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Improving the management of diabetes and its eye problems in Nepal

Submission date
26/04/2019

Recruitment status
No longer recruiting

Registration date
07/05/2019

Overall study status
Completed

Last Edited
14/06/2023

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
Management of diabetes is emerging as a major public challenge for Nepal. 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 usually provided to diabetic patients through 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 Nepal is the inclusion of a multidisciplinary (holistic) diabetic intervention tool that is culturally appropriate. Such a multidisciplinary tool would focus on various interventions to improve knowledge/awareness about diabetes, physical activity, diet or meal plan, goal setting and attendance for a diabetic eye check-up. Furthermore, there is a need to monitor diabetic patients closely to ensure that they follow the intervention given at home. In this study, we aim to examine the effectiveness of a culturally appropriate multidisciplinary diabetic intervention video tool in Nepalese diabetic patients, whilst closely monitoring their compliance.

Who can participate?
Those individuals who have been recently told by their doctor that they have got type 2 diabetes.

What does the study involve?
We will recruit 110 participants in total. Participants will be randomly divided into two groups; participants in group 1 will receive training on multidisciplinary diabetic intervention tool. Training will be provided during the first visit and after 6 weeks by a member of a research team. The training will last for about 20 minutes with frequent breaks and 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. Data will be collected from each participant at the first visit and after three months. All patients will take their diabetic medicine. We will measure data on blood sugar, cholesterol, blood pressure, height, weight, diet, physical activity, at the baseline and after three months and six months from all the participants. We will also closely monitor participant's compliance with the intervention given via telephone call.

What are the possible benefits and risks of participating?
We expect that the results of this study will go on to benefit patients with diabetes in the future

to better self-manage their condition. We 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 can let us know and they will be provided rest for as long as you need it. If participants do not understand anything or have any kind of confusion, they are free to ask questions throughout their participation.

Where is the study run from?
This study will be conducted at the Department of Medicine, Gandaki Medical College and Teaching Hospital, Pokhara, Nepal.

When is the study starting and how long is it expected to run for?
The study starts from 15 May 2019 and is expected to run until December 2021

Who is funding the study?
This research is funded by Global Challenge Research Fund awarded to Vision and Eye Research Unit, Anglia Ruskin University, Cambridge, UK.

Who is the main contact?
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2167

Study information

Scientific Title
Interventions to control diabetes and improve attendance for retinopathy screening in Kaski, Tanahun and Syangja districts of Nepal: a randomised controlled trial

Study objectives
Patients who receive multidisciplinary intervention of diabetic management will have their diabetes controlled significantly better than those who receive normal care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/01/2019, Nepal Health Research Council (Ramshah Path, P.O. Box7626, Kathmandu, Nepal; nhrc@nhrc.gov.np; 00977-42542220), ref: 2167.

Study design
Single-centre randomized double-blinded interventional study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Type 2 diabetes and diabetic retinopathy

Interventions
Patients will be randomly allocated into intervention and non-intervention groups using a lottery method. Patients in the 'intervention' group will receive training on the multidisciplinary intervention tool at the start of the study and again after six weeks. The intervention tool contains video message (appropriate to Nepalese culture) 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 on 'non-intervention (or normal care)' group will not receive any intervention and will be examined at the first visit and after three months.

Data on demographics, knowledge/awareness about diabetes, self-help, lifestyle, information on diet, international physical activity questionnaire, HbA1c, BP, BMI, hip-waist ratio, cholesterol, etc. will be collected from both the patient groups at the first visit and after 12 weeks. A research assistant will recruit patients and the data will be collected by the clinician. They will be masked from each other from knowing which data belong to which group of participant.

Baseline and follow up data will be collected on HbA1c, BMI, blood pressure, cholesterol, demographics, questionnaire on knowledge/awareness about diabetes and its control, self-help, lifestyle, healthy diet, physical activity (International physical activity questionnaire), attendance for diabetic eye screening, goal setting/goals achieved, pedometer recordings, dietary logbook.

Improvement in HbA1c level, blood pressure, cholesterol, knowledge/awareness about diabetes and its control, physical activity, diet, goal setting will be compared between the patient groups at baseline and after three months. 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. Pretesting will be done in 10% of the patients before collecting the data. This will not include study participants.

Intervention Type
Behavioural

Primary outcome measure
1. HbA1c, blood pressure, cholesterol levels are measured using medical tests and follow up visit for both patient groups.
2. Attendance for diabetic eye check-up is recorded at the follow-up visit.

Secondary outcome measures
1. Body mass index (BMI) is measured at baseline and follow up.
2. Knowledge and awareness of diabetes and its control are measured using a questionnaire at baseline and follow-up.
3. Physical activity is measured using pedometers and an international physical activity questionnaire at baseline and follow-up.
4. Dietary habits are measured by using dietary logbook meal planning at baseline and follow up.
5. Support and strategies for healthy goal setting are measured using a questionnaire at baseline and follow up.

Overall study start date
01/01/2019

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. HbA1c levels of ≥7.5
2. Newly diagnosed cases of type 2 diabetes

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
110

Total final enrolment
110

Key exclusion criteria

1. History of having attended diabetic education workshops/seminars.
2. Unable to provide informed written consent.
3. Self-reporting to have significantly impaired memory functions and other conditions that affect the capacity to give consent such as dementia, stroke, Huntingdon's disease, etc.
4. Sudden, painful loss of vision.
5. From the same family as another patient.
6. Type 1, gestational diabetes.

Date of first enrolment
01/05/2019

Date of final enrolment
30/11/2021

Locations

Countries of recruitment
Nepal

Study participating centre
Gandaki Medical College and Teaching Hospital
Sanchayakosh Bhawan Nayabazar
Prithivichowk
Pokhara
Nepal
33700

Sponsor information

Organisation
Department of Medicine, Gandaki Medical College and Teaching Hospital

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Global Challenge Research Fund

Results and Publications

Publication and dissemination plan
The findings will be communicated to the scientific audience, clinicians and the local policy makers through conference presentations, scientific papers, and report writings. The findings will be used to apply for a larger scale study grant to expand on this research.

Intention to publish date
31/12/2022

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, email: raju.sapkota@anglia.ac.uk
2. Professor Shahina Pardhan: Shahina.pardhan@anglia.ac.uk
3. Dr Tirthalal Upadhyaya: tirtha77@gmail.com

The data requestors will need to sign a data access agreement form that we will develop.

Type of data: non-identifiable raw data. All participants will be allocated random designation like P1, P2, etc. (partiicpant1, participant2). The data will be available from the time they have been published and up to four years. Data may be shared to 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.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/01/2023	14/06/2023	Yes	No