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SMS supporting treatment for people with type 2 diabetes

Submission date	Recruitment status	[X] Prospectively registered
03/07/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/08/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2024	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Treatment for patients with type 2 diabetes could be greatly improved in sub-Saharan Africa. Amongst the problems identified, failure to take medicines to treat diabetes regularly is a major problem. Resources to identify and support patients who are not making best use of medicine in low and middle-income settings are scarce. Mobile phones are widely available in these settings including among people with diabetes and linked technologies such as SMS-text messaging, and have shown promise in delivering low cost interventions efficiently. However, evidence that these interventions will work when carried out at a larger scale, and of the extent to which they will improve health outcomes when added to usual care is limited. The overall aim of this study is to test if sending short message service (SMS) texts works well in improving overall diabetes control in patients and supporting them to adhere to their diabetes treatment compared to usual care.

Who can participate?

Adults (aged at least 18) with type 2 diabetes and access to a mobile phone.

What does the study involve?

First of all, a preparatory study is carried out where patients and staff are interviewed to be sure that the SMS messages are clear, informative and acceptable. We ensure that the technology is embedded in clinical care, and that the message content is appropriate for each of the planned sites. We also collect detailed information about how the systems are set up and used to guide future attempts to set up similar systems in other places and for other long-term conditions. We will extend the qualitative work during and after the main trial to see how the technology is used and how people feel about it. Participants attending each of the centres participating in the study are then randomly allocated to one of two groups. Those in group 1 are sent informative messages, telling them about the benefits of their diabetes treatment and provide reminders and encouragement to take it regularly. Those in group 2 are sent non-health related messages. Each participant is then followed-up for 12 months. Important risk factors for the development of complications in diabetes including blood glucose control and blood pressure control are assessed throughout this period so we can estimate potential health benefits, the costs of doing this, and whether it is cost effective.

What are the possible benefits and risks of participating?
The knowledge gained from carrying out this study will have wide application and provide data, not otherwise available, that will inform health policy and guide future implementation of this type of technology. Participants may find that staying in contact with the study via SMS text-message and answering questions about their experience in taking part helpful. Information from this study will be helpful to the health services and this could benefit the treatment of patients in the future. Participants will be asked to attend two study specific visits that may inconvenience them in terms of time. Participants will have their blood pressure taken that may cause some slight discomfort. We will take two blood samples that may cause some discomfort.

Where is the study run from?
The University of Cape Town (South Africa). University of the Witwatersrand (South Africa) and the The Malawi Epidemiology and Intervention Research Unit (Malawi)

When is the study starting and how long is it expected to run for?
October 2016 to April 2019

Who is funding the study?
Global Alliance for Chronic Disease in partnership with the UK Medical Research Council (UK)

Who is the main contact?
Professor Andrew Farmer

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC Grant Ref: MR/M016498/1

Study information

Scientific Title
Mobile phone text-messaging to support treatment for people with type 2 diabetes in sub-Saharan Africa: a pragmatic individually randomised trial

Acronym
StAR2D

Study objectives
The overall aim of this project is to test the effectiveness of sending short message service (SMS) texts in improving health outcomes and supporting medication adherence in patients with type 2 diabetes in the context of implementing a low-cost, mobile-health communication infrastructure in an operational setting.
The objectives of the clinical trial are to:
1. Evaluate the effectiveness of SMS messages in improving overall diabetes control and supporting adherence to diabetes medicines compared with usual care
2. Examine the incremental cost and cost-effectiveness of introducing a new SMS-text messaging programme into an existing health service setting

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Research Ethics Committee - OxTREC, 10/04/2015, ref: 22-15
2. University of Cape Town Human Research Ethics Committee, 22/05/2015, ref: 126/2015
3. University of the Witwatersrand Human Research Ethics Committee (Medical), 08/06/2015, ref: 14/49
4. Malawi NHSRC, 08/09/2015, #15/7/1425

Study design
Individually randomized controlled two-arm trial stratified by clinical centre

