ISRCTN13319989 https://doi.org/10.1186/ISRCTN13319989

Assessing the effects of an educational intervention for chronic disease management in rural China

Submission date
22/03/2017

Recruitment status
No longer recruiting

Registration date
04/04/2017

Overall study status
Completed

Last Edited
03/07/2025

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
China is facing a serious situation with the increasing prevalence of chronic (long-term) diseases. According to the report published by National Health and Family Planning Commission in 2015, 19% of the population in China suffers from different kinds of chronic diseases. Moreover, the country's previous strategy for chronic disease management has focused on the much more costly hospital care, instead of primary care and self-management in rural areas. High health expenses still prevail, which may also increase the economic burden on patients and influence health care seeking behavior. Hence, new strategies are needed to improve treatment of chronic diseases in rural areas. Currently, different outcomes have been used to test the effects of chronic disease management strategies. Despite an increasing number of studies focusing on type 2 diabetes (T2DM) and high blood pressure (hypertension) management in China, most have been performed in urban areas. Moreover, most researchers test physical outcomes, but other important outcomes such as the patient's perspective, health care seeking behaviour, and the knowledge of healthcare professionals are ignored. The aim of this study is to improve the care of patients with T2DM and hypertension in rural areas through an educational intervention directed at healthcare professionals, to shift the care of patients with T2DM and hypertension from hospital to primary care services.

Who can participate?
Patients aged 35-75 with T2DM or primary hypertension and health care professionals from the participating counties, townships and village clinics

What does the study involve?
The participating areas are divided into different groups according to economic status and health development, and then two areas are randomly selected from each group: one to the intervention group and one to the control group. Patients in the intervention areas receive services including lectures about self-management strategies, follow-up interviews, physical examination, and special medical services (such as medical treatment, transfer treatment, return visits, and clinical care). The healthcare professionals in the intervention groups are provided with professional development including training lessons, regular meetings, team

communications, technical checks, and new performance appraisal. For patients and healthcare professionals in the control areas, current routine health services continue as usual. The patients' blood glucose, blood pressure, health status, satisfaction with health services, health insurance, understanding of diabetes, health seeking behaviour, and out-of-pocket costs of care are assessed before and after the intervention. The health care professionals' knowledge about chronic disease management and their general perceptions about the intervention are assessed before and after the intervention.

What are the possible benefits and risks of participating?
Patients in the intervention areas benefit from receiving information and guidance in issues related to chronic diseases and self-management. Health care professionals who are participating in the intervention may benefit from the possibility of being offered a promotion. Moreover, the intervention contains a performance appraisal, including a bonus and professional development for healthcare professionals. A potential risk for the patients is the leak of information as some sensitive data is collected. In order to reduce the risk of a leak, all members of the research team are asked to sign a confidentiality agreement. There are no risks for healthcare professionals participating in the study.

Where is the study run from?
The study is conducted in three counties in Jiangsu province (Gaochun, Jingjiang, Huaiyin) together with the township health centers and villages clinics in those townships. In total, 22 township health centers are involved in the study. The whole process is led by the research team and coordinated by the local health bureau.

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
The National Natural Science Fund of China

Who is the main contact?
Prof. Dongfu Qian
dqian@njmu.edu.cn

Contact information

Type(s)
Scientific

Contact name
Prof Dongfu Qian

ORCID ID
https://orcid.org/0000-0002-7704-1068

Contact details
Nanjing Medical University
No. 101 Longmian Ave
Nanjing
China
211166

+86 (0)25 8686 2951
dqian@njmu.edu.cn

Additional identifiers

Protocol serial number
No. 71473130

Study information

Scientific Title
Vertical integrated service model: an educational intervention for chronic disease for patients and healthcare professionals in rural China

Study objectives
1. The education-based intervention will have a positive effect on the patients' physical health and their understanding of their chronic disease.
2. The educational intervention will improve the professionalism and understanding of chronic disease management for local healthcare professionals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nanjing Medical University Ethics Committee, 02/08/2015, ref: 300

Primary study design
Interventional

Study design
Cluster randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Optimising care for adult patients with type 2 diabetes or primary hypertension

Interventions
The project is an interventional study conducted in three counties in Jiangsu Province, China. The selection of intervention and control groups is done by the local (township level) health bureaus. They will firstly divide the townships into different groups according to economic status and health development, and then randomly select two townships (one as intervention, one as control) from each group.

The educational intervention will be conducted by a service team which has been assembled by the local health bureau in each county.

