

# Effects of health coaching on health understanding and quality of life for type 2 diabetes patients

<b>Submission date</b> 02/02/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/05/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The increasing prevalence of diabetes has become a challenge for global health professionals. The International Diabetic Federation (2017) notes that around 425 million adults in the world have diabetes. Indonesia, based on basic health research data in 2018, recorded an increase in the prevalence of diabetes in Indonesia from 6.9% (2013) to 8.5% (2018). Type 2 diabetes mellitus accounts for 90% of all diabetes cases. Sherifali et al (2018) state that empirical evidence suggests the best approach in diabetes management is self-management. In Indonesia, the approach used for self-management in diabetes patients is educational, while based on a literature review, health coaching has emerged as an innovative health promotion intervention approach to improve patient compliance with self-management with behaviors that can support efforts to improve health in people with chronic diseases such as diabetes. The purpose of this study was to determine the effect of health coaching on health literacy and quality of life of uncontrolled type 2 diabetes patients.

### Who can participate?

Adult over the age of 17 who was admitted to the Syamsudin hospital with a diagnosis of type 2 diabetes mellitus

### What does the study involve?

Participants will be randomly allocated to the intervention group and the control group. The interventions provided were coaching related to self management, coaching was provided by trained health promoters. Coaching is given 1 time face to face before leaving the hospital and 4 times by telephone in 12 weeks, namely week 1, week 5, week 8 and week 12 after discharge from hospital with a duration of 15-45 minutes. The 1st and 2nd interventions were carried out by hospital staff, while the 3-5th interventions were carried out by primary health care officers.. Before and after the intervention, participants measured their HbA1C scores, health literacy scores and quality of life scores

What are the possible benefits and risks of participating?

There is no direct benefit from this study, participants get hba1c examination within 3 months in a timely manner.

Where is the study run from?

The study is managed by the Syamsudin hospital in collaboration with the university of Indonesian

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

October 2019 to May 2021

Who is funding the study?

University of Indonesia

Who is the main contact?

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

**Study information****Scientific Title**

Effects of health coaching on health literacy and quality of life for uncontrolled type 2 diabetes mellitus patients

**Study objectives**

There are differences in health literacy and quality of life for type 2 diabetes mellitus patients between the intervention group and the control group

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 18/02/2020, The Research and Community Engagement Ethical Committee of the Faculty of Public Health Universitas Indonesia (Dekanat Building, Faculty of Public Health, Universitas Indonesia, Depok 16424, Indonesia; +62 217864975; fkmui@ui.ac.id), ref: Ket-28 / UN2.F10 / PPM.00.02 / 2019

**Study design**

Single centre interventional single-blinded randomized controlled trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Quality of life in patients with uncontrolled type 2 diabetes mellitus

## **Interventions**

Participants are assigned to groups by random allocation using blocked randomization, there are 2 arms, each block 4 subjects, so 6 permutation blocks (AABB, ABAB, ABBA, BBAA, BABA, BAAB). The determination of the block used simple drawing.

The interventions provided are coaching related to self management in behavior change, coaching is provided by trained health promoters. Coaching is given 1 time face to face before leaving the hospital and 4 times by telephone in 12 weeks, namely week 1, week 5, week 8 and week 12 after discharge from hospital with a duration of 15-45 minutes. The 1st and 2nd interventions were carried out by hospital staff, while the 3-5th interventions were carried out by primary health care officers.

The control group received usual care (health education) plus telephone call at week 1, week 4, week 8 and week 12 to monitor target achievement and was given advice with educational methods as needed.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

At baseline and 12 weeks

1. HbA1c is measured using D10 hemoglobin analyzer
2. Health literacy is measured using a questionnaire
3. Quality of life is measured by the Asian Diabetes Quality of Life questionnaire

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **Completion date**

30/05/2021

# **Eligibility**

## **Key inclusion criteria**

1. Age 18 - 65 years
2. Domiciled in the City of Sukabumi
3. HbA1C levels >6.5%
4. Have health insurance
5. Do not experience mental disorders
6. Willing to be a respondent

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients who are pregnant
2. Having anemia or disease with age disorders of erythrocytes
3. Received transfusions in the last 2 - 3 months
4. Having kidney disease
5. Experiencing hearing and/or vision problems
6. Patients with a health education background
7. Patients with serious complications such as stroke/experiencing cerebral vascular problems

**Date of first enrolment**

01/09/2020

**Date of final enrolment**

30/04/2021

**Locations****Countries of recruitment**

Indonesia

**Study participating centre****Syamsudin Hospital**

Jl. Rumah sakit no. 01

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Indonesia

43123

**Sponsor information****Organisation**

University of Indonesia

**ROR**

<https://ror.org/0116zj450>

# Funder(s)

## Funder type

University/education

## Funder Name

Universitas Indonesia

## Alternative Name(s)

University of Indonesia, UI

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Indonesia

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			04/05/2021	No	No