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The trial intervention is mobile phone short message service (SMS) texts. We will allocate patients using a randomly generated assignment plan to receive either informative messages, or non-health related messages. Trial participants allocated to the intervention group will be assigned to receive culturally appropriate text messages including motivational, educational and prompts (reminders) about medication collection with timing guided by the information collected about all participants at baseline visit, from clinic and from pharmacy attendance. Trial participants allocated to the usual care group will receive only non-informational text messages (for example messages thanking the participant for taking part in the study, and a message on their birthday) alongside usual care. Participants allocated to the usual care group, along with all clinic attendees, attendance recorded, but with no further actions relating to the randomly allocated intervention occurring. We will use a remote web-based randomisation programme for time since diagnosis, age, gender and trial site. Randomisation is carried out remotely and independently of the clinic and local research staff.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 11/10/2016 (methods and timepoints of measurement added 26/10/2017):
Change in HbA1c, measured with International Federation of Clinical Chemistry calibrated analyzers linked to a quality assurance scheme from baseline to one year

Previous primary outcome measure (methods and timepoints of measurement added 26/10 /2017):
Change in HbA1c and the proportion of patients collecting 80% or greater of their agreed diabetes related medication derived from routine clinic data

Secondary outcome measures
Current secondary outcome measures as of 11/10/2016:
1. The proportion of patients collecting ≥80% of their agreed diabetes related medication derived from routine clinic data from baseline to one year
2. Change in systolic blood pressure, measured with valid oscillometric device from baseline to one year
3. Changes in lipids, measured with a calibrated analyzer linked to a quality assurance scheme from baseline to one year
4. A combined measure of cardiovascular risk based on HbA1c, lipids and systolic blood pressure measured from baseline to one year
5. The proportion of participants reaching treatment goals (with HbA1c<8% and systolic BP<140mmHg) at one year
6. Change in self-reported measures of health status, measured with the EQ5D-5L self-report measure from baseline to one year
7. Changes in medication taking, measured with a validated, self-report questionnaire from baseline to one year
8. Changes in eating and physical activity, measured with an 8-item 8-point Likert self-report scale from baseline to one year
9. Change in satisfaction with health care, measured with an eleven-item scale, 7-point Likert self-report scale from baseline to one year

Previous secondary outcome measures:
1. Change in systolic blood pressure
2. The proportion of the participants reaching treatment goals (with HbA1c<8% and systolic BP<140mmHg.)
3. Changes in self reported measures of health status
4. Self reported medication taking, eating and physical activity
5. Satisfaction with health care

Overall study start date
01/10/2016

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Able to communicate in one of the predominant official languages spoken in the Western Cape (Cape Town) and Gauteng (Johannesburg) provinces (e.g. English, Afrikaans, isiXhosa, isiZulu and Sesotho), in South Africa and in Malawi, English or the Chichewa language
3. Male or female, aged 18 years of above
4. A diagnosis of type 2 diabetes
5. Taking oral glucose lowering treatment
6. Has access to a mobile-phone (shared access is allowed with permission of phone owner)
7. Knows how to use SMS (it is okay if participant needs help to send or retrieve SMS)
8. Currently lives in the community served by the clinic and plans to live there for the next 18 months

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1065

Total final enrolment
1066

Key exclusion criteria
1. Within three months of a hospital admission for hyperglycaemia or hypoglycaemia
2. Pregnant or within three months post-partum by self-report or with plans to become pregnant in the next 12 months
3. A terminal medical condition
4. Another member of the household already recruited to the trial
5. Participation in the formative work for the intervention

Date of first enrolment
01/10/2016

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Malawi

South Africa

Study participating centre
University of Cape Town
Rondebosch
Cape Town
South Africa
7700

Study participating centre

University of the Witwatersrand
1 Bertha & Jorissen St
Johannesburg
South Africa
2000

Study participating centre
The Malawi Epidemiology and Intervention Research Unit (MEIRU)
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Sponsor information

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University of Oxford

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OX3 7LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Global Alliance for Chronic Disease in partnership with the UK Medical Research Council

Results and Publications

Publication and dissemination plan
The trialists will disseminate their findings through a wide range of routes including briefing meetings with stakeholders, conference presentations and written reports. The main findings, intervention development, trial protocol and process evaluation will be reported in peer-reviewed journals. The main trial findings are anticipated to be published in 2020.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in the non-publicly available Oxford University Primary Care Clinical Trials Unit repository. Requests for sharing of anonymised/de-identified individual participant data and a data dictionary defining each field in the set will be considered by the corresponding author.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	30/05/2019	17/06/2019	Yes	No
Basic results		30/04/2020	30/04/2020	No	No
Other publications	intervention development	15/01/2021	18/01/2021	Yes	No
Other publications	Process evaluation	21/08/2021	23/08/2021	Yes	No
Results article		21/10/2021	26/10/2021	Yes	No
Other publications	Secondary analysis	10/09/2018	18/09/2024	Yes	No