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practice guidelines

Ali Almajwal
University of Wollongong

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**DIETETIC MANAGEMENT OF OBESITY IN SAUDI
ARABIA: TOWARDS EVIDENCE BASED CLINICAL
PRACTICE GUIDELINES**

A thesis submitted in fulfillment of the requirements
for the award of the degree

Doctor of philosophy

From

University of Wollongong

By

Ali Almajwal

B.Sc (Clinical Nutrition, King Saud University, Saudi Arabia)

M.Sc (Nutrition and Dietetics, McGill University, Canada)

Smart Foods Centre

School of Health Sciences

2009

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CERTIFICATION

I, Ali Almajwal declare that this thesis, submitted in fulfillment of the requirements for the award of Doctor of Philosophy, in the Smart Foods Centre and School of Health Sciences, is wholly my own work unless otherwise referenced or acknowledged *below*. The document has not been submitted for qualifications at any other academic institution

Ali Almajwal

15 October 2009

DEDICATION

To my parents, Madi (deceased) and Khaznah

To my wife Nehal

To my children Reema and Muath

For their love and continued support

ACKNOWLEDGEMENTS

There are many people who I need to thank for their help during the course of my thesis. I would firstly like to thank my primary supervisor, Associate Professor Peter Williams, who has generously shared his research knowledge and skills, as well as guiding me through the process of scientific publications and supporting opportunities for conference presentations. Thank you for your time, endless patience, regular encouragement and for the constructive, extensive and quick feedbacks on all aspects of this thesis. I would also like to thank you for your supervision through the teleconferences from overseas and for your visit to Saudi Arabia to supervise and support my work there.

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This research would not have been possible without the wonderful participants whom volunteered the time and experiences. Also I would to thanks all dietitians and other health professionals in Saudi Arabia who participated in the dietetic practices survey, interviews, consultation workshops and Delphi consultations.

To my wife who has always been supportive of my studies while we were away from home and relatives in Canada when I was doing my master program and now in Australia. Thank you for all your encouragement, patience, support, love and your assistance with the children. Now we can return back home and enjoy our life.

LIST OF ABBREVIATIONS

%	Percent
ADA	American Dietetic Association
ANOVA	Analysis of variance
AUC	Area Under the Curve
BG	BodyGem
BMI	Body mass index
BWLP	Behavior weight loss program
Ca	Calcium
CFBG	Capillary fasting blood glucose
CI	Confidence Interval
CRBG	Capillary random blood glucose
CV	Coefficient variation
CVD	Cardiovascular disease
DAA	Dietitians Association of Australia
DEXA	dual-energy X-ray absorptiometry
EBM	Evidence based medicine
EF	Eating frequency
FN	False negative
FP	False positive
FPG	Fasting plasma glucose
GI	Glycaemic index
GL	Glycaemic load
GRADE	Grade of Recommendations, Assessment, Development and Evaluation
HB	Harris-Benedict
HCLF	High-Carbohydrate, Low-Fat
HF	High Fat
Ht	Height
IASO	International Association for the Study of Obesity
IOTF	International Obesity Task Force
IRS	Insulin resistance syndrome

JB I	Joanna Briggs Institute
Kcal	Kilocalorie
Kg	Kilogram
KJ	Kilojoule
L	Liter
LR-	Negative likelihood ratio
LR+	Positive likelihood ratio
m	Meter
m ²	Meter square
Mg	Milligram
Mmol	Millimoles
MOH	Ministry Of Health
MUFA	Monounsaturated fatty acids
NA	Not available
NGCEBM	National and Gulf Centre for Evidence Based Medicine
NGT	Nominal group technique
NHLBI	National Heart, Lung and Blood Institution
NIH	National Institute of Health
NPV	Negative predictive value
NSW	New South Wales
NWCR	National Weight Control Registry
P	Confidence value
PHCCs	Primary health care centers
PPV	Positive predictive value
PUFA	Polyunsaturated fatty acids
r	Pearson's Correlation Coefficient
RCTs	Randomized controlled studies
REE	Resting energy expenditure
ROC	Receiver operator characteristic
RQ	Respiratory quotient
RTE	Ready-to-eat
SD	Standard deviation

