UNIVERSITI PUTRA MALAYSIA

EFFECTIVENESS OF PRACTICE GUIDELINES NUTRITIONAL CARE AND BASIC NUTRITIONAL CARE ON ANTHROPOMETRIC AND METABOLIC OUTCOMES IN TYPE 2 DIABETES MELLITUS PATIENTS AT SULTAN QABOOS UNIVERSITY HOSPITAL, OMAN

ALI OBAID SALIM AL-SHOOKRI

FPSK(p) 2013 10

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By

ALI OBAID SALIM AL-SHOOKRI

Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfillment of the Requirements for the Degree of Doctor of Philosophy

May 2013

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DEDICATION

To Oman, Malaysia, Family and Friends

Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfilment of the requirement for the degree of Doctor of Philosophy

EFFECTIVENESS OF PRACTICE GUIDELINES NUTRITIONAL CARE AND BASIC NUTRITIONAL CARE ON ANTHROPOMETRIC AND METABOLIC OUTCOMES IN TYPE 2 DIABETES MELLITUS PATIENTS AT SULTAN QABOOS UNIVERSITY HOSPITAL, OMAN

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May 2013

Chair: Professor Khor Geok Lin, PhD

Faculty: Medicine and Health Sciences

Diabetes is a common problem worldwide. Oman is facing increased incidence of type 2 diabetes. The prevalence of type 2 diabetes in Oman was 10 – 14% in 2007 and the figure is expected to rise to 14-20% by the year 2025. There is thus a critical need to improve the nutritional care for the increasing cases of type 2 diabetes patients in Oman.

The main objective of this randomized clinical trial is to investigate the effectiveness of the practice guideline nutritional care (PGC) compared to the basic nutrition care (BC) on anthropometric and clinical outcomes in adults with type 2 diabetes in the Sultan Qaboos University Hospital in the Sultanate of Oman.

The sample size required for the study was computed using G*Power 3.1.3 for repeated measures ANOVA, to detect an effect size of 0.24, significance level at

0.05, 95% power, giving a total sample size of 156 for two groups, or about 78 per group. Assuming a 25% dropout rate, the final sample size was increased to 200 subjects, with 100 subjects in each intervention group. Patients were randomly assigned to either the PGC or BC group.

Out of 200 participants who enrolled for the study, 170 men and women aged 30 to 70 years met the inclusion and exclusion criteria. This represents 85% of the 200 subjects enrolled. Out of these, 85 were assigned randomly to the BC group and 85 to the PGC group.

In the BC group, patients had only one appointment with the dietitian during which nutritional goals designed to improve glycemic control were introduced and general principles of nutrition management were discussed with nutritional prescription and education. The PGC group patients had three appointments with a dietitian with specific assessments and intervention measures according to the practice guidelines of medical nutritional treatment developed by American Dietetic Association.

Anthropometric (weight, height, BMI and waist circumference), biochemical (fasting blood glucose, HbA1c, triglycerides, cholesterol, LDL cholesterol and HDL cholesterol), dietary intake (total energy, carbohydrate, fat, cholesterol, saturated fatty acids, monounsaturated fatty acids and polyunsaturated fatty acids) and physical activity (total physical activity MET-minutes/week, walking MET-minutes/week, moderate MET-minutes/week and vigorous MET-minutes/week) variables were measured at three time points (0, 3, 6 months).

The comparison between groups over the study period of 6 months was quantified using Multivariate General Linear Modeling Repeated Measures ANOVA (GLM-ANOVA). Normality was checked for variables using the Kolmogorov-Smirnov test, and equality of variances using Levene's test.

Body weight, BMI, HbA1c,FPG and triglycerides values of PGC group at 3 months and 6 months were significantly lower than values at time entry, with no significant change in levels of cholesterol, LDL cholesterol and HDL cholesterol over the study period.

There is no significant change in anthropometric or glycemic outcomes in BC group over the entire period of study. BC group values of cholesterol at 3 months and HDL cholesterol at 6 months were significantly lower compared to values at time of entry.

