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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Research Protocols

Title: Supporting people with type 2 diabetes in effective use of their medicine through mobile health technology integrated with clinical care to reduce cardiovascular risk (SuMMiT-D): an effectiveness and cost-effectiveness randomised control trial protocol

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List of practices and lead primary care physicians

Ashton Medical Group	Dr Omair Razzaq
The Sides Medical Practice	Dr Laurence Cribbin
Peterloo Medical Centre,	Dr Imran Ghafoor
Marine Lake Medical Practice	Dr James Perry
Vauxhall Primary Health Care	Dr David Lewis
St Georges Medical Centre	Dr Rebecca Sinfield
Station House Surgery	Dr David Cowling
Pendle Medical Partnership	Dr Tim Smith
Queen Square Medical Practice	Dr Rachel Woolley
Heswall & Pensby Group Practice	Dr Stephen Forster
Lancaster Medical Practice	Dr Michael Wong
Pendle View Medical Centre	Dr Umesh Chauhan
Devonshire Green Medical Centre	Dr Kieran Brown
Cartmel Surgery	Dr Julie Colclough
Ashfields Primary Care Centre	Dr Neil Paul
Kiltearn Medical Centre	Dr Carolyn Paul
Oakenhurst Medical Practice	Dr Amar Ali
Bay Medical Group	Dr Russell Kelton
Darwen Healthcare	Dr Mammen Ninan
Eynsham Medical Group	Ian Binnian
Church Street Practice	Matthew Gaw
Iver Medical Centre	Neetul Shah
Banbury Cross Health Centre	James Kennard
Wing Surgery	Chris Davies
Norden House Surgery	Chris Davies
Whitchurch Surgery	Chris Davies
Liphook and Liss Surgery	Anna Lalonde
Park and St. Francis Surgery	Sam Glanville
Westlands Medical Centre	Helen Pandya
Andover Health Centre	Lucy Allen
The Bosmere Medical Practice	Dirk Konig
Mid Devon Medical Practice	Will Edney
Chilcote Surgery	E. Funnell
The Swan Practice	Chris Davies
Crewkerne Health Centre	Christopher Krasucki
Cheriton Bishop Surgery	James Hayter
Lawrence Hill Health Centre	Jack Ogden
Phoenix Health Group	Naomi Vernon
West Walk Surgery	Sam Davies
Rendcomb Surgery	Clare Henderson
Cotswold Medical Practice	Nicholas Hodgkins
Greenway Community Practice	Liz Grimshaw
Mendip Vale Medical Practice	Richard Reed

List of TSC members

Prof Andrew Farmer
Prof Peter Bower
Prof Ly-Mee Yu
Prof Kamlesh Khunti (Chair)
Mr Steve England
Prof Falko Sniehotta
Prof Christopher Weir

TIDieR checklist for the Supporting people with type 2 diabetes in effective use of their medicine through mobile health technology integrated with clinical care (SuMMiT-D) trial		
1.	**Brief name**	Supporting people with type 2 diabetes in effective use of their medicine through mobile health technology integrated with clinical care (SuMMiT-D)
2.	**Rationale or theory**	Systematic reviews of text messages used to support patients to adhere to treatment, and of mobile health interventions in diabetes, identify some effective interventions. There are a few trials testing the impact of brief messaging in type 2 diabetes, but they do not have systematically developed interventions based on theory and evidence and are at risk of bias.(1, 2) Recent trials of text-messaging for cardiovascular risk prevention and blood pressure lowering have shown clinically relevant changes in outcomes compared with usual care.(3, 4) In addition, there is substantial evidence(5) that tailored interventions are more effective than generic interventions. 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 particular individuals or to small subgroups of individuals; they therefore more precisely target the determinants of the individual's behaviour. SuMMiT-D (SUpport through Mobile Messaging and digital health Technology for Diabetes) is a programme of work comprised of three phases: formative work, a feasibility trial and a large scale, effectiveness randomised controlled trial of a mobile phone-based system intended to deliver brief, tailored, behaviour-change messages to people with type 2 diabetes focusing on use of medication, lifestyle and other aspects of diabetes management. 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 and mapped these onto a standard taxonomy for behaviour change techniques (BCT), that is, active ingredients of interventions used to promote behavioural change.(6, 7) Based this work on the views of people with type 2 diabetes about the acceptability of this approach,(8) we then developed a large set of messages to target each BCT,(9) and examined which types of messages are most useful and easy to understand for people starting and taking an oral diabetes medicine and the extent to which it might be helpful for patients to decide on the types of messages they want to receive. We carried out a feasibility study,(10) and confirmed that the trial processes were acceptable and feasible,(11) and that the response to messages corresponded to that observed in the formative work.(12)

