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

Submission date
02/02/2021

Recruitment status
No longer recruiting

Registration date
05/02/2021

Overall study status
Completed

Last Edited
04/05/2021

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
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

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

Primary study design
Interventional

Study design
Single centre interventional single-blinded randomized controlled trial

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
Sukabumi - West Java
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?
Protocol file			04/05/2021	No	No