SFA	Saturated fatty acids
SIGN	Scottish Intercollegiate Guidelines Network
TEE	Total energy expenditure
TEF	Thermic effect of food
TFI	Total dietary fat intake
UK	United Kingdom
UOW	University of Wollongong
USA	United States of America
VCO ₂	Carbon dioxide production
VO ₂	Oxygen consumption
Vs	Versus
WC	Waist circumference
WHO	World Health Organization
WHR	Waist-to-hip ratio
WMD	Weighted mean differences
WRC	Whole room calorimetry
wt	Weight

PUBLICATIONS

Peer reviewed publications in support of this thesis

- Almajwal A, Williams P, Batterham M. Planning for the development of evidence based guidelines for the nutritional management of obesity in Saudi Arabia. *New Egypt J Med*. 2008, 38 (1): 34-39
- Almajwal A, Williams P, Batterham M. Current dietetic practices of obesity management in Saudi Arabia and comparison with Australian practices and best practice criteria. *Nutrition & Dietetics*. 2009;66:94-100
- Almajwal A, Al-Baghli N, Batterham M, Williams P, Al-Turki K, Al-Ghamdi A. Performance of Body Mass Index in predicting diabetes and hypertension in the Eastern province of Saudi Arabia. *Ann Saudi Med*. 2009;29(6):437-445
- Almajwal A, Williams P, Batterham M. Validity of the BodyGem™ calorimeter and prediction equations for the assessment of REE in overweight and obese Saudi male. *Nutr Clin Prac* (Submitted January 2010)

Peer reviewed conference publications and presentations in support of this thesis

- Almajwal, A., Williams, P. & Batterham, M. 2008, 'Development of evidence-based clinical guidelines for the nutritional management of obesity in Saudi Arabia - Project methodology and update', 4th Saudi Annual Evidence Based Medicine Conference and Workshops, King Fahad Medical City, Riyadh, pp. 25 (oral presentation)
- Almajwal, A., Williams, P., Batterham, M. & Alothman, A. 2008, 'Planning for the development of evidence based guidelines for the nutritional management of obesity in Saudi Arabia'. Dietitians Association of Australia. 26th National Conference, *Nutrition and Dietetics* 65 (Supp 11):A26. (poster presentation)
- Almajwal, A., Williams, P. & Batterham, M. 2008, 'Current dietetic practices of dietitians in Saudi Arabia and comparison with Australian practices and best practice criteria'. Dietitians Association of Australia. 26th National Conference, *Nutrition and Dietetics* 65(Supp11):. A26 (poster presentation)

TABLE OF CONTENTS

CERTIFICATION.....	3
DEDICATION.....	4
ACKNOWLEDGEMENTS.....	5
LIST OF ABBREVIATIONS.....	7
PUBLICATIONS.....	10
TABLE OF CONTENTS.....	12
LIST OF APPENDICES.....	16
LIST OF TABLES.....	18
LIST OF FIGURES.....	21
ABSTRACT.....	22
CHAPTER 1: INTRODUCTION.....	24
PART A: GENERAL INTRODUCTION	25
1.1 Scope of thesis	
1.2 Prevalence of obesity in Saudi Arabia	
1.3 Current dietetic practices with obesity in Saudi Arabia	
1.4 Evidence based medicine (EBM) organizations in Saudi Arabia and the region	
1.5 Thesis aims	
PART B: PLANNING FOR THE DEVELOPMENT OF EVIDENCE BASED GUIDELINES FOR THE NUTRITIONAL MANAGEMENT OF OBESITY IN SAUDI ARABIA.....	29
1.6 Abstract	
1.7 Introduction	
1.8 Methods	
1.9 Results	
1.10 Discussion	

