Improving Patients' Education towards Management of Diabetes Mellitus

Gepubliceerd: 17-11-2016 Laatst bijgewerkt: 18-08-2022

Patient education plays significant role in disease management Patient education and understanding reduces the complications and adverse outcomes.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28380

Bron
NTR

Verkorte titel
IPEUDM study

Aandoening

Diabetes mellitus

Ondersteuning

Primaire sponsor: Dr. Syed Wasif Gillani
Department of Clinical Pharmacy
College of Pharmacy, Taibah University, Al Madinah Al Munawarrah
Email: wasifgillani@gmail.com (SWG)
TEL: +966538419573
Overige ondersteuning: Dr. Syed Wasif Gillani
Department of Clinical Pharmacy
College of Pharmacy, Taibah University, Al Madinah Al Munawarrah
Email: wasifgillani@gmail.com (SWG)
TEL: +966538419573

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

Patient education plays significant role in disease management
Patient education and understanding reduces the complications and adverse outcomes.

Onderzoeksopzet

0 - 3 - 6 Months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Taibah University

Syed Wasif Gillani
KSA

[default]
The Netherlands

Wetenschappelijk

Taibah University

Syed Wasif Gillani
KSA

[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-12-2016
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

Dr. Syed Wasif Gillani
Department of Clinical Pharmacy
College of Pharmacy, Taibah University, Al Madinah Al Munawarrah
Email: wasifgillani@gmail.com (SWG)
TEL: +966538419573