Patients in the intervention group will receive the following services:
1. Lectures mainly focusing on prevention and self-management strategies for chronic disease,

nutrition and physical activity, proper health behaviours, and psychological counselling
2. Periodical follow-up interviews along with an annual physical examination
3. Special medical service, including helping patients with medical treatment, transfer treatment, return visit, and clinical care, etc

Healthcare professionals in the intervention group will receive the following services:
1. Training lessons for the village GPs.
2. Regular meetings to discuss their work progress
3. Team communications about analysing patients' conditions or formulating personalized therapeutic regimens
4. Technical checks to inspect the patients' disease monitoring schemes, prevention and treatment plans
5. New performance appraisal for doctors and nurses containing two parts:
5.1. Bonus for those who do well in the project
5.2. Opportunities for professional development for outstanding doctors or nurses

For patients and healthcare professionals in the control areas, current routine health services will continue as usual and there will be no service team.

The intervention will last for one year in two counties and for two years in the third county. During this period, the county level and township level health bureaus will be responsible for administrating the whole process. The research team will conduct periodical quality controls.

Intervention Type
Behavioural

Primary outcome(s)
For patients:
1. Physiological measures (blood glucose/glycosylated haemoglobin (HbAlC)/blood pressure), collected during the medical examination
2. Health status, measured using the generic health-related quality of life instrument EQ-5D
3. Satisfaction with health services, health insurance, understanding of diabetes, health seeking behaviour and patients' out-of-pocket costs of care, assessed using a questionnaire
Measured at baseline and follow-up (12 months after start of intervention)

Key secondary outcome(s)
For healthcare professionals:
1. Knowledge about the current epidemiological situation of chronic disease in their own village, assessed through a knowledge test
2. The general procedure of diagnosing and registering chronic disease, assessed through in-depth interviews
3. The chronic disease management situation before and after intervention, assessed through in-depth interviews
4. Their general perceptions about the intervention, assessed through in-depth interviews
Measured at baseline and follow-up (12 months after start of intervention)

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. Diagnosed with type 2 diabetes (FBG ≥7.0 mmol/l, and/or 2hPBG ≥11.1 mmol/l) or primary hypertension (SBP ≥140mmHg, and/or DBP ≥90mmHg) and has been on medications for more than one month
2. Aged 35-75
3. Lived in the intervention/control areas for more than two years (no records of moving within the last year)
4. Has no plan of moving from the intervention/control areas or no long-term travelling plans (more than one year)
5.Has his/her records on the chronic disease management information system of township health center or village clinic, and has accepted the chronic disease service provided by township health center or village clinic
6. Willing to participate in this project and has a preferable compliance, cognition and receptivity

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Has serious complications of diabetes or hypertension (for example, diabetic foot III/IV, diabetic retinopathy IV or higher, diabetic nephropathy IV/V, hypertension III)
2. Has been diagnosed with secondary hypertension
3. Has been diagnosed with any other serious disease, such as terminal stages of cancer, AIDS, etc
4. Pregnant women or patients with psychiatric problems

Date of first enrolment
01/01/2015

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
China

Study participating centre
Nanchengji Health Center
China
223341

Study participating centre
Yangzhuang Health Center
China
223305

Study participating centre
Xindu Health Center
China
223302

Study participating centre
Lingqiao Health Center
China
223306

Study participating centre
Zhaoji Health Center
China
223343

Study participating centre
Yuanji Health Center
China
223303

Study participating centre
Wangxing Health Center
China
223307

Study participating centre
Sanshu Health Center
China
223333

Study participating centre
Qiqiao Health Center
China
211302

Study participating centre
Zhuanqiang Health Center
China
211305

Study participating centre
Yangjiang Health Center
China
211313

Study participating centre
Dongba Health Center
China
211301

Study participating centre
Chunxi Health Center
China
211399

Study participating centre
Gubai Health Center
China
211316

Study participating centre
Gucheng Health Center
China
211304

Study participating centre

Yaxi Health Center
China
211303

Study participating centre
Dongxing Health Center
China
214533

Study participating centre
Xieqiao Health Center
China
214513

Study participating centre
Houhe Health Center
China
214525

Study participating centre
Chengnan Health Center
China
214599

Study participating centre
Huifeng Health Center
China
214532

Study participating centre
Gushan Health Center
China
214522

Sponsor information

Organisation
Nanjing Medical University

ROR
https://ror.org/059gcgy73

Funder(s)

Funder type
Government

Funder Name
National Natural Science Fund of China

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Dongfu Qian (dqian@njmu.edu.cn)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2019	31/07/2019	Yes	No
Results article		20/03/2020	06/06/2023	Yes	No
Results article		02/07/2025	03/07/2025	Yes	No
Protocol article	protocol	20/07/2018		Yes	No