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The role of text messages in helping people to change to a healthy lifestyle to stop them from getting diabetes type 2

Submission date
24/05/2018

Recruitment status
No longer recruiting

Registration date
04/06/2018

Overall study status
Completed

Last Edited
25/11/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Pre-diabetes is a condition where the person is not yet diabetic but is at a great risk to be so. A person with pre-diabetes has high blood sugar but not high enough to be called diabetic. A major way to stop a pre-diabetic from becoming diabetic is to have good amount of daily physical activity and eat a healthy diet. There are many ways to help people live a healthy lifestyle. The aim of this study is to see whether encouraging people through text messages helps them to eat healthily and move more.

Who can participate?
People above the age of 18 who are pre-diabetic

What does the study involve?
Participants are randomly allocated to one of two groups. One group is sent the text messages and the other group does not get any messages. Their blood sugar is measured to see which group benefited more. Both groups also get a standard education session on how to eat healthily and move more.

What are the possible benefits and risks of participating?
The expected side effect is a little pain from the needle when taking blood to test blood sugar.

Where is the study run from?
King Saud University Medical City (Saudi Arabia)

When is the study starting and how long is it expected to run for?
September 2018 to December 2020 (as of 19/10/2018)

Who is funding the study?
King Abdulaziz City for Science and Technology (Saudi Arabia)

Who is the main contact?
Dr Rasmieh AlZeidan

Contact information

Type(s)
Public

Contact name
Dr Rasmieh Alzeidan

Contact details
PO Box 102599
Riyadh
Saudi Arabia
11685

Additional identifiers

Protocol serial number
E-17-27607

Study information

Scientific Title
The effectiveness of the text messages to modify lifestyle prevent or delay the onset of type 2 diabetes mellitus among university employees and their families with impaired glucose tolerance in Saudi Arabia: a randomized controlled trial

Study objectives
The trialists hypothesize that the intervention group will have a significant bigger reduction in HA1C than the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB of King Saud University, College of Medicine, 03/10/2017, ref: E-17-27607

Study design
Prospective parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pre-diabetes

Interventions
A computer-generated randomization sequence (Matlab randperm version 6) based on Marsaglia's algorithm to randomly allocate patients (1:1) to individually tailored phone messaging or to a control group that received standard life modification advice at baseline visit only.

The intervention is lifestyle modification text messages that are tailored to the participant according to the Trans Theoretical Model (TTM) stage of change. Both control and intervention groups will receive a baseline standard lifestyle modification education session, and both groups take metformin tablets as prescribed by their treating physician.

Intervention Type
Behavioural

Primary outcome(s)
1. Incident type 2 diabetes measured at the end of the study after 24 months
2. Hyperglycemia measured by HbA1c at baseline and 24 months

Key secondary outcome(s)
1. Level of low density lipoprotein cholesterol (LDL-C) at baseline and 24 months
2. Systolic diastolic blood pressure at baseline and 24 months
3. Body weight at baseline, 12 months and 24 months
4. Physical activity level checked at every 6 month follow up visit and at 24 months
5. Fruit/vegetables intake portions consumed per day at 24 months
6. Incidence of myocardial infarction, stroke, death and re-hospitalization checked through subjects' electronic file at the end of the study

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. ≥ 18 years old
2. Speak and read Arabic or English as applicable
3. Use text messages on their mobile phones
4. Have prediabetes
5. HbA1c value between 5.7-6.4%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. < 18 years old
2. Pregnant women
3, Any subject who has overt diabetes

Date of first enrolment
01/09/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Saud University Medical City
Saudi Arabia
11472

Sponsor information

Organisation
King Saud University

ROR
https://ror.org/02f81g417

Funder(s)

Funder type
Government

Funder Name

King Abdulaziz City for Science and Technology

Alternative Name(s)
KACST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan
The access for data will be restricted to the minimal considering the patients' privacy and upon the approval of King Saud University IRB as it is not clear to what extent the trialists can share data from the legal point of view in Saudi Arabia.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/11/2019	25/11/2019	Yes	No