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How does a strategy combining education, motivation and counselling affect outcomes in type 2 diabetes patients?

Submission date
12/12/2018

Recruitment status
No longer recruiting

Registration date
20/12/2018

Overall study status
Completed

Last Edited
21/12/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aim
Diabetes Mellitus is a chronic disease that requires life-long management and continuous monitoring to prevent complications. DM has increased dramatically in the Middle East. Diabetes mellitus is a challenge to health professionals, including nurses as the adults need to be empowered for a lifelong self-care management. Socio-cultural factors influence an individual's actions towards goal attainment and outcomes like body mass index, fasting blood glucose, blood pressure and glycemic control. The study aimed to examine the clinical primary outcomes using cognitive behavioural multi-modality strategies among Omani adults with T2D.

Who can participate?
Omani adults were eligible for the study if they were aged > 18 years and above met the medical diagnosis of T2D who spoke and understood Arabic or English.

What does the study involve?
The primary clinical outcomes measured were fasting blood glucose (FBS in mmol/L), glycosylated haemoglobin (HbA1c in %), systolic and diastolic blood pressure (SBP/DBP in mm Hg), and body mass index (BMI in kg/m2) in ISI units. The intervention group (intent to treat) received the cognitive behavioural education using the multi-modality strategies included a structured diabetes education, an animated digital video, motivational interviewing, and a telephone counselling.

What are the possible benefits and risks of participating?
There are no risks of participating in the study. The potential benefits of participating are improving the self-efficacy and self-care activities and behaviours among adults with T2D.

Where is the study run from?
The study is run from the outpatient clinics in Sultan Qaboos University Hospital.

When is the study starting and how long is it expected to run for?
The adults were drawn into a common pool to form the sampling framework during the study period between 2 January 2015 and 30 July 2016.

Who is funding the study?
This study was supported by the Sultan Qaboos University grant (IG/CN/AHCC/14/2).

Who is the main contact?
Melba DSouza, email: melba123@rediffmailcom; desouzamelba123@gmail.com

Contact information

Type(s)
Scientific

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Protocol serial number
N/A

Study information

Scientific Title
A randomized clinical trial to examine the levels of body mass index, fasting blood glucose, blood pressure and glycemic control using Multi-Modality Strategies among adults with type 2 diabetes.

Acronym
MMS

Study objectives
The levels of body mass index, fasting blood glucose, blood pressure, and glycemic control among adults with type 2 diabetes do not change with the use of multi-modality strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Sultan Qaboos Institutional, College, and the Hospital Ethics Review Board, 12/12/2014, ref. IG/CN/AHCC/14/02.

Study design
Two arm, prospective, interventional trial, randomized control trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Methodology used a randomized control trial (RCT) prospective interventional design, with an intervention group and control group in the study. The two-arm RCT was used to evaluate the effects of the multi-modality strategies in improving the primary outcomes (body mass index, fasting blood glucose, blood pressure and glycosylated hemoglobin) among adults with type 2 diabetes (T2D).

A stratified block randomization system was created to generate the blocks and later a random allocation sequence. After the adults were assigned into blocks, a simple randomization using a random number table was performed within each block to allocate the adults to the intervention and the control group. The wash-out period between the baseline and the initial recruitment was 2 weeks to eliminate the effect of the treatment before an active study treatment begins.

The intervention group received the treatment cognitive behavioural education using the multi-modality strategies included a structured diabetes education, an animated digital video, motivational interviewing, and a telephone counselling. The intervention group consisted of adults signed up a cognitive behavioral educational with the diabetes nurse educator for one weekly session for 3 months (a total of 36 hours). The total duration of treatment was 3 months (a total of 36 hours), follow up at the end of the 3 months and the end of the 6 months.

Adults in the control group received only the structured diabetes booklet as a routine and standard hospital information in the outpatient clinics performed by the nurse educator in the outpatient clinic in the selected hospital.

Intervention Type
Behavioural

Primary outcome(s)
1. Fasting blood glucose (FBS in mmol/L) was measured using reliable glucose meters and test strips regulated by the US Food and drug administration was used to ensure safety. One Touch Ultra2 System Kit 1 was used to test the fasting blood sugar levels after an overnight fast. A fasting sugar level less than 100 mg/dl (5.6 mmol/L) is normal and was taken an analysed in the laboratory.
2. Glycosylated haemoglobin (HbA1c in %) was used to monitor blood glucose control over a period of time, indicated an average blood sugar level for the past 2-3 months. An A1c level of

6.5% or higher on two separate tests indicated diabetes and was performed on a valid hemoglobin analyzer Quo-Lab HbA1c.
3. Systolic and diastolic blood pressure (SBP/DBP in mm Hg) was measured using an upper arm blood pressure monitor uA-767 Plus Omron's valid monitor.
4. Body mass index (BMI in kg/m2) in ISI units was measured using a reliable height and weight instrument to balance from digital body height and weight scale.

Key secondary outcome(s))
N/A

Completion date
30/07/2016

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Met the medical diagnosis of type 2 diabetes
3. Counselled about anti-diabetic medications
4. Spoke and understood Arabic or English
5. Had been to the doctor in the last 2 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Complex health problems

Date of first enrolment
02/06/2015

Date of final enrolment
30/12/2015

Locations

Countries of recruitment
Oman

Study participating centre
Sultan Qaboos University Hospital
Sultan Qaboos University,
Al Khoud
Muscat
Oman
123

Sponsor information

Organisation
Sultan Qaboos University

ROR
https://ror.org/049xx5c95

Funder(s)

Funder type
University/education

Funder Name
Sultan Qaboos University IG/CN/AHCC/14/02

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 Melba DSouza. Email: melba123@rediffmailcom; desouzamelba123@gmail.com .

Type of data: numbers in MS excel, data will become available in March 2019 and will be available until April 2019 (1 month)

Access criteria: Shared link on the Google drive with the requesting community of interest

Type of analysis: descriptive statistics

Consent was obtained from the adults with type diabetes regarding the dissemination of data. Human and research ethics approval was granted by the Institutional, College, and the Hospital

Ethics Review Board for a single site trial in a selected hospital. Participation was voluntary, and withdrawal from the study was permitted without any consequences to personal and health care in the study. Study codes or identification numbers were used on the surveys to protect the adult’s responses and prevent anyone viewing the data from determining the adult's identity. Data information was anonymous, and the adult's name with the identifiers was removed from the cover sheet on the datasheet responses to protect the adults' identity after completion.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		18/12/2018	18/12/2018	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes