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Enhanced diabetes-cardiovascular management through primary health care in Pakistan

Submission date
14/06/2012

Recruitment status
No longer recruiting

Registration date
09/08/2012

Overall study status
Completed

Last Edited
04/11/2019

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
Diabetes is a lifelong condition that causes a person's blood sugar level to become too high. Pakistan ranks seventh among the global top ten countries with highest number of people with diabetes. The prevalence of type 2 diabetes above the age of 25 years is around 10%. About 20% and 30% of diabetics are expected to have associated hypertension (high blood pressure) and hypercholesteremia (high blood cholesterol). Currently primary health care identifies only about 10% of the estimated prevalent type 2 diabetes cases, and the quality of care being offered for diabetes and associated heart disease is far from satisfactory. A set of guidelines and materials with sound scientific evidence is required for expanding care delivery through strengthened primary care facilities. The aim of this study is to develop and test an intervention for delivering quality care to type 2 diabetes patients.

Who can participate?
Patients aged over 25 with type 2 diabetes

What does the study involve?
Participating primary healthcare facilities are randomly allocated to either enhanced case management of type 2 diabetes or routine type 2 diabetes case management. The care participants receive is the same whether they take part in the study or not. If they agree to take part their care records are used to assess the management services at the clinic for high blood pressure and associated illnesses. Participants have to come twice for a blood test, once at the start of the study and once at the end of study. This monitoring is free of charge.

What are the possible benefits and risks of participating?
The care participants receive is the same whether they take part in the study or not. If they take part they may have the usual or slightly different procedures (more information/data is taken if they take part in the study). The results will help to find the best way to care for patients like them in the future. There are no direct benefits to the patient, but this study hopes to improve the care of patients with high sugar levels and associated illnesses at private clinics in the country. There are no added risks involved in participating in this study,

Where is the study run from?
Pakistan, with the involvement of the University of Leeds (UK)

When is the study starting and how long is it expected to run for?
January 2012 to December 2016

Who is funding the study?
University of Leeds (UK)

Who is the main contact?
Dr Amir Khan
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSLTLM11019

Study information

Scientific Title
Enhanced diabetes-cardiovascular management through primary health care in Pakistan: a cluster randomized trial

Study objectives

How effective and feasible is it to achieve better glycemic control (primary) and BP/cholesterol control and adherence to appointments (secondary) among adult type 2 diabetes patients attending the strengthened primary health care facilities?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee University of Leeds, 20/02/2011, ref: HSLTLM11019
2. NBC-90 National Bioethics Committee, Pakistan, 30/04/2012

Study design
Cluster randomized controlled trial with two arms

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetes and cardiovascular disease

Interventions
Intervention arm:
Enhanced case management of type 2 diabetes patients through strengthening of primary healthcare facilities. The case management enhancement mainly includes:
1. Availability of context sensitive guidelines and materials for case management
2. Health staff trained on operational guidelines and materials
3. Supplement material support for managing type 2 diabetes and associated hypertension (and hyper-cholesterol) conditions
4. Standardized recording and reporting
5. Enhanced facility monitoring
6. Facilitated referral linkages with district head quarter hospital and
7. Better retrieval of patients with delayed follow-up visits

Control arm
The control for comparison is a routine set of activities for type 2 diabetes case management at primary health care facilities. The only addition will be
1. Enhanced screening and diagnosis

2. Introduction of Type 2 Diabetes-CVD register for collecting core data set on patients attending these control facilities
3. Drug supply ordering by DHO/RHC in a regular manner as before to the Rural Health Clinics (RHCs)
4. Introduction of a information leaflet which includes lifestyle modification and when/where to seek help in case of any complications

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Glycaemic control among registered Type 2 diabetes cases. The case registration will be taken mainly from the Type 2 diabetes care register at each facility.
2. The mean change in Hb1AC measurement, i.e change of mean HbA1c at 18 months of follow-up compared to the baseline (at registration), will be used for assessing the glycemic control.

Secondary outcome measures
1. To compare the mean treatment success (attending and HbA1Ac < 7.5%, or FBG <7)
2. To compare the mean hypertension control (< 130/80) and total cholesterol (<200) achieved in the adult Type 2 diabetes patients, with associated hypertension and hyper-cholesterol conditions
3. To conduct incremental cost effectiveness analysis of managing adult type 2 diabetes patients at Primary Health Care (PHC) facilities in Punjab, Pakistan
4. To inform the provincial strategic plan for managing type 2 diabetes and associated hypertension and hyper-cholesterol conditions in Punjab

Overall study start date
01/01/2012

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. All type 2 diabetes patients of both genders, age > 25 years
2. Resident of the catchment area of the respective facility (RHC/tehsil hospital)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Total of 448 patients (224 in each arm) will be included in the study

Total final enrolment
495

Key exclusion criteria
1. Those not giving consent for the study
2. Does not meet inclusion criteria

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Pakistan

Study participating centre
Association for Social Development
Islamabad
Pakistan
44000

Sponsor information

Organisation
University of Leeds - COMDIS-HSD (UK)

Sponsor details
Leeds Institute of Health Sciences
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/hsphr/research/NCIHD/comdis-hsd.html

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018	04/11/2019	Yes	No