PART C: PLAN OF THESIS.....	39
1.11 Thesis hypotheses	
1.12 Studies undertaken	
CHAPTER 2 METHODOLOGY.....	42
2.1 Introduction	
2.2 BMI and obesity classification	
2.3 Methods for assessment of energy expenditure	
2.4 Evidence based clinical practice guidelines	
CHAPTER 3: CURRENT DIETETIC PRACTICES OF OBESITY MANAGEMENT IN SAUDI ARABIA AND COMPARISON WITH AUSTRALIAN PRACTICES AND BEST PRACTICE CRITERIA...	60
3.1 Abstract	
3.2 Introduction	
3.3 Methods	
3.4 Results	
3.5 Discussion	
CHAPTER 4: PERFORMANCE OF BODY MASS INDEX IN PREDICTING DIABETES AND HYPERTENSION IN THE EASTERN PROVINCE OF SAUDI ARABI.....	76
4.1 Abstract	
4.2 Introduction	
4.3 Methods	
4.4 Results	
4.5 Discussion	

CHAPTER 5: VALIDITY OF THE BODYGEM™ CALORIMETER AND PREDICTION EQUATIONS FOR THE ASSESSMENT OF REE IN OVERWEIGHT AND OBESE SAUDI MALES..... 93

5.1 Abstract

5.2 Introduction

5.3 Methods and Materials

5.4 Results

5.5 Discussion

5.1 Abstract

CHAPTER 6: DEVELOPMENT OF EVIDENCE BASED CLINICAL PRACTICE GUIDELINES..... 115

6.1 Introduction..... 115

6.2 Methodology..... 117

6.2.1 Adaptation of existing evidence based statements

6.2.2 Development of new evidence based statements

6.2.3 Development of new consensus statements

6.3 Results..... 128

6.3.1 Adaptation of existing evidence-based statements

6.3.2 Development of new evidence based statements

6.3.2.1 Effect of Calcium/dairy diet on body weight in adults

6.3.2.2 Effect of Polyunsaturated fatty acids and Monounsaturated fatty acids
on body weight in adults

6.3.2.3 Effect of low glycemic index diet on body weight in adults

6.3.2.4 Effect of Fiber intake on body weight in adults

6.3.2.5 Effect of eating frequency and breakfast intake on body weight in adults

6.3.2.6 Accuracy of equations for the calculation of REE in obese people

6.3.3 Development of new consensus statements

CHAPTER 7: SUMMARY AND CONCLUSIONS.....	219
7.1 Summary of the research	
7.2 Significance of the research	
7.3 Limitations and future research	
REFERENCES.....	226
APPENDICES.....	249

LIST OF APPENDICES

Appendix A: Quality Criteria Checklist.....	250
Appendix B: Dietetic practices survey – English version.....	254
Appendix C : Dietetic practices survey – Arabic version.....	264
Appendix D: Dietetic practices survey – samples of the web-based form.....	273
Appendix E: Dietetic practices survey – Ethics Approval.....	276
Appendix F: Dietetic practices survey – Introductory letter and participant information sheet (English version).....	277
Appendix G: Dietetic practices survey – Introductory letter and participant information sheet (Arabic version).....	279
Appendix H : BodyGem and prediction equations study – recruitment advertisement	281
Appendix I: BodyGem and prediction equations study – Screening questionnaire....	282
Appendix J: BodyGem and prediction equations study –Participant Information Sheet.....	284
Appendix K: BodyGem and prediction equations study – Consent Form.....	287
Appendix L: BodyGem and prediction equations study – Ethics Approval.....	289
Appendix M: Delphi consultations study- Participants list.....	290
Appendix N: Delphi consultations study-Ethics Approval.....	291

Appendix O: Delphi consultations study- Invitation Email.....	293
Appendix P: Delphi consultations study-Participant Information Sheet.....	294
Appendix Q: Delphi consultations study-Delphi Emails.....	296
Appendix R: Workshop on the development of consensus statements.....	298
Appendix S: Delphi consultations study-First round questionnaire.....	305
Appendix T: Delphi consultations study-Round 1 Feedback and Final Round Questionnaire.....	314
Appendix U: Delphi consultations study- Round 2 Feedback and Final report.....	321
Appendix V: Draft clinical practice guidelines for nutritional management of obesity in Saudi Arabia.....	327

LIST OF TABLES

Table 1.1: Mean level of agreement with specific statements ranked by participants (n=46)

Table 3.1 Demographic profile of survey respondents (n=253)