		Usual care	Condition-specific tailored text messaging system plus usual care
			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 behaviour change techniques 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. Frequency of messages received using a particular type of behaviour change technique can be modified based on a participant's response to individual messages received. The style of messages will be patient-centred and will encourage patients to seek further relevant information (including the use of links where possible to selected external websites e.g. Diabetes UK).
3.	**Materials**	Available health materials on type 2 diabetes routinely provided by the health care service.	
4.	**Procedures**		1. All participants were sent a system user guide by email. 2. Timing of messages selected by participant 3. Types of brief messages a) Welcome messages (confirming sign-up) b) Message with instructions about use of system c) Brief treatment and lifestyle adherence support messages randomly selected from library (with rules that ensured individual messages were not repeated) and sent several times per week, each week for 6-months

			d) Reminders of how to use the system to "Like" and "Dislike" messages, STOP and PAUSE sending of messages e) Thank you message at end of study
5.	**Intervention provider**	Automated SMS text-message delivery platform using open-source software and third-party bulk SMS-delivery provider	
6.	**Modes of delivery**	Intervention delivered via 160 characters SMS-text sent to individual participant's own handset. Initial message sent to all enrolled participants is a "Welcome "message confirming sign-up, thereafter after automated messages sent to individual participants as per randomised allocation for 12 months. All trial participants receive infrequent (maximum every four weeks) non-health related messages sent to all participants for trial related purposes including to maintain participant interest in the trial.	
7.	**Location where intervention occurred**	Community	
8.	**Number of times intervention was delivered over what time period**		Brief messages sent three (minimum) to four (maximum) times per week for 6-months
9.	**What, why, when, how intervention was personalised or adapted**		1. The times of day and days of the week for messages is selected by participant 2. The group (behavioural change technique) from which messages are sent is modified on the basis of the participant sending "likes" and "dislikes" as text-messages
10.	**Modifications during the trial**	Nil	None
11.	**Planned intervention delivery**	Brief messages will be sent using an automated system independent of trial and clinical staff. Participants will be told that not everyone will be receiving the same messages. Participants will also be asked not to share their health messages with others. Intervention fidelity (receipt of messages and linkage to an individual) will be checked by response to the REGISTER request. Message delivery reports will be monitored throughout the trial to check the intervention is being delivered as planned. Messages not delivered (network unavailable etc.) will be resent up to three times. Where message delivery fails after three sequential attempts a failed message protocol will be initiated to track the participant and up-date their phone number if required.	

12.	**Actual intervention delivery**	Will be monitored during trial, blind to allocated group

