ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: March 19, 2020

ClinicalTrials.gov ID: NCT04313829

Study Identification

Unique Protocol ID:	DM-202003.01
Brief Title:	Pharmacist Counseling on the Health-related Quality of Life of Patients With Type 2 Diabetes Mellitus
Official Title:	Impact of Pharmacist Counseling on the Health-related Quality of Life of Patients With Type 2 Diabetes Mellitus: a Cluster Randomized Controlled Study
Secondary IDs:	

Study Status

Record Verification:	March 2020
Overall Status:	Completed
Study Start:	August 1, 2017 [Actual]
Primary Completion:	February 1, 2018 [Actual]
Study Completion:	August 31, 2018 [Actual]

Sponsor/Collaborators

Sponsor:	Universitas Padjadjaran
Responsible Party:	Sponsor
Collaborators:	Ministry of Research, Technology and Higher Education of the Republic of Indonesia

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: No. 146/H4.8.4.5.31/PP36-KOMETI Board Name: Health Research Ethics Committee of the Faculty of Medicine Board Affiliation: Hasanuddin University Phone: +62 81241850858 Email: Address: Lantai 3 Gedung Laboratorium Terpadu Jl. Perintis Kemerdekaan Kampus Tamalanrea Km. 10 Makassar, 90245

Data Monitoring:

Study Description

Brief Summary: The quality of life (QoL) of patients with type 2 diabetes mellitus (T2DM) is a measure of the successful outcomes of therapy. The program of management of chronic diseases “Program Pengelolaan Penyakit Kronis” (Prolanis) among patients with hypertension and T2DM is a new strategy of the Badan Penyelenggara Jaminan Sosial (BPJS), which is the Indonesian national health insurance system. The impact of pharmacist counseling interventions on health-related QoL (HRQoL) was analyzed in Prolanis T2DM patients.

Detailed Description: A cluster randomized controlled trial that was designed to include two groups (control (n = 111) and intervention (n = 109) groups), and pre- and post-test procedures were conducted. The participants were Prolanis T2DM patients who attended four primary health-care centers (Puskesmas) in Makassar City, South Sulawesi, Indonesia from August 2017 to August 2018. The intervention group received systematic counseling for 6 months. The data were collected using the Bahasa Indonesia version of the European Quality of Life 5 Dimensions 5 Levels (EQ-5D-5L) questionnaire and were analyzed using EQ-5D preference weight for each health state with the Indonesian EQ-5D-5L value Set. Furthermore, the EQ-5D index and the EQ-5D VAS score were calculated and HbA1c levels were assessed.

Conditions

Conditions: Type 2 Diabetes Mellitus

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Supportive Care

Study Phase: N/A

Interventional Study Model: Parallel Assignment
All patients provided written informed consent before participating in the study. The participants were administered the EQ-5D-5L questionnaire in the first month of the study, as a pre-test procedure. The patients in the control group participated in the standard Prolanis T2DM program for 6 months and were asked to fill out the questionnaire again at the 6-month time point, as a post-test procedure. The patients in the intervention group participated in the standard Prolanis T2DM program and received a 15 min face-to-face counseling session from a pharmacist once a month for 6 months. At the 6-month time point, subjects in the intervention group were asked to fill out the EQ-5D-5L questionnaire again, as a post-test procedure. Patients in the control group also received a 15 min face-to-face counseling session from a pharmacist once a month for 6 months after the intervention study was completed.

Number of Arms: 2

Masking: Single (Care Provider)
Cluster randomization by institution was used in this study. The four Puskesmas were randomized by asking the person in charge of the Prolanis at these centers to choose a closed envelope containing an identifier indicating the

control group or the intervention group. Two Puskesmas were used as the control group and the remaining two were used as the intervention group.

Allocation: Randomized

Enrollment: 220 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Active Comparator: Intervention group The intervention group received Pharmacist counseling for 15 minutes include giving standard medicine information service and explaining the validated pharmacist counseling module which contained the T2DM causes and symptoms, the reasons for the importance of therapy, the non-pharmacological and pharmacological therapies available (drug names, strengths, indications, rules of use, side effects, interactions, and storage), the purpose of controlling blood sugar levels, medications that need to be avoided, and guidelines for missed dose.	Behavioral: Pharmacist Counseling Intervention We used the counseling module (in the form of a guide book) for pharmacist-based counseling that had been validated regarding constructive content by an endocrinologist and a pharmacist expert in diabetes drug counseling. The module explained the T2DM causes and symptoms, the reasons for the importance of therapy, the non-pharmacological and pharmacological therapies available (drug names, strengths, indications, rules of use, side effects, interactions, and storage), the purpose of controlling blood sugar levels, medications that need to be avoided, and guidelines for missed doses. The pharmacists should explain all the content within the module in 15 minutes to each patient of the intervention group each month for 6 months. As an ethical consideration, the control group patients were given the same explanation module through pharmacist counseling after the study finished.
No Intervention: Control group The control group received standard medicine information services by Pharmacists.	

Outcome Measures

Primary Outcome Measure:

1. Measurement of Quality of Life (QoL) using the Euro Quality of Life 5 Dimension 5 Level (EQ-5D-5L) questionnaire
   The QoL of Prolanis T2DM patients was measured using the Euro Quality of Life 5 Dimension 5 Level (EQ-5D-5L) questionnaire.

   The EQ-5D-5L questionnaire consists of two parts: a descriptive system and a Visual Analogue Scale (VAS).

   The descriptive system describes the health state and consists of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Patients who reported problems were then categorized into two categories, a “has no problem” category (health state code of 1) and “has problem” category (health state code of 2–5) for each level of each dimension.

   The second part of the EQ-5D-5L questionnaire is the EQ-VAS, which is a thermometer-like scale (ranging from 0 to 100) that reflects the patient’s health in general. EQ-VAS represents the patient perspective, where zero indicates the worst imaginable health state and 100 reflects the best imaginable health state.

   [Time Frame: 6 months]

Secondary Outcome Measure:

2. Measurement of HbA1c
   Measurement of HbA1c was done over a period of 2-4 months. In addition, HbA1c was also be considered compatible with therapy.

   [Time Frame: 6 months]

Eligibility

Minimum Age:	18 Years
Maximum Age:	65 Years
Sex:	All
Gender Based:	No
Accepts Healthy Volunteers:	No
Criteria:	Inclusion Criteria:

- Registration in the Prolanis at BPJS Makassar City,
- Age between 20 and 65 years,
- HbA1c level ≥6.5%, and
- Willingness to participate in research by signing an informed consent (for all T2DM patients with or without comorbidities)

Exclusion Criteria:

- Irregular control schedules,
- Incomplete medical record data,
- Circumstances that did not allow filling out the questionnaires (e.g., inability to speak, see, or hear)

Contacts/Locations

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IPDSharing

Plan to Share IPD: No

References

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Links:

Available IPD/Information:	