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Patient-led education to improve diabetes management in a low-income setting: A randomized controlled trial in Aceh, Indonesia

Submission date
18/02/2019

Recruitment status
No longer recruiting

Registration date
28/02/2019

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a disease where blood glucose levels are elevated and can lead to severe complications if left untreated. Diabetes has become one of the main contributors to the burden of disease in Indonesia. It is not easy to live with diabetes and it is important to care for your diabetes also when you are not at the doctor. Until now, many people with diabetes in Indonesia have blood glucose levels considered to be too high, which can have dangerous consequences for their health.
This study investigates, if available healthcare can be complemented by peer education. Peer education uses highly motivated and trained diabetes patients to educating and support other untrained people with diabetes in small groups to help them improve their disease managment in daily life. Small changes in lifestyle and medication adherence can help to prevent many diabetes complications.

Who can participate?
Everybody with type 2 diabetes seeking care at one of the Puskesmas in Banda Aceh and Aceh Besar can participate, as long as he or she is between 20-79 years old.

What does the study involve?
Some of the participants will be asked to become peer educators. They will receive specific training about diabetes management and then go on to establish and lead a group of people with diabetes to share what they learned during their training. Study participation is voluntary and you can stop any time if you wish to. To participate in the study, participants will need to provide small blood drops to measure their blood sugar and lipid levels. That information will be used to assess the success of the peer education intervention. Participants can also use it to discuss the results during their next doctor appointment.

What are the possible benefits and risks of participating?
Risks: In the peer education sessions you will learn about the health risks of diabetes. This may lead to an increase in anxiety about the consequences of high blood glucose levels. Also, because the person leading the education group is not a healthcare professional, there is a risk

that they may provide you with wrong information about diabetes and diabetes treatment. To prevent that, we will carefully select the peer educators and emphasize the need to follow education materials during the peer education sessions.
Benefits: Participants will learn more about their diabetes and how to treat it. This may lead to better blood glucose levels and better health in the long run. Further, participants will receive information of blood tests not normally carried out at Puskesmas, which provide important information about their blood glucose levels and can be used as a basis to discuss future diabetes treatment.

Where is the study run from?
Syiah Kuala University (Indonesia)

When is the study starting and how long is it expected to run for?
February 2019 to January 2021

Who is funding the study?
The study is funded by the International Diabetes Federation as part of the BRiDGES 2 program.

Who is the main contact?
Dr Marthoenis, marthoenis@unsyiah.ac.id

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BR2-R1-PE1

Study information

Scientific Title
The effect of peer education in addition to standard care on HbA1c and diabetes management compared to standard care in people with diabetes in Aceh, Indonesia.

Study objectives
Peer education is an effective measure to improve HbA1c levels in people with diabetes receiving standard diabetes care in government-mandated community health clinics in Banda Aceh and Aceh Besar, Indonesia

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/06/2018, Ethics committee of the University of Goettingen (Von-Siebold-Str. 4 37075 Göttingen, Germany; +49 551 39-28240; ethikkommission@zvw.uni-goettingen.de), ref: n/a
2. Approved 12/03/2018, The Research Ethics Committee of Nursing Faculty of Syiah Kuala University (Banda Aceh, Indonesia; +626518053041; etik.fkep@gmail.com), ref: 113000211117

Study design
Interventional multicentre trial with random allocation at the health facility level into non-blinded treatment and control groups, where the control group receives standard care plus the intervention and the control group receives standard care only.

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Patients are recruited at their primary care health posts (Puskesmas). Randomization than takes place at the level of the Puskesmas, i.e. every participant from one Puskesmas is either in the treatment or control group, depending on where the Puskesmas is randomized to. We are planning to have two peer education groups per Puskesmas of 11-13 participants each, i.e. two peer education groups per Puskesmas. Peer education groups will gather locally, if possible using the facilities of the Puskesmas, though this will depend on local circumstances. Data is gathered via personal interviews using questionnaires. Blood tests are carried out to determine HbA1c and cholesterol levels of participants. For the blood test, the participant will need to donate blood samples via a blood draw from the arm. Blood will be taken during the interview process so that there is no need for the participant to visit a laboratory. Participants will be informed about their test results.

Selected diabetes patients will be trained as peer educators and then establish peer education groups so that they can help diabetes patients participating in these groups to reduce or prevent problematic health behaviours and improve self-management of diabetes. Peer education groups will meet once per month. The control group will not receive any additional training before the intervention is concluded.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 29/12/2020:
Glycated haemoglobin (HbA1c), measured using HbA1c measurement device with a drop of blood taken from the finger at baseline and after 20 months

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Previous primary outcome measure:
Glycated haemoglobin (HbA1c), measured using HbA1c measurement device with a drop of blood taken from the finger at baseline, after 9 and 18 months

Key secondary outcome(s))
Current secondary outcome measures as of 29/12/2020:
1. Total cholesterol, measured using point of care measurement device with drop of blood taken from finger at baseline and after 20 months
2. High-density lipoprotein, measured using point of care measurement device with drop of blood taken from finger at baseline and after 20 months
3. High-density lipoprotein, measured using point of care measurement device with drop of blood taken from finger at baseline and after 20 months
4. Triclycerides, measured using point of care measurement device with drop of blood taken from finger at baseline and after 20 months
5. Quality adjusted life years, measured using EQ-5D-3L at baseline and after 20 months
6. Physical Activity, measured via WHO Global Physical Activity Questionnaire at baseline and after 20 months

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Previous secondary outcome measures:
1. Total cholesterol, measured using point of care measurement device with drop of blood taken from finger at baseline, after 9 and 18 months.
2. High-density lipoprotein, measured using point of care measurement device with drop of blood taken from finger at baseline, after 9 and 18 months.
3. High-density lipoprotein, measured using point of care measurement device with drop of blood taken from finger at baseline, after 9 and 18 months.
4. Triclycerides, measured using point of care measurement device with drop of blood taken from finger at baseline, after 9 and 18 months.
5. Quality adjusted life years, measured using EQ-5D-3L at baseline, after 9 and 18 months.
6. Physical Activity, measured via WHO Global Physical Activity Questionnaire at baseline, after 9 and 18 months.

Completion date
31/01/2021

Eligibility

Key inclusion criteria
1. Type 2 diabetes patients treated in Puskesmas in the intervention area for diabetes
2. Agreed to undergo the whole process of peer education
3. Agreed to carry out all biomarker measures included in the protocol
4. Aged 20-79 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
79 years

Sex
All

Total final enrolment
534

Key exclusion criteria
1. Type 1 diabetes
2. Enrolled in other research program

Date of first enrolment
18/02/2019

Date of final enrolment
10/04/2019

Locations

Countries of recruitment
Indonesia

Study participating centre
Syiah Kuala University
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Banda Aceh
Indonesia
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Sponsor information

Organisation
Georg-August-Universität Göttingen

ROR
https://ror.org/01y9bpm73

Funder(s)

Funder type
Research organisation

Funder Name
International Diabetes Federation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Till Seuring, t.seuring@gmx.de. All raw de-identified participant data will be made available indefinitely one year after the conclusion of the trial. Data will be made available for

non-profit scientific research purposes. Consent for data sharing with other researchers was obtained from participants. Interested researchers will need to provide us with their name, affiliation, and the goal of their research project for which they want to use the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/09/2019	04/09/2019	Yes	No
Interim results article		20/03/2023	06/03/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes