

Improving Patients' Education towards Management of Diabetes Mellitus

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28380

Source

NTR

Brief title

IPEUDM study

Health condition

Diabetes mellitus

Sponsors and support

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Intervention

Outcome measures

Primary outcome

At the end of study (six-months) participants of control arm were compared with Pharmacist counselling arm and flashcard arm for:

disease related-knowledge,

understanding of care practices

Secondary outcome

impact of education base activity on Hb1Ac

Study description

Background summary

This is a randomized (systemic), Multi-center parallel-group longitudinal interventional study. The study participants consist of patient diagnosed with type 2 diabetes mellitus and attending the outpatient department (OPD) for diabetic treatment. A total of 200 participants in this study will have an 80% power to detect a 0.5% difference in patient education & understanding variables in the intervention parallel groups and control arm. In order to compensate 20% loss in follow-up in each arm researcher plan to randomize a total of 300 patients (100 per arm) with type 2 diabetes mellitus to the intervention parallel groups and control arm of the study. Patients may be self-referred or referred through their primary physician. All eligible patients were screened to be included in this study. Eligible patients were also introduced to the study protocol by research coordinator to confirm participation. Patients who were interested to participate in this study, required to sign a research consent form. Patients, who were illiterate, acquire an impartial witness to explain the study protocol before participation. During the data collection process, all study forms were labelled with a unique study identifier. All collected forms were stored in a locked file cabinet in a locked office. Researcher will check for any missing or outlier values. Researcher has developed a questionnaire with multiple response questions. At the end of study (after 6 months) all the participants required to fill the questionnaire. Questionnaire consist of 24 questions (4 questions from each domain), linguistic /paraphrasing assistance provided to participants (though questionnaire previously validated). Researcher then analyse the responses and conclude participants response to represent effective arm. Data analysis was made using IBM SPSS Statistics, version 22 (Armok, NY). A probability of <0.05 was considered statistically

significant for all tests. All variables were analyzed using descriptive analysis. Unadjusted comparisons between study arms were made using t-tests for continuous variables or chi-square tests for discrete variables. All data will be presented before and after adjustment for confounding and interaction.

Study objective

Patient education plays significant role in disease management

Patient education and understanding reduces the complications and adverse outcomes.

Study design

0 - 3 - 6 Months

Intervention

Control Arm

Participants randomized into the control group did not receive unsolicited feedback but will continue to receive their usual medical care as per usual when visiting their doctors but are allowed to contact the research facilitator as if necessary. Participants in all three groups were required to report researcher once monthly (schedule time/date) for assessments. All the three groups screened for Hb1Ac every 3 months.

ARM 1: Flashcard Arm

Eligible participants were provided with a self-developed flashcards with disease-related information. Participants need to meet researcher on monthly basis for assessment and collection of new flashcards. All the disease-related information divided into 6 main headings; disease definition and epidemiology, risk factor and prevention, dietary care (recommended plans), treatment care, self-care practices (including self monitoring blood glucose SMBG) and critical clinical parameters (symptoms of hypo / hyperglycemic episodes). Participants received each domain flashcards on monthly basis visit. Figure 2; showed the sequence of flashcards distributed among participants. Similar pattern is applied in pharmacist counselling arm instead the information is conveyed in counselling sessions.

ARM 2: Pharmacist Intervention Arm

Participants were referred through their primary physician or clinic nurses. Eligible participants were provided with a systemic booklet and homework book to record their daily activities. Also researcher has developed a monthly glucose-monitoring schedule together with counselling session (each session is about 20-40 min, depending on patients feedback response). Researcher reminds the group participants for regular counselling sessions and also provides schedule dates with time during enrolment. Both date and time confirmed with

patient feasibility and convenience, however participants still reserve the right to change the either time/date or both with 24-48 hours prior notice to researcher.

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Eligibility criteria

Inclusion criteria

- a. Type 2 diabetes diagnosed by a physician at least six months prior to study enrolment determined via self-report with verification (medical records and current treatments)
- b. Aged 18-75 (Malaysian national only)
- c. Access to transportation for regular follow-ups
- d. Patients can read with no visual impairment (flashcard arm only)

Exclusion criteria

Not pregnant or any other medical conditions that can impede participation.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	15-12-2016
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-11-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6062
NTR-old	NTR6209
Other	EDM-1511-2016 : Protocol ID

Study results

Summary results

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