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Improving the management of diabetes and its eye problems in India

Submission date
23/01/2020

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
16/01/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Management of diabetes is emerging as a major public challenge for India. Interventions to improve knowledge/awareness about diabetes and its complications, self-help (attending doctor's appointments, compliance with treatment), and lifestyles (exercising, avoiding smoking /alcohol consumption) are available by different methods such as workshops, radio/television interviews, community events, and street marches by professionals involved in diabetes management. However, what is lacking with diabetes management in India and particularly in Darjeeling district is the inclusion of a multidisciplinary (holistic) diabetic intervention tool that is culturally appropriate. Such a multidisciplinary tool would focus on various interventions together to improve knowledge/awareness about diabetes, physical activity, diet or meal plan, goal setting and attendance for diabetic eye check-up. Furthermore, there is a need to monitor diabetic patients closely to ensure that they follow the intervention given at home. The aim of this study is to examine the effectiveness of a culturally appropriate multidisciplinary diabetic intervention video tool in diabetic patients in Darjeeling, whilst closely monitoring their compliance.

Who can participate?
Patients who have been told by their doctor that they have type 2 diabetes

What does the study involve?
Participants will be randomly divided into two groups using a lottery method. Participants in group 1 will receive training on the multidisciplinary diabetic intervention tool which includes easy to understand video clips in the local language. Training will be provided during the first visit by a member of a research team. The training will last for about 25 minutes with frequent breaks and adequate time to ask questions if participants do not understand any aspects of their participation. Participants in group 2 will not receive any training on the intervention tool, but will receive normal diabetic care. Data will be collected on blood sugar, blood pressure, height, weight, diet, physical activity, at the first visit and follow-up visits after 3 months and 6 months from both the participant groups. All participants will follow their diabetic management and take their medicine as advised. The researchers will also closely monitor participant's compliance to the intervention given via telephone call.

What are the possible benefits and risks of participating?
It is expected that the results of this study will benefit patients with diabetes to better self-manage their condition. The researchers do not expect any concerning risks to participants. Participants' blood samples will be taken under the direct supervision of a consultant doctor using standard procedures. If participants feel tired during the training they will be provided rest for as long as they need it. If participants do not understand anything or have any kind of confusion, they are free to ask questions throughout their participation. They can withdraw at any time without any of their normal management been affected.

Where is the study run from?
Kurseong Sub-divisional Hospital (India)

When is the study starting and how long is it expected to run for?
March 2020 to December 2021

Who is funding the study?
Anglia Ruskin University (UK)

Who is the main contact?
Dr Anupama Biswas
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Contact information

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Public

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Additional identifiers

Protocol serial number
04

Study information

Scientific Title
Intervention to control diabetes and diabetic eye complications in Darjeeling, India

Study objectives
Diabetic patients who are trained on a multidisciplinary intervention tool of diabetic management will have their diabetes controlled significantly better than those who are not.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/07/2019, ethics board of Kurseong Sub-Divisional Hospital (Medical Superintendent, Kurseong district, Darjeeling, India, 734101; Tel: +91 (0)906466971, +91 (0)354 2254218 (medical superintendent); Email: kurseonghospital@gmail.com), ref: 04-D/1682 KSDH146/A/TO/-

Primary study design

Interventional

Study design
Single-centre hospital-based randomized interventional study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diabetes and diabetic retinopathy

Interventions
Patients meeting the inclusion criteria will be recruited from Kurseong Sub-Divisional Hospital, Darjeeling, India through a consultant doctor who specializes in diabetic eye examinations, and is a member of the research team (Dr Biswas).

Patients will be randomly allocated into intervention and non-intervention groups using a lottery method. Patients in the 'intervention' group will attend workshops and receive training in the form of video at the start of the study. The intervention tool contains culturally appropriate short video clips (12 minutes) on knowledge/ awareness about diabetes and its control, misconception about diabetes, physical exercise, diet, goal setting, diabetic eye complications, and the importance of attending diabetic retinopathy screening. Patients in the 'non-intervention (or normal care)' group will not be trained on the intervention tool and will be examined at the first visit and after 3 and 6 months. All patients will take their prescribed diabetes medicine irrespective of which group they belong to.

Data on demographics, BMI, knowledge/awareness about diabetes, self-help, lifestyle, information on diet, physical activity, fasting blood sugar, BP, etc. will be collected from both the patient groups at the first visit, after 3 months and 6 months. A research assistant will recruit patients and the clinical data will be collected by the clinician. The data will be masked and the data collector will not have any knowledge of which group of patients (intervention or non-intervention) the data belong to.

The researchers will also record how many patients attended diabetic eye examinations since they were trained on the intervention tool at the follow-up visits. There will be an equal number of males and female participants between the study groups, and also that the participants will be of similar age between the groups.

Intervention Type
Mixed

Primary outcome(s)
1. Fasting blood sugar and blood pressure levels measured using lab tests at the first and follow up visits after 3 and 6 months
2. Attendance for diabetic eye check-up recorded using hospital records or participants medical files at the follow-up visits

Key secondary outcome(s)

1. Body mass index (BMI) obtained by measuring heights and weights at baseline and follow-up visits after 3 and 6 months
2. Knowledge and awareness of diabetes and its control, healthy lifestyle and diet, measured using a questionnaire at baseline and follow-up visits after 3 and 6 months

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Fasting blood sugar levels of ≥126 mg/dL
2. Patients diagnosed to have type 2 diabetes by a doctor
3. Patients who are able to provide informed written consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
110

Key exclusion criteria
1. Patients with history of having attended diabetic education workshops/seminars
2. Patients who are unable to provide informed written consent
3. Patients self-reporting to have significantly impaired memory functions and other conditions that affect capacity to give consent such as dementia, stroke, Huntingdon’s disease, etc
4. Patients with sudden, painful loss of vision
5. More than one patients from the same family
6. Patients with type 1 or gestational diabetes

Date of first enrolment
01/03/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
India

Study participating centre
Kurseong Sub-Divisional Hospital
Kurseong
Darjeeling district
India
734101

Sponsor information

Organisation
Kurseong Sub-Divisional Hospital

Funder(s)

Funder type
University/education

Funder Name
Anglia Ruskin University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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 by emailing the following members of the research team:
1. Dr Raju Sapkota (raju.sapkota@anglia.ac.uk)
2. Prof. Shahina Pardhan (Shahina.pardhan@anglia.ac.uk)
3. Dr Anupama Biswas (hamalpinkey@gmail.com)
The data requestors will need to sign a data access agreement form.

Type of data: non-identifiable raw data. All participants will be allocated a random designation like P1, P2, etc. (participant 1, participant 2). The data will be available from the time they have been published and up to 4 years. Data may be shared with the scientific community through journal publications and conference presentations, but participants will always remain anonymous. All participants will provide written consent for taking part in the study prior to data collection. The datasets generated and/or analysed will be included in the subsequent results publication depending upon the requirement of the publishing journal.

IPD sharing plan summary

Available on request