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Phone call based educational intervention for diabetes management

Submission date
28/02/2022

Recruitment status
No longer recruiting

Registration date
06/04/2022

Overall study status
Completed

Last Edited
12/06/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Diabetes is a serious condition where the blood sugar level is too high. In spite of various awareness programs and educational camps, the number of individuals with diabetes is increasing at an alarming rate. Uncontrolled diabetes would lead to various diabetes-associated complications such as heart disease, eye disorders, kidney issues, and neurological disorders. The disease burden is not only directly from diabetes but also from various diabetes-associated conditions.
Diabetes can be self-managed to a great extent by adopting lifestyle behaviours such as diet control, physical activities, periodic doctor visits and investigations and medication adherence. These practices require the involvement of patients in self-care practices. Empowering patients with the education and awareness required to manage diabetes is very important. Traditional educational programs on diabetes management have lacked accessibility, approachability and availability. The aim of this study is to identify the impact of telephone call based diabetes education on the control of blood sugar and knowledge of diabetes.

Who can participate?
Patients with type 2 diabetes

What does the study involve?
Participants are randomly allocated to the case group or the control group. The case group receive diabetes management education through weekly phone calls for a period of 12 months. Control group participants do not receive any education. Blood sugar and knowledge of diabetes management among the groups will be compared at the start of the study and after 4, 8 and 12 months to find the impact of phone call based education.

What are the possible benefits and risks of participating?
Participants can get their HbA1C tests conducted free of cost as an incentive to participate in the study. Case group participants get diabetes management education through phone calls leading to increased knowledge of diabetes. No risks are involved in the study.

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?
February 2016 to February 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Kanakavalli K. Kundury
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
JSSMC/11/5976/2016-17

Study information

Scientific Title
Studying the impact of providing diabetes education through phone calls on the control of hyperglycaemia and knowledge of diabetes

Acronym
Madhuram

Study objectives
Providing continuous education through phone calls reduces HbA1C values and enhances knowledge in individuals with diabetes

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 30/11/2016, Institutional Ethical Committee, JSS Medical College (JSS Academy of Higher Education & Research, Sri Shivarathreeshwara Nagar, Mysore, Karnataka, 570015, India; +91 (0)821 2548337, 2548338; jssmc09@gmail.com), ref: JSSMC/11/5976/2016-17

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Other

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

Interventions
The study is conducted at a tertiary care teaching hospital for 12 months duration. Individuals with diabetes are recruited into the study with informed consent. The participants were randomly allocated to case and control groups using a random sampling method. The participants in the case group receive continuous diabetes education through phone calls. The educational intervention on diabetes includes disease awareness, diabetes management practices, diet control, medication adherence, the role of physical activity, periodic doctor visits, investigations and monitoring for diabetes-associated comorbid conditions. Orientation/re-orientation camps are conducted once every 4 months and weekly phone calls are made to study subjects in the case group. The control group participants receive no education.

HbA1C investigations are conducted in both case and control groups four times during the study period. HbA1C values and knowledge among the case and control group participants are compared to assess the impact of the telephone call based educational intervention.

Intervention Type
Behavioural

Primary outcome(s)
HbA1C values measured using ion exchange chromatography at baseline, 4, 8 and 12 months

Key secondary outcome(s)
Knowledge of diabetes management measured using a questionnaire at baseline, 4, 8 and 12 months

Completion date
28/02/2020

Eligibility

Key inclusion criteria

1. Patients with type 2 diabetes
2. Having no complex disease conditions like cardiovascular diseases (CVDs), terminally ill conditions with cancer and AIDS
3. Participants should have a reasonable ability to operate mobile phones and speak in the local language or English
4. Able to give consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
273

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/01/2019

Date of final enrolment
12/02/2019

Locations

Countries of recruitment
India

Study participating centre
JSS Hospital
M.G.Road
Mysore
India
570004

Sponsor information

Organisation
JSS Medical College and Hospital

ROR
https://ror.org/02xf0fd83

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Kanakavalli K. Kundury (kanakavalli.dhsms@jssuni.edu.in).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/02/2023	12/06/2023	Yes	No