**Effects of Health Coaching on Health Understanding and Quality of Life for Type 2 Diabetes Patients: Randomized Controlled Trial**

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**Background :**The increasing prevalence of diabetes globally is a challenge for health professionals. health coaching is a new approach to behavior change intervention in diabetes patients. This study aims to assess the effect of health coaching on health literacy and quality of life for type 2 diabetes patients.

**Method :**134 Type 2 diabetes patients hospitalized were randomized into 2 groups. The intervention group received a health coaching program, while the control group received an educational program. Subjects were followed for 12 weeks. Outcomes were compared between baseline and endpoint (12 weeks). The outcome measures measured were HbA1c, health literacy and quality of life.

**Discussion:** Health coaching is regulated to support the optimization of diabetes patient self-management in controlling glycemic by increasing health literacy so as to improve quality of life. If proven effective, the health coaching approach will be offered as an approach to managing diabetes patients in health services in Indonesia.

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Keywords: Type 2 diabetes, health coaching, HbA1c, Health Literacy, Quality of Life

**Background**

Diabetes is a global health threat which increases in prevalence from time to time, regardless of socio-economic status or national borders. In 2019 around 463 million adults (20-79 years) in the world are living with diabetes and it is estimated that this will increase to 700 million by 2045, of which 79% are in low and middle income countries [1]. Indonesia ranks 7th in the number of cases of diabetes aged 20 - 79 years globally with a prevalence of 10.7% and is predicted to increase to 13.7% in 2030 [2]. In Indonesia, it is reported that the prevalence of diabetes has increased from 6.9% in 2013 to 8.5% in 2018 [3]. The National Health Insurance (JKN) data also shows an increase in the number of cases and financing of diabetes services in Indonesia from 135,322 cases with financing of Rp 700.29 billion in 2014 to 322,820 cases with financing of Rp 1,877 trillion in 2017 [4].

Diabetes is a chronic disease that occurs when the pancreas does not have the ability to produce insulin, or when the body cannot properly use the insulin it produces [1]. Diabetes is the leading cause of blindness, kidney failure, heart attack, stroke and amputation of the lower limbs and is estimated to be the seventh leading cause of death in 2016 [5]. Management of diabetes is carried out by multidisciplinary measures, the goal of diabetes management is to improve the quality of life for people with diabetes [6]. In Indonesia, the approach to diabetes management is pharmacological therapy, medical nutrition therapy, physical therapy and education on behavior change towards a healthy lifestyle [6].

The best and key approach in diabetes management is self management [7,8]. A new diabetes management approach is needed to improve self-management skills in diabetic patients. A patient-centered approach to optimize patient empowerment in glycemic control [9]. Health coachingis an innovative health promotion intervention approach to improve patient adherence to self-management of behaviors that can support efforts to improve quality of life in people with chronic diseases such as diabetes [7, 10]. In the UK, health coaching is one of the innovation programs in the health sector [11]. Health coaching is a patient-centered approach in which patients at least define their goals, use their potential and become active learners, control and increase accountability for their health [12].

Health coaching in diabetic patients has a significant impact on glycemic control and oral health management in high-risk patients compared to health education [13]. Health coaching in diabetic patients can improve the patient's ability to control glycemic [14,15,16,17,18,19]. The ability of glycemic control can improve the quality of life of diabetic patients [8]. The ability of glycemic control is also influenced by the patient's ability to understand his condition, medication and self-management [20]. This study aims to assess the effect of health coaching compared to health education on the ability of type 2 diabetes patients to understand and apply health information related to their disease and self-management which affects glycemic control and quality of life.

**METHOD**

**Participants**

The research settings were hospital and community. Study subjects were recruited from patients at the referral hospital in Sukabumi City with a diagnosis of type 2 diabetes who were treated and followed in the community until week 12 after hospitalization. Selection of subjects based on inclusion and exclusion criteria. The inclusion criteria for this study were:

#### Age> 17 years

#### Domiciled in Sukabumi

#### HbA1C levels> 6.5%

* + - 1. Have health insurance

#### Do not experience mental disorders

#### Willing to be a respondent

While the exclusion criteria for this study were:

1. Patients who are pregnant
2. Have anemia or have erythrocyte age disorders
3. Received transfusions in the last 2-3 months
4. Having kidney disease
5. Have hearing and / or vision problems
6. Patients with a health education background
7. Patients with severe complications such as stroke / experiencing decreased consciousness

**Intervention**

**Intervention Group**

Subjects in the intervention group will receive coaching on self-management to support health-related behavior changes 5 times within 12 weeks with a duration of 30-45 minutes per session. Coaching is carried out by a coach, namely hospital health promoters and primary health services (Puskesmas) who have received 20 hours of training. The first meeting is done face-to-face in the hospital when the patient is going discharge. The second meeting was held at week 1 after discharge by telephone by the hospital coach. Meetings 3 (week 4), 4 (week 8) and 5 (week 12) are conducted by telephone by the coach of the Puskesmas. At the initial meeting, the subjects were coaching and given a monitoring card containing their goals and action plans for self-management related to their health risk factors.

