ISRCTN10342151 https://doi.org/10.1186/ISRCTN10342151

Diabetes text study

Submission date	Recruitment status	[_] Prospectively registered
27/11/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
11/03/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/04/2023	Nutritional, Metabolic, Endocrine	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Diabetes is a condition that causes a person's blood sugar level to become too high. Inulin is the hormone (produced by the pancreas) that controls the amount of glucose in the blood. There are two main types of diabetes: Type 1 where the pancreas does not produce any insulin and type 2 where the pancreas does not produce enough insulin or the person's cells do not react to insulin.
The aim of this study is to assess whether a program called DATES and made of series of tailored text messages plus usual diabetes care will work better that usual care iin improving glycaemic control (the control of blood sugar level) in people with type 2 diabetes

Who can participate?
Adults with poorly controlled type 2 diabetes mellitus and who are registered at Dasman Institute and in the primary care centres affiliated to the Dasman Institute.

What does the study involve?
Participants will be randomly allocated to one of two groups: usual care or usual care plus DATES program.
Usual care includes face to face appointments with specialists, drug prescribing, lifestyle advice and counselling, weekly texts giving general advice and information.
Usual care plus DATES program: participants will receive motivational text messages to help them in making diet and exercise changes. The messages will contain standardised, personalised and responsive messages. Participants will also have access to a telephone hotline and a website for further information about self-motivation, tips on how to increase physical activity and change to a healthy diet.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dasman Institute and in primary care centres affiliated to the Dasman Institute (Kuwait).

When is the study starting and how long is it expected to run for?
September 2013 to February 2015

Who is funding the study?
The Dasman Diabetes Institute, Kuwait and Kuwait University

Who is the main contact?
Ms Clare Tucker

Contact information

Type(s)
Public

Contact name
Ms Clare Tucker

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DDI Protocol No. RA-2012-006

Study information

Scientific Title
The Diabetes And TEle-mobile Study (DATES): a randomised controlled trial of mobile health intervention to support self-management for people with type 2 diabetes

Acronym
DATES

Study objectives
A package of automated tailored text messages based on motivational interviewing plus usual diabetes care will be more effective than usual diabetes care in improving glycaemic control.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Dasman Diabetes Institute, Kuwait RA/049/2012, 10/06/2012

Study design
Two-arm parallel randomised controlled trial over 12 months

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Usual care
All participants will receive usual diabetes care from the Dasman Diabetes Institute. This includes face to face clinical appointments with the diabetologist, diabetes specialist nurse and dietician, prescribing of medication, lifestyle advice and counselling using adult learning education techniques. They also receive weekly texts giving advice and information about diabetes. The usual care only group will also receive weekly text messages such as thanking them for their participation and regarding the rationale for the study.

Usual care plus DATES intervention
Participants will receive motivational text messages to support them in making diet and exercise changes. The theoretical framework underlying the text messages will be derived from motivational interviewing and cognitive behaviour theory. The messages will contain both standardized, personalized and responsive messages. The text messages will be delivered at set times as well as being responsive to certain requests (e.g. crave). Participants will also have access to a telephone hotline run by the research nurse to provide the additional clinical support that may arise from receiving frequent text messages. They will also have access to a website giving further information about self-motivation, tips on how to increase physical activity and change to a healthy diet in a culturally sensitive framework.

The key features of the intervention will be:

1. Personalising the intervention. At baseline assessment, participants will be asked to identify their top three reasons for wanting better diabetes control. Participants will be provided with prompts if they are unable to generate their own reasons. Prompts may include: for their children/family, to avoid complications (keeping sight, kidney, amputations) to live longer, to avoid insulin, to keep their job, to be happier, to feel physically better.