1. Farmer AJ, McSharry J, Rowbotham S, McGowan L, Ricci-Cabello I, French DP. Effects of interventions promoting monitoring of medication use and brief messaging on medication adherence for people with Type 2 diabetes: a systematic review of randomized trials. Diabet Med. 2016;33(5):565-79.
2. Ricci-Cabello I, Bobrow K, Islam SMS, Chow CK, Maddison R, Whittaker R, et al. Examining Development Processes for Text Messaging Interventions to Prevent Cardiovascular Disease: Systematic Literature Review. JMIR Mhealth Uhealth. 2019;7(3):e12191.
3. Chow CK, Redfern J, Hillis GS, Thakkar J, Santo K, Hackett ML, et al. Effect of Lifestyle-Focused Text Messaging on Risk Factor Modification in Patients With Coronary Heart Disease. JAMA. 2015;314(12):1255.
4. Bobrow K, Farmer AJ, Springer D, Shanyinde M, Yu LM, Brennan T, et al. Mobile Phone Text Messages to Support Treatment Adherence in Adults With High Blood Pressure (SMS-Text Adherence Support [StAR]): A Single-Blind, Randomized Trial. Circulation. 2016;133(6):592-600.
5. Kassavou A, Sutton S. Automated telecommunication interventions to promote adherence to cardio-metabolic medications: meta-analysis of effectiveness and meta-regression of behaviour change techniques. Health Psychol Rev. 2018;12(1):25-42.
6. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81-95.
7. Long H, Bartlett YK, Farmer AJ, French DP. Identifying Brief Message Content for Interventions Delivered via Mobile Devices to Improve Medication Adherence in People With Type 2 Diabetes Mellitus: A Rapid Systematic Review. J Med Internet Res. 2019;21(1):e10421.
8. Bartlett YK, Newhouse N, Long HA, Farmer AJ, French DP. What do people with type 2 diabetes want from a brief messaging system to support medication adherence? Patient Prefer Adherence. 2019;13:1629-40.
9. Bartlett YK, Farmer A, Rea R, French DP. Use of Brief Messages Based on Behavior Change Techniques to Encourage Medication Adherence in People With Type 2 Diabetes: Developmental Studies. J Med Internet Res. 2020;22(5):e15989.
10. Farmer A, Allen J, Bartlett K, Bower P, Chi Y, French D, et al. Supporting people with type 2 diabetes in effective use of their medicine through mobile health technology integrated with clinical care (SuMMiT-D Feasibility): a randomised feasibility trial protocol. BMJ Open. 2019;9(12):e033504.
11. Chi Y, Velardo C, Allen J, Robinson S, Riga E, Judge D, et al. System Architecture for "Support Through Mobile Messaging and Digital Health Technology for Diabetes" (SuMMiT-D): Design and Performance in Pilot and Randomized Controlled Feasibility Studies. JMIR Formative Research. 2021;5(3):e18460.
12. Bartlett YK, Kenning C, Crosland J, Newhouse N, Miles LM, Williams V, et al. Understanding acceptability in the context of text messages to encourage medication adherence in people with type 2 diabetes. BMC Health Services Research. 2021;21(1).

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Supporting people with type 2 diabetes in effective use of their medicine through mobile health technology integrated with clinical care to reduce cardiovascular risk (SuMMiT-D): an effectiveness and cost-effectiveness randomised control trial protocol

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	3
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	After 17
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	17 and following
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	17
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	17
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	17 and appendix
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and	4

		unpublished) examining benefits and harms for each intervention	
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	5
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7 plus TiDierR checklist
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	11
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	11
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	N/A
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	7
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A	9/10

		schematic diagram is highly recommended (see Figure)	
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	8
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	11
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	9/10

Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9/10/11
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12/13
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12/13
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	12
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	2
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg,	N/A

		investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	9
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	16
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	After 18
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	14
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	14
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

Participant ID __ __ / __ __ __ / __ __ __ __ __ __ Date Completed

Your views about your diabetes treatment

(Questionnaire to be adapted for electronic use as well)

This survey is about what you think and feel about your tablets, as well as how you approach taking them. There are no right or wrong answers. We know some of the items might be difficult to answer, but please choose the answer that best describes what you think. When you are completing the survey please think about the tablets you are prescribed to help with your diabetes. **This includes medicines to lower your blood sugar, cholesterol, or blood pressure.** Please note that all of these medicines will be referred to as **'diabetes tablets'** in the questions below.