**Control Group**

Subjects in the control group received continuous education with the same frequency, schedule and duration as the intervention group. Subjects were educated on self-management programs related to their health risk factors before going home and were given control cards for predetermined targets.

**Outcomes**

The primary outcome measures measured were differences in mean HbA1c scores, health literacy scores and quality of life scores between baseline and endpoint 12 weeks in the intervention and control groups, then differences in mean scores between baseline and 12 weeks were compared between the intervention and control groups. Meanwhile, the secondary outcome is compliance with the implementation of self-management action plans.

**Sample Size**

The sample size is determined using the sample formula for the average difference test with a research power of 80%, a 95% confidence interval. Reference differences in means and standard deviation are based on studies [13, 21]. Based on the calculation of the minimum sample size after 10% correction, the number of participants per group is 67, so that the total minimum sample size is 134.

**Assignment of Intervention**

The process of determining the allocation of subjects to the intervention or control group is carried out by the principal investigator (PI). Intervention officers are not involved in determining the assignment of subjects. The random allocation method used is block randomization. Each block consists of 4 subjects so that 6 variations of the permutation result blocks are obtained (AABB, ABAB, ABBA, BBAA, BABA, BAAB), then the researcher randomizes block variations for a number of 134 participants by doing a simple lottery. The order in which patients enter the hospital determines the order of the draw results. Patients who came for an eligibility assessment were assessed as study subjects based on medical record data, after proper PI came to the patient to explain the study and ask for consent. If the patient agrees, then a baseline measure is taken on the outcome variable. Then the PI will contact the intervention provider to get a coaching / education session according to the allocation it gets. The coach / educator will make arrangements for the second session and so on.

**Blinding**

 The subject did not know whether it was included in the intervention group or in the control group, the subject was informed that research was being carried out related to the development of sustainable diabetes management methods. Likewise, the data analyzer did not know the intervention given. Meanwhile, the intervention giver knows their assignment.

**Data collection**

Basic data were collected in the form of demographic data (age, gender, education, marital status, occupation), data related to health and behavior (weight, height, smoking habits, physical activity, diet management, diabetes duration, comorbids and drugs received) and outcome measurement data, namely HbA1c levels, health literacy and quality of life. Demographic data and data related to health and behavior were obtained from patient medical record documents, HbA1c was measured using the D10 hemoglobin analyzer machine, health literacy was measured using the diabetes health literacy survey (DHLS) questionnaire developed by researchers, while the measurement of quality of life used the Asian diabetes quality questionnaire of Life (ADQoL).

**Data management**

Data entry was carried out by the main researcher under the supervision of a supervisor from the University of Indonesia, the data was entered into excel format which was locked with 2 security times, then the researcher coded the categorical scale variables. The researcher submitted the excel data format to an independent data analyst for analysis.

**Statistical Methods**

The statistical analysis plan used was the dependent and independent mean difference test if the baseline data between groups did not show any significant differences. If the baseline data shows a significant difference, then perform the average difference test by controlling the variables that show the difference.

**Monitoring Data**

This study did not form a special monitoring data team, but data monitoring was carried out by prof. Hadi Pratomo and Rita Damayanti as supervisors in this study.

**Ethical Clearence**

This research has received ethical approval from the research and community engagement ethical committee, faculty of public health at the University of Indonesia with number: Ket-28 / UN2.F10 / PPM.00.02 / 2019 on February 18, 2020 signed by the chairman Prof. Dr. dr. Ratna Juwita, MPH.

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Patients with a diagnosis of T2DM who met the criteria

Allocation randomization

Education group (standard care)

Health Coaching intervention group

Subjects filled in agreement after explanation to become research respondents

Initial measurement of research variables (baseline)

Educational standards for planning patients going home in the hospital

Coaching I: performed face to face with duration of 30-45 minutes being hospitalized by the hospital coach

The first week after hospital discharge, follow-up needs for further education / repetition by telephone by the hospital staff

Coaching II: carried out at week 1 after hospital discharge, by telephone duration of 30-45 minutes by hospital staff

Week 4, 8 and 12 after hospital discharge, a follow-up for further education needs / repetition is carried out by telephone by Puskesmas Staff

Coaching III - V: conducted at week 4, 8 and 12 after hospital discharge, by telephone duration of 30-45 minutes by Puskesmas coach

Week 12 was measured the study outcome

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