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Impact of medication therapy management programme on diabetes healthcare outcomes in a community pharmacy setting

Submission date
02/12/2022

Recruitment status
No longer recruiting

Registration date
09/12/2022

Overall study status
Completed

Last Edited
13/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Community pharmacies (CPs) are at the heart of communities because they are the most accessible healthcare settings with a large number of people using their services. As a result, community pharmacists have emerged as a focal point for the modernization of primary and community care services. Literature demonstrated that expanding the roles of community pharmacists could result in numerous patient-related benefits. This study aims to assess the effectiveness of the community pharmacy-based Medication Therapy Management programme compared with standard care in improving patient healthcare outcomes of patients with uncontrolled diabetes.

Who can participate?
Adult patients with uncontrolled diabetes mellitus

What does the study involve?
In this study, we are trying to establish if community pharmacy-based medication reviews can improve diabetes management among patients with uncontrolled diabetes. Patients with uncontrolled diabetes received either systematic medication review or standard care in the community pharmacy and follow-up for a minimum of 6 months.

What are the possible benefits and risks of participating?
Depending on your group allocation, you can have your medication therapy reviewed by an expert pharmacist. This may help you in controlling your diabetes. In the future, this study could help enhance the Saudi health system by introducing a new service offered by community pharmacists. We do not anticipate any disadvantages to participants taking part. You will need to give your time to participate in the study including completing questionnaires and attending follow-up appointments.
However, participation is voluntary, and patients can withdraw from the study at any stage without giving any reason and without any negative consequences on the care provided by the health professionals.

Where is the study run from?
Princess Nourah bent Abdulrahman University (KSA) and the University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
April 2021 to June 2022

Who is funding the study?
No specific funding has been obtained to undertake this trial. However, the lead researcher, Basmah Albabtain is funded by Princess Nourah bent Abdulrahman University (KSA) to undertake her PhD degree at the University of Birmingham

Who is the main contact?
Basmah Albabtain (principal researcher, PhD student), baa985@student.bham.ac.uk

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of medication therapy management programme on diabetes healthcare outcomes in a community pharmacy setting: a randomised controlled study

Study objectives
The community pharmacy-based medication therapy management (MTM) programme is effective compared to standard care in improving diabetic patient healthcare outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 13/07/2020, Ethical Review Board of Princess Nourah bent Abdulrahman University (Riyadh, Kingdom of Saudi Arabia, 11671, PO Box 84428; +966548867916; irb@pnu.edu.sa), ref: 20-0240
2. Approved 15/07/2020, King Fahad Medical City (Riyadh, Kingdom of Saudi Arabia, 11525 PO Box 59046; +96612889999 ext. 26943; InstitutionalReviewBoard@kfmc.med.sa), ref: 20-388E
3. Approved 11/01/2021, Birmingham University (Edgbaston, B15 2TT, UK; +44 (0)1214148101; s.m.waldron@bham.ac.uk), ref: ERN_20-0768

Study design
Randomized control study set up as a 2-arm open-label parallel-group investigation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Medication therapy management for chronic disease patients with uncontrolled diabetes

Interventions
The study involves an intervention group comprising a community pharmacy-based medication therapy management (MTM) programme for a minimum of 6 months and a control group of standard care in community pharmacy practices.

Randomization was provided by an independent person not otherwise involved in the study. Consenting participants were randomized in a 1:1 ratio to either MTM services or standard care. Recruitment was conducted until the required number of participants was enrolled. An allocation sequence was based on a computer-generated (Excel sheet) list of random numbers and sequentially numbered tamper-proof opaque sealed envelopes were used to conceal sequence allocation.

Intervention Type
Other

Primary outcome measure
Hemoglobin A1C (HbA1C) levels measured using a blood test at baseline, 3 and 6 months

Secondary outcome measures
1. Clinical parameters measured using blood test at baseline, 3 and 6 months:
1.1. Blood pressure (BP) (mmHg) (systolic BP and diastolic BP)
1.2. Lipid profile (mg/dl) (low-density lipoprotein [LDL], total cholesterol [TC], triglyceride [TG])
1.3. Albumin-to-creatinine ratio (ACR) (mg/g) and serum creatinine (sCr) (mg/dl)
2. Description of MTM programme measured using chi-square tests and reported as no. and % using Stata/SE 17 at baseline, 3 and 6 months:
2.1. Number of patient visits
2.2. Number and type of referrals
2.3. Pharmacist consultation time per participant (minutes)
3. Number and types of drug-related problems (DRPs):
3.1. DRPs that need an additional drug
3.2. Supply drugs without indication
3.3. Adverse drug reaction
3.4 Ineffective drug
3.5. High/low dose
3.6. Noncompliance
4. Health services utilization including the number and reasons for hospitalization or ED during the study period measured using the Firth-type logistic regression and reported as no. and % using Stata/SE 17 at baseline, 3 and 6 months
5. Patient medication adherence measured using the Medication Adherence Report Scale-5 (MARS-5) at baseline and 6 months
6. Diabetes distress measured using the Diabetes Distress Scale (DDS) at baseline and 6 months
7. Patient satisfaction with pharmacist services using The Patient Satisfaction with Pharmacist Services Questionnaire (PSPSQ 2. 0) at 6 months

Overall study start date
13/04/2021

Completion date
21/06/2022

Eligibility

Key inclusion criteria
1. Uncontrolled diabetes (defined as having glycated haemoglobin blood (HbA1c) ≥ 8%)
2. Age 18 years and over
3. Able to provide informed consent
4. Have a continuous active status with the medical center (defined as having a record of at least 1 visit in the 6 months before screening)
5. Speak either Arabic or English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160 patients, 80 in each arm

Total final enrolment
160

Key exclusion criteria
1. Severe mental illness or dementia or significant cognitive impairment
2. Gestational diabetes
3. Unstable acute complications/illness

Date of first enrolment
13/04/2021

Date of final enrolment
08/09/2021

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Health Kingdom Community Pharmacy
Riyadh
Saudi Arabia
14254 alfayha

Sponsor information

Organisation
Princess Nourah bint Abdulrahman University

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University/education

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https://ror.org/05b0cyh02

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Sponsor type
University/education

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ROR
https://ror.org/03angcq70

Funder(s)

Funder type
University/education

Funder Name
Princess Nourah Bint Abdulrahman University

Alternative Name(s)
Princess Nora University, Princess Nora Bint Abdulrahman University, PNU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Findings will also be presented at national and international conferences.
3. Since this is part of a PhD research project, the electronic version of the thesis will be deposited in the University of Birmingham e-repository.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request after 1 year of completion of the study and publication of the first manuscript. Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed on a case-by-case basis by the trial coordination committee in discussion with the clinical investigators (CIs). Please contact Basmah Albabtain (basmah.albabtain@outlook.com). These data will also be added to the University of Birmingham e-

repository after the successful defence of a PhD thesis. Please note that the link for the e-repository will be shared once data is deposited.

The type of data that will be shared: All requested data.
Whether consent from participants was required and obtained: Yes, a consent form was required and obtained from all participants before the randomization.
Comments on data anonymization: Anonymity was preserved by removing identifiable data and assigning all participants a unique study identification number. Furthermore, data that can be linked to a particular individual were fully anonymized before publishing, or not published at all. We followed ethical and legal practice and all information were handled in confidence. All data obtained were anonymized and kept on a password-protected personal computer. Only the research staff had access to those data.
Any ethical or legal restrictions: No.
Any additional comments: None.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/05/2021	08/12/2022	Yes	No
Results article		01/08/2024	13/02/2025	Yes	No