2. Intensity: Participants will receive 3 text messages a day for 12 months: 2 standard text messages that everyone receives and one personalized message based on the nature of the personal reasons for better diabetes control.
3.Target behaviours: this will be a rolling programme of automated messages delivered to all participants in the intervention group. It will consist of a standardised database of chronologically ordered core messages (around 170-180 messages) will be sent to everybody that covers the 2 target behaviours over the first 6 month period. These will be repeated in the second 6 months. Some messages will target cognitions (thoughts) and others behaviours. i.e.:
1-3 months: 2 standard messages/daily targeting diet, weight and healthy eating plus 1 personalized message/daily
4-6 months: 2 standard messages/daily targeting physical activity and exercise plus 1 personalized message/daily
7-12 months: Repeat of diet and exercise messages from months 1-6 plus 1 personalized message/daily
4. A personalised database of text messages (around n=100) tailored for the individual based on diabetes status, demographic and psychological characteristics (including the motivational drivers identified in point 1) will be generated using an algorithm-based coding that instructs the computer software as to which personal packages of messages to send.
5. Responsiveness: Participants will be invited to text CRAVE or LAPSE when they are feeling particularly vulnerable to a relapse. CRAVE will indicate that the participant is thinking about pursuing an unhealthy behaviour (e.g. eating a high calorie food, or avoiding their exercise regime) but have not acted upon this yet. LAPSE will indicate that patients have acted upon their cravings and need support to reengage with their good intentions. A responsive database of text messages will be used to encourage patients to maintain their healthy habits when they text CRAVE or LAPSE.
6. Medical care: If participants have any medical queries related to their diabetes. For instance, if they are concerned their blood sugars are too high, too low, or they have missed medication or other symptoms they can call the study Helpline for immediate advice between 9am and 12 midnight.
7. Participants will be provided with a wallet sized card including the Helpline phone number, the text codes and definitions (i.e. CRAVE and LAPSE) and a website address where they can receive additional information regarding diabetes care, healthy eating (including recipes) and exercise.
8. Participants will be sent a pedometer and instructions on how to use and free samples of healthy foods developed by the Dasman Diabetes Institute chef.

Intervention Type
Behavioural

Primary outcome measure
Difference in HbA1c from baseline to 12 months between the 2 arms

Secondary outcome measures
Difference from baseline to 12 months between the 2 arms in body mass index, physical activity, fasting lipids, and quality of life. We will also measure HbA1c at 6 months into the treatment to examine the rate of change in glycaemic control and to minimise attrition

Overall study start date
01/09/2013

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Adults with poorly controlled type 2 diabetes mellitus and who are registered at Dasman Institute and in the primary care centres affiliated to Dasman. Type 2 diabetes will be defined according to current World Health Organisation criteria. Poorly controlled diabetes will be defined as having at least one HbA1c value of > 8% in the preceding 12 months and at recruitment despite standard care defined as the offer of at least 2 diabetes clinic reviews in the same time period.
2. On diet and/or oral hypoglycaemic agents and/or once daily long acting insulin where glycaemic control is monitored by the HbA1c and not by regular self monitoring of blood glucose by patient.
3. Age 18-75 years to increase the representativeness of the sample and to be inclusive of all ages.
4. Fluent in spoken Arabic or English and have a reading age in Arabic or English of a minimum age 7 years.
5. Officially resident in Kuwait.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Duration of type 2 diabetes less than 1 year as these patients are still coming to terms and adjusting to the diagnosis and the self care roles.
2. Women who are gestational or planning pregnancy as they have specialist diabetes care needs
3. People with severe mental illnesses such as psychosis, learning difficulties, dementia excluded from the medical records and by checklist from the physician.
4. People with advanced cancer or diabetes complications (renal failure as measured by ACR > 50, above ankle amputation, registered partially blind) or terminal conditions.
5. Inability or unwillingness of individual or legal guardian/representative to give written informed consent.
6. Multiple insulin doses regimens as this will increase the need for more clinical resources to provide a more intensive biofeedback service requiring more clinician support. The purpose of the M-and-M study is to test whether a stand-alone psychological intervention delivered in a virtual media with minimum clinical support can be effective as an adjunct to usual diabetes care.

7. People who do not have access to a mobile phone or the internet.
8. Individuals with another member of their household participating in the study

Date of first enrolment
01/09/2013

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
Kuwait

Study participating centre
Dasman Diabetes Centre
Kuwait
-

Sponsor information

Organisation
Kuwait University

Sponsor details
Faculty of Medicine
Department of Medicine
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Kuwait
Kuwait
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Sponsor type
University/education

ROR
https://ror.org/021e5j056

Funder(s)

Funder type
University/education

Funder Name
Kuwait University

Funder Name
Dasman Institute, Kuwait

Results and Publications

Publication and dissemination plan
Submission of current protocol to peer-reviewed journal in next 3 months (Q1 2015). Submission of results when complete to peer reviewed international journal within 12 months (end of 2015). Submission of process evaluation to peer reviewed international journal within 18 months (Q2 2016).

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/11/2018		Yes	No
Statistical Analysis Plan			04/04/2023	No	No