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
1.	It is easy to take my tablets as prescribed	☐	☐	☐	☐	☐
2.	I am confident that I can take my diabetes tablets as prescribed	☐	☐	☐	☐	☐
3.	Without my diabetes tablets I would be very ill	☐	☐	☐	☐	☐
4.	My health in the future will depend on my diabetes tablets	☐	☐	☐	☐	☐
5.	I sometimes worry about the long-term effects of my diabetes tablets	☐	☐	☐	☐	☐
6.	I sometimes worry about becoming too dependent on my diabetes medicine	☐	☐	☐	☐	☐
7.	I want to take my diabetes tablets as prescribed every day over the next 3 months	☐	☐	☐	☐	☐

Participant ID: ___/___ ___/___ ___ ___ ___ ___

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
8.	I will take my diabetes tablets as prescribed every day over the next 3 months	☐	☐	☐	☐	☐
9.	Taking my diabetes tablets as prescribed is something I do without thinking	☐	☐	☐	☐	☐
10.	Taking my diabetes tablets as prescribed is something I do without noticing that I do	☐	☐	☐	☐	☐
11.	I am confident that I am able to take my diabetes tablets as prescribed even when something disrupts my routine	☐	☐	☐	☐	☐
12.	I am confident that I can take my diabetes tablets as prescribed even when I feel well	☐	☐	☐	☐	☐
13.	I have made a detailed plan for when to take my diabetes tablets	☐	☐	☐	☐	☐
14.	I have made a detailed plan about exactly where to take my diabetes tablets	☐	☐	☐	☐	☐
15.	I have made a detailed plan for what to do to help me take my diabetes tablets as prescribed when facing barriers to do so	☐	☐	☐	☐	☐
16.	I have made a detailed plan for how to deal with unpleasant side effects of taking my diabetes tablets as prescribed	☐	☐	☐	☐	☐
17.	During the last 4 weeks I consistently monitored when,	☐	☐	☐	☐	☐

Participant ID: ___/___ ___ ___/___ ___ ___ ___ ___

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
	where, and how I took my diabetes tablets					
18.	During the last 4 weeks I really tried hard to take my diabetes tablets as prescribed	☐	☐	☐	☐	☐
19	I know when I have missed a dose of medication	☐	☐	☐	☐	☐
20.	I use things around me to help me to take my diabetes tablets as prescribed (e.g. notes, phone reminders)	☐	☐	☐	☐	☐
21.	I change things around me to prompt me to take my diabetes tablets as prescribed	☐	☐	☐	☐	☐
22.	I have had somebody help me to take my diabetes tablets as prescribed	☐	☐	☐	☐	☐
23.	I have felt supported in taking my diabetes tablets as prescribed	☐	☐	☐	☐	☐
24.	If I needed help, there would be somebody who could help me to take my diabetes tablets as prescribed	☐	☐	☐	☐	☐
25.	Given the effort I have put into taking my diabetes tablets, I am content with my diabetes control	☐	☐	☐	☐	☐
26.	I am content with what I have experienced as a result of taking my diabetes tablets	☐	☐	☐	☐	☐
27.	It is likely that I will develop complications, or experience worse complications from my	☐	☐	☐	☐	☐

		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree
	diabetes if I do not take my tablets					
28.	I feel very at risk of developing complications, or experiencing worsening of existing complications from my diabetes if I do not take my tablets	☐	☐	☐	☐	☐
29.	If I don't take my diabetes tablets when something disrupts my routine, I am sure that I am able to start taking them again	☐	☐	☐	☐	☐
30.	If I don't take my diabetes tablets for any reason, I can start taking them again even if I feel well	☐	☐	☐	☐	☐
31.	Taking an active role in my health care is the most important factor in determining my health and ability to function	☐	☐	☐	☐	☐
32.	I am confident that I can take actions that will help prevent or minimise some symptoms or problems associated with my health condition	☐	☐	☐	☐	☐
33.	I feel the messages I received were useful to me	☐	☐	☐	☐	☐
34.	I think it was easy to follow the advice suggested	☐	☐	☐	☐	☐
35.	It would be helpful for me to continue receiving messages like this, about my diabetes tablets	☐	☐	☐	☐	☐

Participant ID: __ __ / __ __ __ / __ __ __ __ __ __

If you have any comments about this survey, please leave them below.

