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Health literacy intervention on type 2 diabetes in China

Submission date
27/08/2014

Recruitment status
No longer recruiting

Registration date
22/09/2014

Overall study status
Completed

Last Edited
02/01/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a chronic condition that causes the amount of sugar in a persons blood to be too high. It happens when the body doesnt produce enough insulin or doesnt respond to insulin very well (insulin resistance). It can cause a number of long-term health problems such as kidney failure and limb amputation, and can lead to partial or complete blindness. It is therefore very important for patients to make changes to their lifestyle and learn how to manage their diabetes. In this study, we are looking at how a modified Chinese version of a set of materials developed to help patients understand and self-manage their condition (Diabetes Education Toolkit) can help them to keep the glucose in the blood at a healthy level (glycemic control). The studys findings should help to show the importance of people understanding their condition in terms of them better being able to manage their disease and improve their health.

Who can participate?
Adults aged at least 18 with type 2 diabetes, hemoglobin A1c ≥ 7.5%, from eight communities of Shanghai, China.

What does the study involve?
The participants are randomly allocated into one of two groups (an intervention and a control group). Their hemoglobin A1c levels are measured and they take part in a survey that assesses their health and diabetes literacy. The control group then are treated as usual and the intervention group tale part in a comprehensive health literacy course for 12 months. Follow up surveys and measurements are carried out for all patients at 3, 6, 12 and 24 months after the start of the study where we compare the HbA1c level between the two groups.

What are the possible benefits and risks of participating?
The participants in the intervention group will obtain additional education on diabetes self-management. There will be no immediate direct benefit for those in the control group. But there should be benefits to all diabetes patients in the future, particularly for those with low literacy levels, because the results of the study are likely to influence how the government provides healthcare services in the future. There are no risks to taking part.

Where is the study run from?
Fudan University in collaboration with Vanderbilt University and Shanghai CDC (China)

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
China Medical Board (CMB) (USA)

Who is the main contact?
Professor Wanghong Xu
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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200032

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Grant 13-159

Study information

Scientific Title
A randomized trial on using a comprehensive health literacy strategy to improve self-management skills and glycemic control in chinese patients with type 2 diabetes

Study objectives
Participants randomized to the intervention arm will have significant improvements in HbA1C, blood pressure, lipids, self-management behavior, self-efficacy, and other patient outcomes important to improving diabetes care when compared to the control group participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)
IRB of School of Public Health, Fudan University (IRB00002408 & FWA00002399), 28/06/2013, ref. IRB#2013-06-0451

Study design
A cluster randomized controlled trial (RCT)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
The intervention will include two main components:
1. Modified Chinese version of Diabetes Education Toolkit, a set of plain-language tools to aid provider-patient communication about diabetes management
2. A modified Chinese version of Clear Health Communication Curriculum (CHCC), a structured training program for healthcare providers to improve diabetes-related counseling communication skills, with specific attention to issues of literacy and numeracy
Control group:
Will receive usual care which refers to education according to the Chinese Guideline for Diabetes Care and Education, which is widely used in China.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome will be changes in HbA1c at baseline and at 3, 6, 12, and 24 months of intervention. HbA1c level will be measured by a blood test.

Secondary outcome measures

Other measures include self-care behaviors, blood pressure, cholesterol, and utilization of clinical services. Incremental costs per behavioral, biologic and QALY change will also be determined. This will be measured at baseline and at 3, 6, 12, and 24 months of intervention.

Overall study start date
01/01/2015

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Patient has a clinical diagnosis of type 2 diabetes
2. Age 18-85 years
3. Most recent HbA1c >=7.5%
4. Patient agrees to participate in the study for the full two years duration

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
800

Total final enrolment
799

Key exclusion criteria
1. Poor visual acuity (vision worse than 20/50 using Rosenbaum Pocket Screener)
2. Significant dementia, or psychosis (by health provider report or chart review)
3. Terminal illness with anticipated life expectancy < 2 years

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
China

Study participating centre
138 Yi Xue Yuan Road
Shanghai
China
200032

Sponsor information

Organisation
China Medical Board (CMB) (USA)

Sponsor details
2 Arrow Street
Cambriage
United States of America
MA 02138

Sponsor type
Government

Website
http://www.chinamedicalboard.org

Funder(s)

Funder type
Government

Funder Name
China Medical Board (CMB-OC) (USA)

Alternative Name(s)
CMB

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

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?
Protocol article	protocol	20/12/2014		Yes	No
Results article	results	19/11/2019	02/01/2020	Yes	No