Table 3.2 Comparison of the assessment approaches and service provision for weight management by dietitians in Saudi Arabia in 2007 and Australia in 2002

Table 3.3 Comparison of the use of recommended strategies for weight management used by dietitians in Saudi Arabia in 2007 and Australia in 2002

Table 4.1 Population characteristics (n = 195,851)

Table 4.2 Diagnostic performance of BMI in detecting diabetes and/or hypertension using optimal BMI cut-off values based on the shortest distance in ROC curves in Saudi adults, Eastern province, 2004, (n = 195,851)

Table 4.3 Risk of diabetes and/or hypertension associated with increasing BMI in Saudi adults, Eastern province, 2004, based on regression analysis (n = 195,851)

Table 4.4 Diagnostic performance of BMI in detecting diabetes and/or hypertension using optimal BMI cut-off values based on the significant association using logistic regression in Saudi adults, Eastern province, 2004, (n = 195,851)

Table 5.1 Subjects characteristics (n=38)

Table 5.2 Energy predictive equations

Table 5.3 Accuracy of REE, VO₂ and RQ measured by WRC and BG

Table 5.4 Accuracy of REE measured by BG and REE predicted from prediction equations

Table 6.1 Main elements and approaches used for the development of the clinical practice guidelines

Table 6.2 Statements adopted from existing obesity guidelines

Table 6.3 Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Table 6.4 Calcium and body weight: type, quality and number of supportive and non supportive studies

Table 6.5 Evidence Summary: PUFA and weight loss in adult

Table 6.6 Evidence Summary: MUFA and weight loss in adults

Table 6.7 PUFA and intake and weight loss: type, quality and number of supportive and non supportive studies

Table 6.8 MUFA intake and weight loss in adults

Table 6.9 Evidence Summary: low glycemic index diet and weight loss in adults

Table 6.10 Low glycaemic index diet and weight loss: type, quality and number of supportive and non supportive studies

Table 6.11 Evidence Summary: Fiber intake and weight loss in adults

Table 6.12 Fiber intake and weight loss in adults: type, quality and number of supportive and non supportive studies

Table 6.13 Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Table 6.14 Meal frequency and weight loss in adults: type, quality and number of supportive and non supportive studies

Table 6.15 Breakfast intake and weight loss in adults: type, quality and number of supportive and non supportive studies

Table 6.16 Evidence Summary: validation studies used to evaluate the Harris-Benedict equation in obese participants

Table 6.17 Evidence Summary: validation studies used to evaluate the Mifflin equation in obese participants

Table 6.18 Evidence Summary: validation studies used to evaluate the Owen equation in obese participants

Table 6.19 Evidence Summary: validation studies used to evaluate the Schofield equation in obese participants

Table 6.20 Evidence Summary: validation studies used to evaluate the WHO/FAO/UNU equation in obese participants

Table 6.21 Accepted statements with their scores in percentage

LIST OF FIGURES

Figure 1.1: Recent changes in the prevalence of obesity (% of the population with BMI > 30) in Saudi Arabia

Figure 1.2: Framework for the PhD program of studies

Figure 2.1 ROC curves for perfect, good and worthless tests

Figure 2.2 Human Whole Room Calorimeter in UOW

Figure 2.3 BodyGem device and its mouthpiece and nose clip

Figure 4.1 ROC curve showing the performance of BMI in predicting diabetes and hypertension

Figure 5.1 Bland-Altman plot of differences in REE measures between two BG measurements with the same device in overweight and obese Saudi males (n=35).

Figure 5.2 Bland-Altman plot of differences in REE measures between one WRC measure and the mean of two BG measurements in overweight and obese Saudi males (n=38).

Figure 5.3 Bland-Altman plot of differences in REE measures between WRC measure and 3 predictive equations (HB, WHO, Schofield) in overweight and obese Saudi males (n=38).

Figure 6.1 Steps in Guideline Development

Figure 6.2 Delphi technique procedures

ABSTRACT

Obesity is one of the most common disorders encountered in clinical practice and has major public health implications. It is also one of the most difficult and frustrating disorders to manage successfully. The prevalence of overweight and obesity in Saudi Arabia is high and increasing over recent years. Management of obesity should be based on the best available scientific evidence. At present, there are no national clinical practice guidelines of use by dietitians and other health practitioners for the management of obesity. Since dietetics is a relatively new profession in Saudi Arabia there is little published data available in this area.