Thank you for completing this survey

Please return to the SuMMiT-D study team in the envelope provided.

If you have any questions, please contact xxxxxxxxxxx

Participant ID ___ ___ / ___ ___ ___ / ___ ___ ___ ___ ___ **Date Completed** DD / MMM / YYYY

Your Use of the Health Service

Please read the instructions carefully. If you have any questions please contact xxxxx

(Questionnaire to be adapted for electronic use as well)

This questionnaire is about any services you have used or the costs you have had to meet because of your diabetes or because of other health reasons.

1. **Over the past three months, have you been seen at your GP surgery?**
(*include visits for the SuMMiT-D study*)

No ..... ☐ Please go to question 2

Yes ..... ☐ Please state number of times below

	Number of visits over the past three months
Seen by a doctor	
Seen by a practice nurse / diabetes nurse	
Seen by a phlebotomist (takes blood)	
Seen by a health care assistant	
Seen by any other healthcare **professional at your GP's surgery** - please state below:	
Example: Pharmacist	*Example: 1*
✎	
✎	

2. **Over the past three months, have you been seen at home by, or spoken to, a doctor, nurse or any other healthcare professional?**

No ..... ☐ Please go to question 3

Yes ..... ☐ Please state number of times below

	Number of home visits over the past three months
Seen by a doctor at home	
Seen by a nurse at home	
Seen by any other healthcare professional at home - please state below:	

Example: Health care assistant	*Example: 6*
Telephone or video consultation with a doctor	
Telephone or video consultation with a nurse	
Used NHS 111	
Telephone or video consultation with any other healthcare professional at home – please state below:	
Example: Diabetes specialist nurse	*Example: 1*

3. **Over the past three months, have you been seen at a hospital outpatients department or clinic?**

No ..... ☐ Please go to question 4

Yes ..... ☐ Please state number of times below

	Number of visits over the past three months
Seen by a hospital based specialist doctor	
Seen by a diabetologist (diabetes specialist)	
Seen by an ophthalmologist (eye specialist)	
Seen by a nephrologist (kidney specialist)	
Seen by any other hospital based specialist doctor - please state specialty below:	
Example: *Orthopaedic specialist*	*Example: 2*
Seen by a specialist nurse	
Seen by a diabetes educator	
Seen by a dietician	
Seen by a podiatrist (foot specialist)	
Seen by any other healthcare professional at a hospital outpatients department, not already mentioned - please state below:	
Example: *Physiotherapist*	*Example: 2*

Participant ID: ___ ___ / ___ ___ ___ / ___ ___ ___ ___

4. **Over the past three months, have you been admitted to hospital as an inpatient** *(stay overnight)* **or as a day case?**

No …… ☐ Please go to question 5

Yes …….. ☐ Please fill in the table below

Stay no.	Number of nights over the past three months	Record hospital and ward specialty.	Record any surgery
1			
2			
3			
4			
5			

5. **Over the past three months, have you been to a hospital A&E** *(casualty)* **department?**

No …… ☐ Please go to question 6

Yes …… ☐ If 'yes' how many times? _____

6. **Over the past three months, have you made use of the ambulance service on any of the occasions you have told us about above?**

No …… ☐ Please go to question 7

Yes …… ☐ If 'yes' how many times? (Count each single journey) _____

7. **Over the past three months, have you seen any of the following people through the NHS or social services because of your diabetes or because of other health reasons?**

Social service	**Delete as appropriate**	**How many times?** *If no, please insert 0*
Example: Optician	*Yes ~~/ No~~*	*Example: 2*
Optician (free eye test or NHS voucher)	Yes / No	
Social Worker	Yes / No	
Occupational Therapist	Yes / No	
Physiotherapist	Yes / No	
Psychologist	Yes / No	
Counsellor	Yes / No	
Other person - please state below:	**How many times?**	[redacted]
✎		
✎		

8. **Over the past ONE month, have you taken any medicines/tablets (either prescribed or bought over the counter)?**
(Please include **all** medicines/tablets that you have taken, including those for your diabetes, such as those to lower blood sugar, cholesterol, or blood pressure)

No ..... ☐ Please go to question 9.