At the end of 3 months, the PGC group's mean value of FPG was significantly lower than that of the BC group. The PGC group's mean values for waist circumference, HbA1c, cholesterol, LDL cholesterol and triglycerides were also significantly lower than those values for the BC group at the end of 6 months of the study.

The mean values for the dietary intake of total energy, carbohydrate, protein, fat, cholesterol, saturated fatty acids and polyunsaturated fatty acids in the PGC group reduced significantly during the first 3 months compared to the beginning of the study. The significant reduction continued during the following 3 months for the intake of carbohydrate, protein, fat and cholesterol. However, there were no significant changes shown in the mean values for the intake of total energy, saturated

fatty acids and polyunsaturated fatty acids at 6 months compared to values at 3 months within the PGC group.

The dietary intake mean values of total energy, carbohydrate, fat, cholesterol, saturated fatty acids and polyunsaturated fatty acids of the PGC group at 3 months and 6 months were significantly lower than the corresponding mean values of the BC group at the same periods of study. At 6 months of the study, the PGC group showed significantly lower saturated fatty acids intake than that of the BC group.

It was found that total physical activity MET-minutes/week of the PGC group increased significantly during the first 3 months. The same was found for walking MET-minutes/week, moderate MET-minutes/week and vigorous MET-minutes/week values. At 6 months, total physical activity, walking and vigorous MET-minutes/week values did not show significant differences compared to the values at 3 months. The PGC mean values for MET-minutes/week of total, walking, moderate and vigorous physical activity at 3 months and 6 months were significantly higher than the values of the BC group at the same study periods.

The Practice Guideline Nutrition therapy provided by dietitians to patients with type 2 diabetes did not show significant improvements in anthropometric (weight and BMI) outcomes over the period of the study compared to patients who received Basic Nutritional Care.

In summary, the glycemic control and lipid profile outcomes improved significantly with the application of the Practice Guideline Nutrition therapy compared to the

Basic Nutritional Care. The patients' average HbA1c, triglycerides, cholesterol, LDL cholesterol values at the end of the study period were significantly lower in the PGC group than for the BC group. The significant improvement in HbA1c and lipid profile of the PGC group was accompanied by significant increase in the physical activity levels and improved dietary intake. As a result, we conclude that the metabolic outcomes of type 2 diabetes subjects improved with the Practice Guidelines Nutritional care compared to the Basic Nutritional Care, and that more intensive and longer duration medical nutrition therapy are needed for better anthropometric outcomes.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

KEBERKESANAN PANDUAN AMALAN PENJAGAAN PEMAKANAN (PGC) BERBANDING DENGAN PENJAGAAN PEMAKANAN ASAS (BC) KE ATAS HASIL ANTRO DAN METABOLIK DI KALANGAN PESAKIT DI HOSPITAL UNIVERSITI SULTAN QABOOS, OMAN

Oleh

ALI OBAID SALIM AL-SHOOKRI

Mei 2013

Pengerusi: Professor Khor Geok Lin, PhD

Fakulti: Perubatan dan Sains Kesihatan

Penyakit kencing manis merupakan penyakit umum di seluruh dunia. Oman sedang menghadapi peningkatan insiden penyakit kencing manis jenis 2. Prevalen penyakit kencing manis jenis 2 ini di Oman adalah 10 - 14% pada tahun 2007 dan prevalen ini dijangka meningkat kepada 14-20% menjelang tahun 2025. Oleh sebab itu terdapat keperluan kritikal bagi meningkatkan penjagaan pemakanan untuk kes-kes yang semakin bertambah daripada para pesakit kencing manis jenis 2 di Oman.

Objektif utama kajian klinikal rawak ini adalah untuk menyiasat keberkesanan panduan amalan penjagaan pemakanan (PGC) berbanding dengan penjagaan pemakanan asas (BC) kepada hasil antropometri dan metabolik di kalangan orang dewasa dengan penyakit kencing manis jenis 2 di Hospital Universiti Sultan Qaboos di Kesultanan Oman.

