Role of pharmacist in diabetes management at community pharmacy

Submission date 12/05/2017	**Recruitment status** No longer recruiting	[ ] Prospectively registered
		[ ] Protocol
Registration date 16/05/2017	**Overall study status** Completed	[ ] Statistical analysis plan
		[X] Results
Last Edited 15/06/2023	**Condition category** Nutritional, Metabolic, Endocrine	[ ] Individual participant data

Plain English summary of protocol

Background and study aims

Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. About 415 million people suffered from diabetes in 2014 and it is expected that this will increase to 642 million by 2040. In Pakistan, about 6.9% of the adults suffered from diabetes in 2015 and it is estimated that this will increase up to 8.2% by 2040. Presently, in Pakistan, most people visit public and private sector hospitals for the management and treatment of diabetes, but since the doctors are extremely overburdened in most healthcare settings, they cannot give ample consultation time to the patients. In Pakistan, one doctor caters to the healthcare needs of almost 1073 patients, which represents a very low doctor to patient ratio. The problem can be dealt effectively if community pharmacists play a role in controlling and managing diabetes. Community pharmacists have ample medical knowledge and can provide both the appropriate information as well as sufficient time for controlling and managing diabetes. To date, very few studies from Pakistan have explored the role of pharmacists in diabetes management, specifically in community pharmacies. The aim of this study is to assess the impact of pharmacist-led interventions on blood sugar control and patient satisfaction in diabetes management at a community pharmacy.

Who can participate?
Patients aged 18-70 with type 2 diabetes

What does the study involve?
Participants are randomly allocated to either the control or the experimental group. The control group receive routine medications and diet plan. The experimental group receive interventions about self-management, quality of life, medication adherence, blood sugar control and knowledge about the disease. Information is provided through a diet chart, a foot care chart, and a low and high blood sugar chart, and the importance of exercise and medication by conversation with the participants. All participants are followed up 1 month later to check their blood sugar and their satisfaction with the services provided during this study.

What are the possible benefits and risks of participating?
The study may help the patient to control and manage their diabetes. There are no direct risks associated with participating in this study.

Where is the study run from?
Well Plus Community Pharmacy (Pakistan)

When is the study starting and how long is it expected to run for?
December 2016 to August 2017

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

Who is the main contact?
Mr Muhammad Abubakar

Contact information

Type(s)
Scientific

Contact name
Mr Muhammad Abubakar

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Contact details
Khawaja Farid campus
Railway Rd
Bahawalpur
Pakistan
63100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Patient satisfaction with pharmacist-led interventions in diabetes management at a community pharmacy: a randomised controlled trial

Study objectives

Pharmacist-led interventions have a positive impact on diabetes-related knowledge of patient, perception of self-management of the disease, quality of life of patient, medication adherence, glycemic control and patient satisfaction about the services provided at community pharmacy during the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pharmacy and Research Ethics Committee (PREC) at the Department of Pharmacy, the Islamia University of Bahawalpur, 22/12/2016, ref: 43-2016/PREC

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Other

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
Simple random sampling was used for the participants. There are different intervention strategies for the control and the experimental group:
1. The control group received routine medications and dietary plan and no intervention was applied.
2. The experimental group received interventions about self-management, quality of life, medication adherence, glycemic control and knowledge about the disease. Intervention related information was provided through a diet chart, a foot care chart, and a hypo- and hyper-glycemic chart, and the importance of exercise and medication by verbal conversation with the participants.

The total duration of intervention and follow-up was up to 1 month from the date of registration into the trial.

Intervention Type
Other

Primary outcome measure

1. Glycemic control, measured using the strip method Accu check performa meter at baseline and after the completion of 1 month of intervention
2. Patient satisfaction about the services provided during trial, measured using the DDSM-Q after the completion of 1 month of intervention

Secondary outcome measures

1. Perception of self-management of diabetes, measured using the DDSM-Q
2. Disease state knowledge, measured using the DDSM-Q
3. Quality of life, measured using the EQ-5D-3L
4. Medication adherence, measured using the MMAS
Measured at baseline and after completion of 1 month of intervention

Overall study start date

01/12/2016

Completion date

30/08/2017

Eligibility

Key inclusion criteria

1. Patients with type 2 diabetes mellitus (T2DM) diagnosed by a registered medical practitioner
2. Minimum one year T2DM history
3. Age 18-70 years
4. On anti-diabetes therapy
5. Co-morbidity may or may not be present
6. Minimum two follow-up visits within one month period from the date of registration in trial
7. Both male and female

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Type 1 diabetes
2. Diabetes insipidus
3. Gestational diabetes and other forms of diabetes
4. Age <18 and >70
5. Not on anti-diabetic therapy
6. Less than two follow-up visits within one month period from the date of registration in trial

Date of first enrolment
01/12/2016

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Pakistan

Study participating centre
Well Plus Community Pharmacy
Rafi Qamar road, One unit chowk
Bahawalpur
Pakistan
63100

Sponsor information

Organisation
The Islamia University of Bahawalpur

Sponsor details
Khawaja Farid campus
Railway Rd
Bahawalpur
Pakistan
63100

Sponsor type
University/education

Website
http://www.iub.edu.pk

ROR
https://ror.org/002rc4w13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Findings will be published in a high impact journal.

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Muhammad Abubakar.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/08/2021	15/06/2023	Yes	No