Yes ..... ☐ Please fill in the table below. Please provide as much information as you can in the box below about **each of** the medications. Even if you can't remember the exact details, please can you estimate it for us?

Please give the name(s)* of the medicine(s)/tablets. **Brand name where possible*	**Was it prescribed by a doctor?** *Please circle*	**What is the strength of the medicine/tablets?** *e.g. 200mg*	**How many tablets (or volume of liquid) were supplied?** *If you don't have this information, please write 'don't know'*	**If you paid for the medication, how much did it cost you?** *If you don't have this information, please write 'don't know'*
Example: Paracetamol	*Yes / (No)*	*500mg*	*Don't know*	*£0.75*
	Yes / No			£
	Yes / No			£
	Yes / No			£
	Yes / No			£
	Yes / No			£
	Yes / No			£
	Yes / No			£

9. Over the past ONE month, how often have you tested your blood sugar level?

Please ✓ one box only

	Please tick ✓ one box
Never	
Once a week or less	
About 2-6 times a week	
Once a day	
Two or more times a day	

Thank you for completing this questionnaire.

Please return to the SuMMiT-D study office in the envelope provided.

If you have any questions, please contact xxxxx

Participant ID: ___/___ ___ ___/___ ___ ___ ___ ___ Date Completed: DD / MMM / YYYY

Experience of having diabetes

(Questionnaire to be adapted for electronic use as well)

The following questions are about your overall experience of having diabetes. Please read the questions carefully, and choose the option that best describes how you feel.

		MUCH BETTER	BETTER	SAME	LESS
1	Over the last year, how do you feel your understanding of your diabetes has changed?				
2	Over the last year, how do you feel your understanding of your diabetes ***treatment*** has changed?				

		VERY SATISFIED	SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	DISSATISFIED	VERY DISSATISFIED
3	How do you feel about your diabetes ***treatment***?					

		VERY GOOD	FAIRLY GOOD	NEITHER GOOD NOR POOR	FAIRLY POOR	VERY POOR
4	Overall, how would you describe the care for your diabetes you are receiving from your local general practice surgery?					

Thank you for taking the time to complete this questionnaire.

Please return to the SuMMiT-D study office in the envelope provided.

If you have any questions, please contact XXXXX

Examples of text messages and linked behaviour change techniques

Target and category of message	Behaviour change technique/ Belief or concern	Example messages
Medication adherence, BCT	Action Planning	Plan when, where and how you are going to take your medication.
Medication adherence, BCT	Verbal persuasion about capability	If you are struggling with your diabetes tablets then don't worry, you will be able to master it in time. You will get on top of it.c
Medication adherence, BCT	Prompts/ cues	It can be difficult to remember to take your tablets. Why not set an alarm to remind you to take them?
Medication adherence, BCT	Self-monitoring	Find a way to split your tablets into days so you notice when you have forgotten to take your tablets
Medication adherence, BCT	3.2 Social support (practical)	How often do you forget to take your tablets? Take control. Ask your friends and family members to help. Their reminders could help you to improve your diabetes
Medication adherence, BCT	Mental rehearsal of successful performance	Visualise in detail how you will take your tablets tomorrow. This will make it easier when you actually take them
Medication adherence, BCT	Social support (emotional)	If you're not taking your tablets as often as you should, try discussing your feelings with someone.
Medication adherence, BCT	Mental rehearsal of successful performance	Think about situations where taking tablets was easy. How could you make your everyday tablet taking like this?
Medication adherence, beliefs and concerns	Healthcare system related concerns	Lots of questions? Check who the best person to see might be
Diet management	Signposting	Stuck for new ideas? You can search recipes for mains, desserts and snacks online at Diabetes.org.uk