

Assessment of the role of pharmacist to control blood glucose, blood pressure and lipid profile in type 2 diabetic patients

Submission date 21/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/06/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Type 2 diabetes mellitus (T2DM) occurs when the body is not able to control blood glucose (sugar) levels by producing enough insulin. The rates of T2DM are increasing rapidly with increased burden of related complications and high death rate in Pakistan. T2DM is considered as a major risk factor for heart diseases. Several studies have established that T2DM can be responsive to different interventions, pharmacological (using medications) and non-pharmacological, aimed at improving blood glucose control. Recent guidelines have recommend comprehensive, patient centered diabetes management plans to be undertaken by integrating healthcare providing team including physicians, nurses, pharmacists, dieticians and mental health professionals in a chronic care model.

The aim of this study is to evaluate the effectiveness of pharmacist's interventions in diabetes management as part of health care providing team in primary health care setting of Lahore, Pakistan by implementing patient centered approach in individualized pharmaceutical care planning including both pharmacological and non-pharmacological aspects.

Who can participate?

Adults aged 18 and older who have T2DM

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive their routine treatment from their physician. Those in the second group receive their routine treatment from their physician and are asked to see pharmacist every four weeks and follow the instructions given for their needs related to their diabetes management. Participants are followed up at three, six and nine months to provide blood and urine samples.

What are the possible benefits and risks of participating?

Participants may benefit from routine medical examinations (as this is often missed due to the costs) and from regular interactions with a pharmacist to support them in their treatment goals. There are no risks associated with participants as all the pharmacists support is based on current guidelines on diabetes management and in collaboration with registered physicians.

Where is the study run from?
Murad Clinic (Pakistan)

When is the study starting and how long is it expected to run for?
October 2015 to June 2017

Who is funding the study?
Investigator initiated and funded (Pakistan)

Who is the main contact?
Dr Hamid Saeed

Contact information

Type(s)
Scientific

Contact name
Dr Hamid Saeed

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HEC/1000/UCP1926

Study information

Scientific Title
Study on A1c Management by Pharmacist in Lahore: A randomised controlled trial to assess the effectiveness of interventions by pharmacist in management of type 2 diabetes mellitus in collaboration with physician

Acronym

SAMPLE

Study objectives

Type 2 diabetes mellitus can be better managed when a structured pharmaceutical care plan is implemented by pharmacist.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Ethical Committee Punjab University College of Pharmacy University of the Punjab, 18/03/2016, ref: HEC/1000/UCP 1926

Study design

Interventional single-centre longitudinal randomised controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Type 2 Diabetes Mellitus

Interventions

The participants of this study are randomised according to individual patient's enrollment number i.e. the odd numbers were allocated to control arm and even numbers to intervention arm.

Participants in control arm receive their routine treatment from their physician.

Participants in intervention arm receive their routine treatment from their physician and they were asked to see pharmacist every four week and follow the instructions given for their needs related to type 2 diabetes mellitus management

Routine medical examination of all participants in both arms is performed at baseline, three, six and nine months by taking blood and urine samples.

Participants are followed up after every three months for a total treatment duration of nine months. They are tests for their glycated haemoglobin, lipid profile, and blood pressure.

Intervention Type

Mixed

Primary outcome measure

1. Glycated Haemoglobin (HbA1c) is measured using the laboratory results from blood samples at baseline and three, six and nine months
2. Lipid profile is measured using laboratory results from blood samples at baseline, three, six, and nine months
3. Blood pressure is measured using the mercuric sphygmomanometer at baseline, three, six and nine months for both control and intervention arm patients and at every visit i.e. 4 weeks for intervention arm patients

Secondary outcome measures

1. Height (m) is measured using a height rod at baseline, three, six and nine months
2. Weight (Kg) is measured using weighing balance at baseline, three, six and nine months
3. Waist (cm) is measured using measuring tape at baseline, three, six and nine months
4. Serum Creatinine (mg/dL) is measured using blood samples at baseline, three, six and nine months
5. Estimated Glomerular Filtration Rate (eGFR) is measured using Modification of Diet in Renal Disease (MDRD) Equation at baseline, three, six and nine months
6. Hematology Report is measured using blood samples at baseline, three, six and nine months
7. Complete Urine Examination is measured using urine sample at baseline and six months
8. Foot Examination is measured using micro-monofilament and tuning fork at baseline, three, six and nine months

Overall study start date

24/10/2015

Completion date

03/06/2017

Eligibility

Key inclusion criteria

1. Either Male / Female
2. Resident of Lahore City
3. Age 18 Years
4. Haemoglobin 13mg/dL
5. Type 2 Diabetes Mellitus
6. Glycated Haemoglobin (HbA1c) 8% i.e. poorly controlled
7. With or Without Hypertension (HTN)
8. With or Without Diabetic Nephropathy
9. With or Without Hepatosteatorsis (Fatty Liver)
10. Without Psychosis and Cognitive Disorder
11. With or without Insulin use
12. No Pharmacist Involvement in Diabetes Management

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

350 Type 2 Diabetes Mellitus Patients

Total final enrolment

244

Key exclusion criteria

1. The patients with any other type of diabetes mellitus
2. Patients with Glycated Hemoglobin (HbA1c) 8%
3. Patients below age 18 years and above 70 years
4. Patients who refused to sign the consent form
5. Patients who showed no interest for future visit to study site and or participant physicians
6. Patient with cognitive and or psychotic disorders
7. Hospitalised Patients

Date of first enrolment

20/03/2016

Date of final enrolment

20/08/2016

Locations

Countries of recruitment

Pakistan

Study participating centre

Murad Clinic

Private Healthcare Establishment with Punjab Healthcare Commission (Reg. No-R-28152)

23/2 Shalimar Link Road, near Shalimar Hospital

Mughalpura

Lahore

Pakistan

54000

Sponsor information

Organisation

University College of Pharmacy

Sponsor details

Allama Iqbal Campus

Lahore

Pakistan

54000

Sponsor type

University/education

ROR

<https://ror.org/011maz450>

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal. Study design, statistical analysis and even questionnaire will be available soon after publication and end 36 months following publication

Intention to publish date

30/01/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

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	24/06/2019	27/06/2019	Yes	No