Saiz sampel yang diperlukan untuk kajian telah dikira menggunakan G*Power 3.1.3 bagi analisis langkah-langkah yang diulangi dengan ANOVA, pengesanan kesan saiz sebanyak 0.24, tahap signifikan pada 0.05 serta 95% kuasa. Ini telah memberikan saiz sampel sebanyak 156 untuk dua kumpulan atau kira-kira 78 orang per satu kumpulan. Dengan mengandaikan kadar keciciran sebanyak 25%, saiz sampel akhir telah ditambah kepada 200 orang, di mana 100 orang dalam setiap kumpulan intervensi. Pesakit telah diletakkan secara rawak sama ada dalam kumpulan PGC atau kumpulan BC.

Daripada 200 peserta yang mendaftar untuk kajian ini, seramai 170 orang adalah lelaki dan wanita yang berusia 30 hingga 70 tahun serta memenuhi kriteria kemasukan dan kriteria pengecualian. Ini mewakili 85% daripada 200 orang yang mendaftar. Daripada jumlah ini, 85 subjek telah diagih secara rawak kepada kumpulan BC dan 85 subjek lain kepada kumpulan PGC. Kajian klinikal ini dijalankan selama 6 bulan pada tahun 2011.

Dalam kumpulan BC, pesakit hanya mempunyai satu temujanji dengan pegawai dietetik sepanjang kajian ini. Dalam perjumpaan tersebut, matlamat pemakanan yang direka untuk meningkatkan kawalan glisemik telah diperkenalkan dan prinsip umum pengurusan pemakanan telah dibincangkan dengan preskripsi pemakanan dan pendidikan. Manakala, pesakit di kumpulan PGC diberi tiga temujanji dengan pegawai dietetik bersama penilaian tertentu dan langkah-langkah intervensi mengikut panduan amalan rawatan perubatan pemakanan daripada Persatuan Dietetik Amerika.

Pengukuran antropometri (berat badan, ketinggian, Indeks Jisim Tubuh (IJT) dan lilitan pinggang), biokimia (gula dalam darah ketika berpuasa, HbA1c, trigliserida, kolesterol, kolesterol lipoprotein berketumpatan rendah (LDL) dan kolesterol lipoprotein berketumpatan tinggi (HDL), pemakanan (jumlah tenaga, karbohidrat, lemak, kolesterol, asid lemak tepu, asid lemak monotaktepu dan asid lemak politaktepu) dan aktiviti fizikal (jumlah aktiviti fizikal MET-minit/minggu, MET-minit/minggu berjalan, MET-minit/minggu aktiviti sederhana dan MET-minit/minggu aktiviti berat) semua pembolehubah diukur di tiga kadar masa (0, 3, 6 bulan).

Perbandingan antara kumpulan sepanjang tempoh kajian 6 bulan telah ditentukan menggunakan Model Linear Umum Multivariat bagi langkah yang diulang ANOVA (GLM-ANOVA). Kenormalan bagi pembolehubah telah diperiksa dengan menggunakan ujian Kolmogorov-Smirnov, dan kesamaan varians menggunakan ujian Levene.

Kumpulan PGC mempunyai pengurangan yang signifikan dalam berat badan, IJT, HbA1c, gula dalam darah ketika berpuasa dan nilai trigliserida semasa 3 bulan pertama kajian. Pada akhir bulan yang ke-6, nilai purata kumpulan PGC untuk berat badan, HbA1c, gula dalam darah ketika berpuasa dan trigliserida adalah jauh lebih rendah daripada setiap nilai purata mereka di awal kemasukan. Tiada sebarang perubahan yang signifikan terhadap tahap purata kumpulan PGC bagi jumlah kolesterol, kolesterol LDL atau kolesterol HDL sepanjang tempoh kajian.

Pada akhir bulan yang ke-3, nilai purata kumpulan PGC bagi gula dalam darah ketika berpuasa adalah jauh lebih rendah daripada kumpulan BC. Nilai purata kumpulan PGC bagi lilitan pinggang, HbA1c, kolesterol, kolesterol LDL dan trigliserida juga jauh lebih rendah daripada nilai-nilai bagi kumpulan BC pada akhir bulan yang ke-6 kajian.

