with text messages that have been systematically developed to use established behaviour change techniques. Although the trial is focussed on a population selected because of having type 2 diabetes, many, if not most of these people will have other medical conditions, thus it has broader applicability to the wide population of people who have type 2 diabetes alongside other conditions rather than these individuals having to be excluded.

### Conclusions

If effective this intervention could help reduce the burden of complications and increased costs associated with non-adherence. Alongside this trial we are also looking at how this intervention, and those like it, could best be embedded in routine clinical care. This research could also offer a model

for technology-based self-management support that could be extended to other aspects of diabetes care and other long-term conditions.

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Each author has contributed significantly to and is willing to take public responsibility for, one or more aspects of the study. AF, LL and DF conceived the study; AF, DF, PB, NN, KB, LL, RR, VW, JM, BG, CV, LT, DAH, RH and LM-Y were involved in planning the study. All authors are involved in carrying out the study. LJ, SR, KB, YC, RC, CP, CK, NN and JA are involved in data collection. AF and LJ wrote the initial draft of this manuscript; all authors provided revisions and approved the final version.

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## Disclaimer

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

## Data Sharing and dissemination

Access to quantitative trial data will be made available following publication of primary results though a publically accessible repository. Qualitative data cannot be made openly available because of ethical concerns. Conditions of access will be available from the repository. Trial findings will be made available on the ISRCTN website as soon as available and prior to publication. Participants will be informed of findings. Findings will be communicated by conference and social media.

## Competing interests

LT reports personal fees from Sensyne Health: he also worked part-time for the company and has share options in it. CV reported salary support from Sensyne Health and RH reports speaker engagements with honoraria from the following companies: AbbVie, Abbott, Amgen, Astellas, AstraZeneca, Boehringer Ingelheim, Biogen, Gilead Sciences, GlaxoSmithKline, Janssen, Merck Sharp Dohme, Merck, Novartis, Pfizer, Procter & Gamble, Roche, Sanofi, Shire Pharmaceuticals, TEVA, UCB, outside the submitted work. RH is a director of Spoonful of Sugar Ltd, a University College London Business company providing consultancy on treatment engagement and patient support programmes to healthcare policy makers, providers and industry.

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**Figures and tables**

Figure 1: Trial profile

Table 1: Schedule of trial outcomes and measures