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# 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

**Registration date**
26/07/2017

**Overall study status**
Completed

**Last Edited**
27/06/2019

**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
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

### ORCID ID
https://orcid.org/0000-0002-1400-4825

### Contact details
University College of Pharmacy
University of the Punjab
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Lahore
Pakistan
540000

# Additional identifiers

### Protocol serial number
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

## Primary study design
Interventional

## Study design
Interventional single-centre longitudinal randomised controlled study

## Study type(s)
Other

## 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(s)
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

## Key secondary outcome(s)
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. Heamatology 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 tunning fork at baseline, three, six and nine months

### 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 Heamoglobin (HbA1c) 8% i.e. poorly controlled
7. With or Without Hypertension (HTN)
8. With or Without Diabetic Nephropathy
9. With or Without Hepatosteatosis (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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Total final enrolment
244

### Key exclusion criteria
1. The patients with any other type of diabetes mellitus
2. Patients with Glycated Heamoglobin (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 Shalamar Hospital
Mughalpura
Lahore
Pakistan
54000

## Sponsor information

### Organisation
University College of Pharmacy

### ROR
https://ror.org/011maz450

## Funder(s)

### Funder type
Not defined

### Funder Name
Investigator initiated and funded

# Results and Publications

## 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 |