Nilai purata bagi pengambilan makanan untuk jumlah tenaga, karbohidrat, protein, lemak, kolesterol, asid lemak tepu dan asid lemak politaktepu dalam kumpulan PGC berkurangan dengan signifikan semasa 3 bulan pertama berbanding daripada di awal kajian. Pengurangan yang signifikan ini berterusan selama 3 bulan berikutnya untuk pengambilan karbohidrat, protein, lemak, dan kolesterol. Walau bagaimanapun, tidak terdapat sebarang perubahan yang signifikan ditunjukkan dalam nilai purata bagi pengambilan jumlah tenaga, asid lemak tepu dan asid lemak politaktepu pada bulan yang ke-6 berbanding nilai pada bulan yang ke-3 dalam kumpulan PGC.

Purata pengambilan makanan untuk nilai jumlah tenaga, karbohidrat, lemak, kolesterol, asid lemak tepu dan asid lemak politaktepu bagi kumpulan PGC pada bulan yang ke- 3 dan bulan yang ke-6 adalah jauh lebih rendah daripada nilai-nilai purata yang sepadan dikumpulan BC pada tempoh yang sama kajian. Pada bulan yang ke-6 kajian, kumpulan PGC menunjukkan jauh lebih rendah untuk pengambilan asid lemak tepu berbanding kumpulan BC.

Kajian telah mendapati bahawa jumlah MET-minit/minggu untuk aktiviti fizikal kumpulan PGC meningkat dengan ketara semasa 3 bulan pertama. Keputusan yang sama juga telah didapati untuk MET-minit/minggu bagi berjalan, MET-minit/minggu

aktiviti sederhana dan nilai MET-minit/minggu aktiviti berat. Pada bulan yang ke-6, jumlah MET-minit/minggu aktiviti fizikal, berjalan dan aktiviti berat tidak menunjukkan perbezaan yang signifikan berbanding nilai pada bulan yang ke-3. Purata nilai kumpulan PGC untuk MET-minit/minggu bagi jumlah aktiviti, berjalan, aktiviti fizikal sederhana dan aktiviti berat pada bulan yang ke-3 dan bulan yang ke-6 adalah jauh lebih tinggi daripada nilai kumpulan BC pada tempoh kajian yang sama.

Panduan Amalan Pemakanan terapi yang disediakan oleh pegawai dietetik untuk pesakit kencing manis jenis 2 tidak menunjukkan peningkatan yang ketara dalam ukuran antropometri (berat badan dan IJT) sepanjang tempoh kajian berbanding dengan pesakit yang menerima Penjagaan Pemakanan Asas.

Secara ringkasnya, hasil kawalan glisemik dan profil lipid secara signifikannya meningkat dengan pengamalan mengikut Panduan Amalan Pemakanan terapi berbanding Penjagaan Pemakanan Asas. Purata HbA1c pesakit, trigliserida, kolesterol, nilai kolesterol LDL pada akhir tempoh kajian adalah jauh lebih rendah dalam kumpulan PGC daripada kumpulan BC. Peningkatan yang ketara dalam profil HbA1c dan lipid bagi kumpulan PGC telah diiringi oleh peningkatan yang ketara dalam tahap aktiviti fizikal dan pengambilan makanan yang lebih baik. Hasilnya, kita dapat menyimpulkan bahawa hasil metabolik pesakit kencing manis jenis 2 meningkat dengan Panduan Amalan penjagaan Pemakanan berbanding Penjagaan Pemakanan Asas, dan serta terapi pemakanan perubatan yang lebih intensif diperlukan untuk hasil antropometri yang lebih baik.

ACKNOWLEDGEMENTS

All praises and thanks are due to Allah who gave me competence to finish my study and to acquire the knowledge in science; and peace and blessings are upon His Trustworthy and Honest Messenger.

I do not have enough words to express my gratitude to all who directly or indirectly contributed to the accomplishment of this study and shared my journey towards exploring my knowledge.