This thesis aimed to describe the current dietetic practices of obesity in Saudi Arabia and to develop a draft set of national clinical practice guidelines for obesity management. The present thesis includes three main projects. Based on the outcomes of these projects, a draft of evidence-based practice guidelines for the nutritional management of obesity in Saudi Arabia was prepared.

The first project (Chapter 3) involved dietitians to investigate the context and better understand the range of current practices in obesity management in Saudi Arabia, demand for and level of service, and barriers to obesity management. Analysis of the study showed that Saudi Arabian dietetic practice for the management of obesity does incorporate most practice recommendations, but some specific elements are rarely used. The most common assessment approaches were assessment of BMI, exercise habits and weight history while the most common strategies for obesity management were dietary total fat reduction and increased incidental daily activity. The major barriers for establishment of a weight management clinic were inadequate resources and administration and referral issues. None of the participants used local obesity guidelines but 61% of participants relied on international guidelines.

The second project included two studies focused on the validity of the most important practical tools used for the classification of obesity (Chapter 4) and the assessment of energy requirements (Chapter 5) since research has been lacking in this area in the Saudi population. The first study examined the use of different BMI cut-off points for obesity classification. Results indicated that the diagnostic usefulness of BMI alone in

defining obesity is limited in the Saudi adult population, for both men and women. It seems likely that limiting management of obesity only to those individuals with a BMI ≥ 30 , as defined by the WHO, may mean that many Saudis at risk of serious co-morbidities could be missing necessary interventions. The second study assessed the accuracy of prediction equations and a popular hand-held calorimeter (BodyGem) for assessment of resting energy expenditure (REE). Based on the findings of this study it was concluded that the Harris-Benedict, Schofield and WHO equations tend to predict REE more accurately than the BodyGem device. However, their accuracy was not clinically acceptable on an individual level. Therefore, the value of the use of both BodyGem devices and predictive equations is still uncertain for Saudi population and more research is needed in this area.

The third project (Chapter 6) focused on the development of draft clinical practice guidelines, based on a review of existing international guidelines, supplemented with systematic literature reviews, and refined through the use of consultation workshops and Delphi technique consultations with Saudi experts and practitioners. Findings from the systematic mini reviews provided low to medium level evidence for the use of some novel dietary interventions such as the high intake of calcium, PUFA or fiber to assist with weight loss or maintenance. There was also similar evidence for the use of a low glycemic index diet. Higher eating frequency, not exceeding 6 meals per day, may also help in weight reduction. Regular breakfast intake also appears to be associated with lower body weight. Consultations workshops and Delphi consultations indicated that there are cultural differences between Saudi Arabian population and other Western populations. Therefore, specific consensus statements were developed to cover practice areas such as behavioral modifications, dietary counselling strategies, physical activity and obesity management in Ramadan.

In summary, this thesis has provided clinical practice guidelines for obesity management in Saudi Arabia. The application of these guidelines will improve nutritional management of obesity and enable dietitians and other health professionals to use approaches based on the best available evidence.

CHAPTER 1

INTRODUCTION

Some parts of this thesis have been published or submitted for publication in peer-reviewed journals. Therefore, they are included in the thesis in the format of a published paper.

CONTENTS:

PART A: GENERAL INTRODUCTION

- 1.1 Scope of thesis
- 1.2 Prevalence of obesity in Saudi Arabia
- 1.3 Current dietetic practices with obesity in Saudi Arabia
- 1.4 Evidence based medicine (EBM) organizations in Saudi Arabia and the region
- 1.5 Thesis aims

PART B: PLANNING FOR THE DEVELOPMENT OF EVIDENCE BASED GUIDELINES FOR THE NUTRITIONAL MANAGEMENT OF OBESITY IN SAUDI ARABIA

