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Effect of integrated care services on glycemic control and cardiovascular risk factors

Submission date
17/08/2016

Recruitment status
No longer recruiting

Registration date
19/09/2016

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and Aim
Saudi Arabia has one of the highest number of people with diabetes in the world, with studies estimating that approximately 24% of the population have the condition. This is around three times more than the worlds average. In addition to risks of developing further disease and even death, type 2 diabetes (T2DM) take up a lot of healthcare resources and costs. Diabetes is known to significantly increase the risk of vascular diseases such as heart diseases and stroke. This risk can be prevented or at least delayed by intensive glycemic (blood sugar) control along with the control of associated risk factors such as hypertension (high blood pressure). However, many T2DM patients do not adequately follow the measures needed to prevent this risk.Most patients with T2DM are managed by primary care physicians (general practioners). However, long gaps between patient visits and limited time with patients can result in clinical inertia (for example lack of increasing treatments as needed) and consequently less than optimal achievement of treatment goals. Several strategies have been described to overcome barriers to efficient diabetes management at primary care settings, including a multidisciplinary team approach for diabetes management. This approach has been proven to be successful in improving diabetes care in primary care patients. The aim of the current study was to test the impact of a multidisciplinary diabetic care program on glycated hemoglobin (HbA1c – a test to measure the average amount of sugar in the blood over a three month period) and cardiovascular (for example heart) risk factors among patients with poorly controlled T2DM in a primary care setting.

Who can participate?
Adults with poorly controlled type 2 diabetes

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (control group) are given standard medical care from their family physician. Those in group 2 (intervention group) are enrolled into a multidisciplinary care program. Each participant is treated by a multidisciplinary team which includes family medicine physicians, clinical pharmacist specialists, a diabetes health educator, a dietician, and a social worker. All participants in both groups are followed up for approximately ten months, during which time their HbA1c levels are regularly measured.

What are the possible benefits and risks of participating?
Participants in the intervention group may find that their glycemic control has improved. The are no risks to the participants as standard care is included in both groups.

Where the study run from?
The Al-Wazarat Healthcare Center (Saudi Arabia)

When is the study starting and how long is it expected to run for?
October 2013 to January 2015

Who is funding the study?
Prince Sultan Military Medical City (PSMMC)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SA555

Study information

Scientific Title
The impact of integrated care program on glycemic control and cardiovascular risk factors in adults patients with type 2 diabetes at Al-Wazarat Healthcare Center (WHC) in Saudi Arabia: an interventional parallel-group controlled study

Study objectives
Integrated care is more efficient in glycemic control and reducing cardiovascular risk factors than standard care in type 2 diabetic patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research ethics committee at Prince Sultan Military Medical City (PSMMC), 12/02/2014, ref: 555

Study design
Interventional randomized parallel-group double-blinded controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
264 poorly controlled type 2 diabetes patients were randomly assigned to either a control or intervention group.

The control group consists of patients who received standard medical care. The patients in this group worked with their family medicine physician only.

The intervention group consists of patients who were assigned to work with a multidisciplinary care program. The multidisciplinary team consists of family medicine physicians (standard care), clinical pharmacist specialist (severed as cases Manager), a diabetes health educator, a dietitian, and a social worker. The roles of the diabetes health educator, dietitian, and social worker are as follows:

Diabetes health educator roles:
It is an interactive – collaboration ongoing process that involves the person with diabetes and the educator.
1. Assessment of individual specific educational needs
2. Explanation of the nature of the disease
3. Explanation of the interaction between foods, exercise, and medication.

4. Assessment and collaboration on an individual plan of care
5. According to individual needs, the most appropriate standing point will be determined
6. Education and behavioral intervention directed towards helping to achieve self-management goals.
7. Explain insulin injection instruction with a demonstration.
8. Medication instruction
9. Prevention and management of hypo & hyperglycemia.
10. Explain demonstrate self-glucose monitoring, urine testing for between and interpretation of results
11. Explanation of Ramadan, Haj and traveling management
12. Foot care, daily assessment, and action to be taken in case of a problem
13. Discussion of long term complication including screening for early intervention
14. Evaluate patient if able to learn the desired behavior
15. Evaluate the program if it goals and objectives are achieved

Role of dietitian:
1. Assess patient's dietary habits
2. Planning dietary regimes to suit the needs of each patient case-by-case
3. Modify wrong patient conception about diet
4. Monitor weight and advice accordingly

Social Worker Role:
1. Assisting patients with financial issues
2.Facilitate the treatment of physically challenged patients (wheelchairs, home visits, etc.)
Randomization process:
Each patient was given a unique number (1 - 264). A computerized random number generator programmed to generate 132 numbers between 1 and 264. This sequence was agreed on priory as the control group, the remaining 132 numbers not chosen by the generator are considered the intervention group. The patients and outcomes assessors (laboratories, family medicine physicians, nurses who work at the Chronic Disease Department) were blinded to randomization process.

Follow-up period:
The participants were followed-up for a median of 10 months between March 2014 and February 2015.

Intervention Type
Other

Primary outcome measure
1. Glycated hemoglobin (HbA1c), measured from blood samples taken at baseline, 3, 6 and 9 months.
2. Lipid profile (HDL-cholesterol, LDL-cholesterol, Triglycerides), measured using commercial equipment (Dimension®, Dade Behring, Germany) at baseline, 3, 6 and 9 months

Secondary outcome measures
1. Fasting plasma glucose (FPG), measured using the fasting plasma glucose test using blood samples taken at baseline, 3 months, 6 months, and 9 months
2. Blood pressure, measured using a validated automatic sphygmomanometer (OMRON M4-I) when the participant is in a sitting position (weekly measurement for 9 months)
3. Weight measured in kg on a scale

4. BMI, calculated as the ratio between weight and height (kg/m2) at baseline, and 9 months
5. Serum cardiac troponin T (cTnT) and Creatine Kinase MB Isoenzyme (CK-MB), from blood taken at baseline, 3, 6, and 9 months

Overall study start date
14/10/2013

Completion date
29/01/2015

Eligibility

Key inclusion criteria
1. Age 18 and older
2. Diagnosed with Type 2 Diabetes Mellitus
3. Receiving care at the WHC
4. Had at least two clinic visits before the study
5. Can provide informed consent
6. Poor glycemic control (HbA1c level >10) (86 mmol/mol) or persistent elevation of HbA1c >8 (64 mmol/mol) for one year or more)
7. Failure to respond to therapeutic insulin dose of > 2 units/kg or 200 units irrespective of weight
8. Inadequate adherence to insulin
9. Uncontrolled hypertension or hyperlipidemia with a maximum possible combination of medications
10. Comorbidity such as cardiovascular, renal, or hepatic disease
11. Inadequate continuity of care (such as recurrent missed appointment for insulin titration)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
263

Key exclusion criteria
1. Type 1 Diabetes Mellitus (these patients receive care from the Endocrinology department which will compromise the standardized level of care
2. Type 2 Diabetes Mellitus patients who receive care from Endocrinology department or other departments
3. Patients younger than 18 years old
4. Patients who cannot provide informed consent

Date of first enrolment
28/02/2014

Date of final enrolment
28/01/2015

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
The Al-Wazarat Healthcare Center (WHC)
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Organisation
Prince Sultan Military Medical City

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00mtny680

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Prince Sultan Military Medical City (PSMMC)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/01/2018		Yes	No