

A group visit model to support diabetes patients self-management in rural communities of Shanghai

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| Submission date 26/05/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 07/06/2012 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 11/12/2012 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims?

Support of patient self-management is a key component of effective diabetes care and improved patient outcomes. A series of peer-led community-based disease-specific self-management programs including diabetes have been developed, tested and disseminated in Shanghai in the last ten years. However, the strategy of using trained lay leaders to support patient self-management faced challenges in rural communities in Shanghai. The aim of this study is to develop a Chinese diabetes group visit program as an alternative approach to support patient self-management and to examine its effectiveness on self-management behaviors, self-efficacy and health status for patients in rural communities of Shanghai.

Who can participate?

This study aims to recruit about 200 community-dwelling patients with type 2 diabetes from two rural communities in Shanghai, China.

What does the study involve?

Two groups will be created. One group will receive 12 monthly group visit sessions. Each session consists of 1.5-hour group self-management education and 1-hour one-on-one visits with health care providers. The group self-management education sessions will focus on helping participants build confidence in their ability to deal with diabetes by incorporating self-efficacy enhancing strategies, including monthly action planning and feedback, modelling of behaviors by participants for one another, reinterpretation of symptoms, practicing self-management skills, and group problem-solving. The other group will receive usual care.

At the end of the study, we will compare changes in self-management behaviors (diet, aero exercise, practice of cognitive symptom management, communication with doctor, and examining feet); self-efficacy to manage diabetes in general; and health status (self-rated health, energy, health distress, level of fatigue, illness intrusiveness, depression, body mass index, systolic and diastolic blood pressure levels) between the two groups.

What are the possible benefits and risks of participating?

Participants who are randomly allocated to the intervention group will receive an additional 12

monthly diabetes group visit sessions helping them improve their confidence, skills and knowledge to self-manage their type 2 diabetes.

By taking part in this study there are no risks of physical or psychological injury or harm.

Where is the study run from?

The study is conducted by Songjiang District Center for Disease Prevention and Control in collaboration with Fudan University.

When is the study starting and how long is it expected to run for?

The study started in January 2007 to recruit participants and ended by June 2008.

Who is funding the study?

The Initiative for Cardiovascular Health Research in Developing Countries (IC-HEALTH) (ref: ICH /DIA/PDG/O6/03) and Songjiang District Center for Disease Prevention and Control, Shanghai, China .

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A group visit model to support diabetes patients self-management in rural communities of Shanghai: a randomized trial

Study objectives

A group visit model offering patients routine primary care in combination with group support and self-management education will improve self-management behavior, self-efficacy to manage diabetes and health status indicators for patients with type 2 diabetes in rural communities of Shanghai.

Ethics approval required

Old ethics approval format

Ethics approval(s)

School of Public Health Ethics Committee, Fudan University, 02 December 2006, ref: 06-021

Study design

One year randomized single blinded trial

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 group will receive 12 monthly diabetes group visit sessions. Each session consists of a 1.5-hour self-management group education and 1 hour one-on-one visits with health care providers. The control group will only receive usual care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Change in self-management behavior scores (diet, aero exercise, practice of cognitive symptom management, communication with doctor, and examining feet)
2. Change in self-efficacy score (self-efficacy to manage diabetes in general)
3. Change in health status indicators (self-rated health, energy, health distress, level of fatigue, illness intrusiveness, depression, body mass index, systolic and diastolic blood pressure levels)

With the exception of the questions about diet, examining feet, body mass index (BMI), and blood pressure levels, which were developed for this study, all measures had been previously validated.

Secondary outcome measures

Baseline scores for self-management behaviors and self-efficacy to manage diabetes in general and health status

Overall study start date

01/01/2007

Completion date

30/06/2008

Eligibility

Key inclusion criteria

1. Men and women aged 35-80 with type 2 diabetes confirmed by medical records
2. Community dwelling
3. Willing to be assigned to any of the study groups

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Patients aged less than 35 years or more than 80 years
2. Patients with mental illness or stroke
3. Patients with severe physical disability that would prevent attendance or participation in the groups

Date of first enrolment

01/01/2007

Date of final enrolment

30/06/2008

Locations

Countries of recruitment

China

Study participating centre

1050 North Xi Lin Road

Shanghai

China

201620

Sponsor information

Organisation

Fudan University (China)

Sponsor details

School of Public Health

138 Yi Xue Yuan Road

Shanghai

China

200032

Sponsor type

University/education

Website

<http://sph.fudan.edu.cn/>

ROR

<https://ror.org/013q1eq08>

Funder(s)

Funder type

Research organisation

Funder Name

Initiative for Cardiovascular Health Research in Developing Countries (India) ref: ICH/DIA/PDG/O6/03

Funder Name

Songjiang District Center for Disease Prevention and Control (China)

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 | 03/12/2012 | | Yes | No |