







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

<b>Submission date</b> 18/02/2019	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
<b>Registration date</b> 28/02/2019	<b>Overall study status</b> Completed	 Protocol added
<b>Last Edited</b> 06/03/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	 SAP not yet added
		 Results not yet added and study completed for more than 2 years
		 Raw data not yet added
		 Study completed

## Plain English Summary

### 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 management 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

### Contact name

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Scientific

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

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 hypothesis

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

**Secondary study design**

Cluster randomised trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available.

**Condition**

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 measure**

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

**Secondary outcome measures**

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.

**Overall study start date**

01/08/2017

**Overall study end date**

31/01/2021

## Eligibility

**Participant 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

**Age group**

Adult

**Lower age limit**

20 Years

**Upper age limit**

79 Years

**Sex**

Both

**Target number of participants**

900: 36 cluster with 25 participants each

**Total final enrolment**

534

**Participant exclusion criteria**

1. Type 1 diabetes
2. Enrolled in other research program

**Recruitment start date**

18/02/2019

**Recruitment end date**

10/04/2019

## Locations

**Countries of recruitment**

Indonesia

**Study participating centre****Syah Kuala University**

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## Sponsor information

**Organisation**

Georg-August-Universität Göttingen

**Sponsor details**

Centre for Modern Indian Studies (CeMIS)

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## Sponsor type

University/education

## Website

<https://www.uni-goettingen.de/de/prof.+dr.+sebastian+vollmer/450695.html>

## ROR

<https://ror.org/01y9bpm73>

# Funder(s)

## Funder type

Research organisation

## Funder Name

International Diabetes Federation

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Main results, i.e. the effectiveness and cost-effectiveness of peer education to reduce HbA1c levels, will be published in 2021.

In 2020 we plan to publish basic results on diabetes control and metabolic syndrom in people with type 2 diabetes in our trial.

## Intention to publish date

30/11/2021

## 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?
<a href="#">Protocol article</a>	protocol	02/09/2019	04/09/2019	Yes	No
<a href="#">Interim results article</a>		20/03/2023	06/03/2024	Yes	No