- 1.6 Abstract
- 1.7 Introduction
- 1.8 Methods
- 1.9 Results
- 1.10 Discussion

PART C: PLAN OF THESIS

- 1.11 Thesis hypotheses
- 1.12 Studies undertaken

PART A: GENERAL INTRODUCTION

1.1 SCOPE OF THESIS

This thesis was undertaken in the broad research area of nutritional management of obesity in Saudi Arabia. More specifically, the research was focused on the development of evidence based clinical practice guidelines for nutritional management of obesity in Saudi Arabia. In addition to the description of the current dietetic practices of the treatment of obesity in Saudi Arabia, this thesis validated the use of body mass index (BMI) for obesity classification and the use of some practical tools for the assessment of resting energy expenditure (REE) for overweight and obese Saudi people. Despite the importance of these validations processes for obesity management, research has been lacking in this area in the Saudi population.

1.2 PREVALENCE OF OBESITY IN SAUDI ARABIA

Obesity has become a global epidemic and the prevalence of both overweight and obesity is still increasing in Saudi Arabia. Data from a cross-sectional study (1985-1988) on 19,598 individuals showed that the prevalence of obesity was 14.2% in men and 23.6% in women (1). Another study conducted from 1989 to 1994 on adults aged more than 18 years old, showed an overall obesity prevalence of 20.5% (2). A community-based national epidemiological household survey (3), conducted between 1990-1993, showed that the overall prevalence of obesity and overweight was 50.9% and 56.9% for males and females, respectively. For obesity, the overall prevalence was 22.1%; males 17.8% and females 26.6%. The findings of these surveys demonstrate the significant recent increases in the prevalence of obesity ($BMI \geq 30$) in Saudi Arabia (Figure 1.1). A 5 year National Epidemiology Health survey was conducted between 1995-2000 to study cardiovascular disease and its risk factors (4). This survey involved 17,232 male and female Saudi subjects aged 30-70 years. Results showed that the overall obesity prevalence was 35.6% of the survey population. The prevalence of overweight was 36.9%, which make 72.5% of Saudi population either overweight or obese. Furthermore, females were more obese than males, with prevalence rates of 44% and 26.4%, respectively. The significance of obesity in females has been confirmed in several studies (1, 3-6).

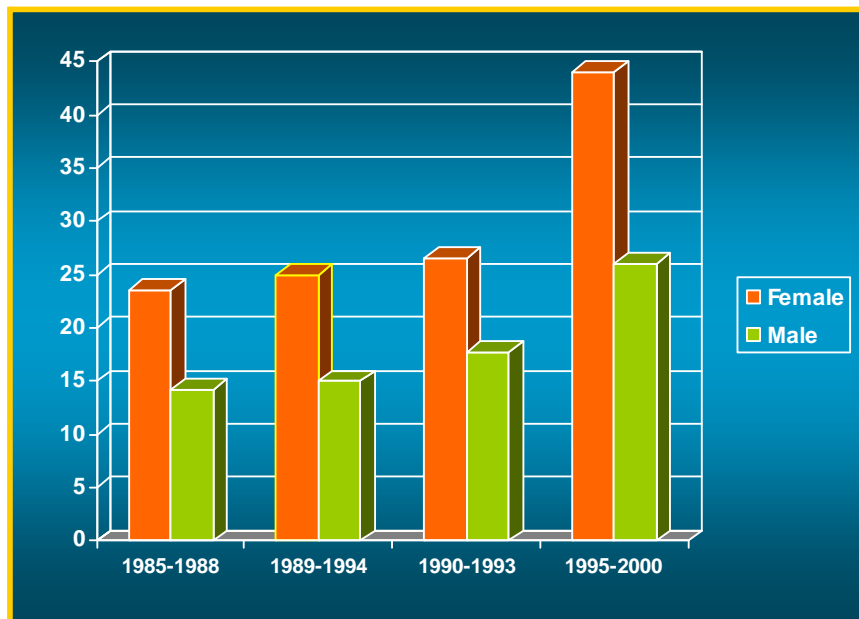


Figure 1.1: Recent changes in the prevalence of obesity (% of the population with BMI ≥ 30) in Saudi Arabia (1-4)