My thanks and gratitude to my supervisor, Professor Dr. Khor Geok Lin, the chairman of the Supervisory Committee, for her trust in my capability to join the PhD program at the Faculty of Medicine and Health Sciences, UPM, and for providing advice, encouragement, support, guidance and comments throughout the academic program and research. Deep obligation and indebtedness and most sincere gratitude are offered to her for her continuous guidance during all the stages of my research work, and for her willingness to help, listen and assist in every way, in the midst of her heavy responsibilities.

I am also equally grateful to members of the Supervisory Committee: Associate Professor Dr. Masoud Yahya Al-Maskari, Faculty of Medicine and Health Sciences, Sultan Qaboos University; Dr. Chan Yoke Mun, and Dr. Loke Seng Cheong, Faculty of Medicine and Health Sciences, UPM for their kind help in data analysis, valuable suggestions, and for providing advice, encouragement, support, guidance and comments throughout the academic program and research. I truly appreciate Dr

Loke's critical suggestions and invaluable comments regarding the statistical aspects which I found very useful in preparing this thesis.

I would also like to take this opportunity to express my sincere appreciation to Univeriti Putra Malaysia and Sultan Qaboos University for supporting my thesis work. I sincerely appreciate and acknowledge the assistance of the staff, laboratory assistants and graduate students in the Department of Nutrition and Health Sciences in Univeristi Putra Malaysia.

I would like to thank my Parents, who have always encouraged and support me to go for higher studies. Very special thanks to my wife Layla Al-shukaily for providing me the support and encouragement throughout my study period. Thank you my sons Nabhan and Abdulrahman and my daughters Jana, Lubna and Tamara for your inspiration.

Special thanks for my friends Mohamad Al-Mashali, Fouad Hassan, Sadeq Al-Sheragy, Zaki Tebashy, Mahin Salimi, Mina Bahrani, Laleh Fani Sabiri, brothers, sisters and family members for their continued inspiration and support.

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I certify that a Thesis Examination Committee has met on 27 May 2013 to conduct the final examination of Ali Obaid Salim Al-Shookri on his thesis entitled, "Effectiveness of Practice Guidelines Nutritional Care and Basic Nutritional Care on Anthropometric and Metabolic Outcomes in Type 2 Diabetes Mellitus Patients at Sultan Qaboos University Hospital, Oman" in accordance with the Universities and University Colleges Act 1971 and the Constitution of the Universiti Putra Malaysia [P.U. (A) 106] 15 March 1998. The Committee recommends that the student be awarded the Doctor of Philosophy.

Members of the Thesis Examination Committee were as follows:

Norhaizan binti Mohd Esa, PhD
Associate Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Chairman)

Mirnalini Kandiah, PhD
Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Internal Examiner)

Zalilah binti Mohd Shariff, PhD
Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Internal Examiner)

Ahmad Esmailzadeh, PhD
Associate Professor
Isfahan University of Medical Sciences
Iran
(External Examiner)

NORITAH OMAR, PhD
Assoc. Professor and Deputy Dean
School of Graduate Studies
Universiti Putra Malaysia

Date : 2 August 2013

This thesis was submitted to the Senate of Universiti Putra Malaysia and has been accepted as fulfillment was of the requirement for the degree of Doctor of Philosophy. The members of the Supervisory Committee were as follows:

Khor Geok Lin, PhD
Professor
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Chairman)

Chan Yoke Mun, PhD
Senior Lecturer
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Member)

Loke Seng Cheong, PhD
Senior Lecturer
Faculty of Medicine and Health Sciences
Universiti Putra Malaysia
(Member)

Masoud Yahya Al-Maskari, PhD
Senior Lecturer
College of Medicine and Health Sciences
Sultan Qaboos University
(Member)

BUJANG BIN KIM HUAT, PhD
Professor and Dean
School of Graduate Studies
Universiti Putra Malaysia

Date:

DECLARATION

I declare that the thesis is my original work except for quotations and citations which have been duly acknowledged. I also declare that it has not been previously, and is not concurrently, submitted for any other degree at Universiti Putra Malaysia or at any other institution.

ALI OBAID SALIM AL-SHOOKRI

Date: 27 May 2013

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