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Intervention through short messaging system (SMS) and phone call alerts to manage type-2 diabetics

Submission date
08/01/2020

Recruitment status
No longer recruiting

Registration date
15/01/2020

Overall study status
Completed

Last Edited
28/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes, often referred to as diabetes mellitus, describes a group of metabolic diseases in which the person has high blood glucose (blood sugar), either because insulin production is inadequate, or because the body's cells do not respond properly to insulin, or both. The ill-effects of diabetes include extreme thirst, weight loss, and excessive urination, lack of concentration, foot problems, heart diseases, stroke, cataract and retinopathy. Diabetes can be managed to a great extent with patient education, and systematically monitoring changes in patients with diabetes, their health status and support self-care. With the increasing global rates of diabetic population and the increasing cost of healthcare, diabetes can be managed to a considerable extent at home by self-care.
Despite extensive research and newer methods of interventions, the incidence and prevalence of diabetes is increasing at an alarming rate. According to recent projections by the World Health Organization, the number of diabetics is predicted to cross 450 million by 2020. In India, recent statistics have reported a significant increase in the number of diabetics in the last decade. Poor dietary habits, minimal adherence to treatment regimens, lack of timely education are some of the contributing factors for increased incidence and huge economic burden. Prior studies have demonstrated the efficacy of various self-management tools such as educational programs in better patient care. Among various self-management tools, educating the individuals and alerting them using mobile phone calls and short messaging system are widely adopted due to the increasing mobile phone users and availability of short messaging systems in local languages in the recent years. This study aims to determine the benefit of educating patients through phone calls and SMS in the self-management of diabetes.

Who can participate?
Adults with diabetes who have access to a mobile phone

What does the study involve?
Diabetes education through SMS and phone calls will be provided on a regular basis, and HbA1c levels measured at baseline, 8-months, and 14-months. In addition, feedback about patients' satisfaction and utility of the SMS / Phone calls was collected using questionnaires.

What are the possible benefits and risks of participating?
Benefits: Patients will have access to education on diabetes and its management.
Risks: There are no potential risks observed in the study as we have insisted the participants mentioning that, this study is a hand holding for participants to self manage their diabetes but not a substitute to doctors advice or treatment regimen.

Where is the study run from?
JSS Hospital, Mysore, Karnataka, India

When is the study starting and how long is it expected to run for?
September 2017 to February 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Kanakavalli Kundury
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

JSSMC/11/5976/2016-17

Study information

Scientific Title
Effectiveness of self-management in type-2 diabetic patients through ICT intervention

Study objectives
Mobile phone based diabetes education will have an impact in improved HbA1C values among diabetic individuals

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/11/2016, Institutional Ethical Committee, JSS Medical College (Jagadguru Sri Shivarathreeshwara University, Mysore, Karnataka, India; jssmc@jssuni.edu.in; +91 (0)821-2548337), ref: JSSMC/IEC/11/5976/2016-17

Study design
Single centre interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
The study is conducted for a period of 14 months. Individuals with confirmed Type-2 diabetes visiting JSS Hospital, Mysuru, Karnataka, India will be recruited. JSS Hospital is an 1800-bedded tertiary care multispecialty hospital located in the Mysuru district of Karnataka, India.

Participants will be recruited from Nutrition and Dietetics Department of JSS Hospital. Diabetic patients from General Medicine will be sent to Nutrition and Dietetics department for CBG testing, where the consensus is collected and those who provided positive consent will be considered for the study.

An orientation class is arranged where a diabetologist and a dietician educate the study participants with a PowerPoint Presentation in local language about diabetes and associated co-morbidities, dietary practices, physical activity, medication adherence, periodic doctor visits and life style modifications necessary to self-manage the disease. Participants will be provided with a handout containing information related to diabetes. The handout also contains a tabular form to record their blood sugar values. Subsequently, diabetes education through SMS and phone calls is provided once in a week. Diabetes knowledge assessment and participants feedback on the study is obtained using questionnaires. All the records pertaining to this study will be maintained in an iron safe with a lock and key. The records will be accessible only to the principal investigators of this study. Re-orientation class is arranged after 4 months to assess the participants' knowledge on diabetes management. Any changes in the prescribed medicines /dosing schedule/dose will be noted.

Intervention Type
Behavioural

Primary outcome measure
HbA1c measured using blood test at baseline, 8-months, and 14-months

Secondary outcome measures
Diabetes management practices measured using a novel questionnaire at baseline and 8-months

Overall study start date
10/03/2016

Completion date
12/02/2019

Eligibility

Key inclusion criteria
1. Diabetic with no serious co-morbidities
2. Able to use mobile phones and communicate in local language Kannada or in English
3. Agree to provide consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
380

Total final enrolment
380

Key exclusion criteria
1. Critical illness
2. Doesn’t have mobile phone access

Date of first enrolment
09/09/2017

Date of final enrolment
09/12/2017

Locations

Countries of recruitment
India

Study participating centre
JSS Hospital
Mysore
Karnataka
Mysuru
India
570015

Sponsor information

Organisation
JSS Medical College and Hospital

Sponsor details
Bannimantap, S.S. Nagar
Mysuru
India
570015
+91-821-2548416
jssmc@jssuni.edu.in

Sponsor type
University/education

Website
http://jssuni.edu.in

ROR
https://ror.org/02xf0fd83

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Communicated the manuscript to Plos One Journal.

Intention to publish date
30/01/2020

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/11/2020	11/12/2020	Yes	No
Participant information sheet			28/02/2023	No	Yes
Protocol (other)			28/02/2023	No	No