1.3 CURRENT DIETETIC PRACTICES WITH OBESITY IN SAUDI ARABIA

Dietetics is a relatively new profession in Saudi Arabia and little published data is available about the practice of dietetics. There are only two universities that train clinical dietitians at present. It is estimated that there are around 500 dietetic practitioners in Saudi Arabia, but at present there is no national professional organization providing educational services or developing policy and standards for practice. However, the Saudi Dietetic Association has been recently established and the role and the actual activities of this association will be known soon. There are also no clinical practice guidelines developed for use by doctors, dietitians or other health professionals in Saudi Arabia, in relation to the management of overweight and obesity, therefore it is likely that individual clinicians usually do not follow standard strategies for the assessment and treatment of obese patients.

However, a brief description of typical practice, based on personal experience and communications with professional colleagues is described below.

Physicians usually refer obese patients to dietitians based on a personal decision, since there are no specific criteria for referral. Hospital dietitians can refer their patients after

the discharge from hospital to dietetic consultation at the nutrition outpatient clinic. There are also a number of private clinics where dietitians operate.

For obesity assessment, dietitians usually use weight and BMI to monitor progress. Other measures such as waist circumference and waist-to-hip ratio are rarely used. Also they use a variety of different prediction equations to assess the energy requirements of patients since there are no equations developed to be used for Middle Eastern or Saudi population.

For obesity treatment, there are wide ranges of approaches that are currently described by dietitians. The preferred approaches differ from dietitian to dietitian since there are no formal protocols or guidelines.

1.4 Evidence Based Medicine (EBM) organizations in Saudi Arabia and the region

The organizations that develop practice guidelines can be professional societies, governmental agencies, national non-governmental agencies, or academic institutions (7). In 2004, the National and Gulf Centre for Evidence Based Medicine (NGCEBM) was recognized as the referral centre for EBM in Saudi Arabia and the Arabian Gulf region. NGCEBM is an affiliated center to Evidence Based Clinical Practice Group in McMaster University- Canada. This centre is also a collaborating centre with the Joanna Briggs Institute (JBI) for Evidence Based Healthcare, in the University of Adelaide, Australia. NGCEBM aims to promote the concept and practice of evidence-based medicine in Saudi Arabia and in the Gulf Cooperation Council countries. Recently, guidance for clinical practice guideline development, adaptation and endorsement has been developed by the NGCEBM (8).

In Saudi Arabia, guidelines could be developed in collaboration with several organizations. The main organizations interested in dietetic standards are the recently formed Saudi Dietetic Association, the Ministry of Health (MOH) and the Commission of the Saudi health specialists, in addition to the NGCEBM and World Health Organization (WHO). Preliminary consultation with staff from the last two groups has indicated a willingness to be involved in the endorsement of the present project.

1.5 Thesis aims

The central question of this research program is to examine whether clinical guidelines developed for use by dietitians in Australia and other countries can be effectively adapted for use by dietitians in Saudi Arabia, taking into account some of the issues of cultural influences on clinical practice. The studies in this thesis have examined this question in the context of dietetic practice in relation to obesity management, focusing on two key aspects of practice: (1) the tools used to classify obesity and assess REE of overweight and obese Saudi individuals, and (2) the development of acceptable national clinical practice guidelines for Saudi dietitians.

The following section, written in the format of a published article, presents the outcomes of the first of a series of workshops that were held as part of this project. The primary functions of this workshop were to introduce the project to key stakeholders, present information on best practice in the process of development of clinical guidelines, and to collect the ideas and suggestions of a group of potential users as to their content and format.

PART B: PLANNING FOR THE DEVELOPMENT OF EVIDENCE BASED GUIDELINES FOR THE NUTRITIONAL MANAGEMENT OF OBESITY IN SAUDI ARABIA

This section has been published in the following peer-reviewed paper:

Almajwal A, Williams P, Batterham M, Alothman A. Planning for the development of evidence based guidelines for the nutritional management of obesity in Saudi Arabia. New Egypt J Med. 2008; 38(1):34-39

AA was responsible for the design of the workshop and preparation of the manuscript. AA, PW, A Alothman facilitated the workshop. PW edited the manuscript. All authors were involved in critical discussions of workshop design and outcomes

1.6 ABSTRACT

Objective: To seek agreement from key stakeholders on the main issues, considerations and key questions that need to be addressed when developing evidence based guidelines for nutritional management of obesity in Saudi Arabia.

Methods: Forty six health professionals (including, dietitians, physicians, academics and government representatives) participated in an invited workshop held in Riyadh in June 2007. Participants were divided into groups to discuss five topics: priority areas to include in a critical literature review, best formats for presentation of guidelines, particular local issues to consider, information to be included in appendices, and methods to encourage the adoption and use of the guidelines. A questionnaire was also distributed to participants and they were asked to rank their level of agreement about issues related to the process of guideline development.

Results: Participants agreed that Saudi clinical practice guidelines are necessary for dietitians and other health professionals to guide effective nutritional management of obesity. They also agreed about the most important key questions that need to be addressed in the guidelines. In contrast, there was no general agreement about the best formats of the guidelines and this may be due to the limited use of the guidelines for daily practices. Participants also discussed other topics and their views are summarized

Conclusion: The development of specific clinical practice guidelines for nutritional management of obesity in Saudi Arabia is warranted and will be valued by Saudi dietitians and other health professionals.

1.7 INTRODUCTION

Obesity has become a global epidemic and the prevalence of both overweight and obesity is still increasing in Saudi Arabia (3-6). The latest National Epidemiology Health survey conducted in Saudi Arabia showed that the overall prevalence of overweight and obesity was 72.5 % (4). Therefore, appropriate treatment and strategies should be developed and implemented to manage this problem.

Clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (9). Development of good guidelines should facilitate more consistent, effective and efficient medical care. While such guidelines have been developed for the management of obesity in a number of Western countries, including the USA, Canada, Scotland and Australia (10-15), there are no clinical practice guidelines developed for use by physicians, dietitians or other health professionals in Saudi Arabia, in relation to the management of overweight and obesity. Therefore individual clinicians usually do not follow standard strategies for the nutritional assessment and treatment of obese patients.

Limited literature is available about the use of the evidence based guidelines in Saudi Arabia (SA). Al-Ansary *et al.* (16) conducted a questionnaire study to explore the attitude of primary health care physicians (PHCPs) in Riyadh towards evidence based medicine (EBM). Authors found that PHCPs mainly welcomed EBM but they had a low level of awareness of well-known resources of EBM. However, adaptation and use of Saudi guidelines have been highly recommended (17).

To address this deficit, we have commenced a project to develop such guidelines, focusing on the nutritional management strategies that would be used by dietitians and medical nutrition specialists. The scope of this project will be limited to nutritional aspects of the clinical management of overweight and obese patients and will not include other aspects of management such as pharmacotherapy and surgery. This article presents the outcomes of the first of a series of workshops to be held as part of this project.

The primary functions of this workshop were to introduce the project to key stakeholders, present information on best practice in the process of development of clinical guidelines, and to collect the ideas and suggestions of a group of potential users as to their content and format.

1.8 METHODS

This workshop was conducted in June 2007 at the King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia, led by authors AMA, PGW and AMA. Key stakeholders were invited to attend through letters of invitation. Participants included the potential users of the guidelines and were selected by purposive sampling, based on advice from key local informants. Forty-six health professionals including 5 academic staff, 3 physicians or medical nutritionists, 33 clinical dietitians, and 5 government health representatives attended the workshop. After presentations on the need for the local development of practice guidelines in general (By Dr. Abdullah AL Khenizan, Consultant of family medicine and member of the National EBM Committee) and an overview of the project plan, participants were divided into 5 groups. Each group discussed three out of the following five topics and presented their views to the whole workshop for further comment. Comments were summarized by each group facilitator and recorded by the workshop leaders

The discussions were directed to the following topics:

Topic 1: The key questions that should be included in the critical literature review to guide the development of the guidelines.

Topic 2: The best format for the guideline presentation. Examples of different formats used in American, Australian, Canadian and Scottish obesity guidelines were provided for participants.

Topic 3: The particular differences from Western countries that need to be considered, including meal patterns, dietary choices and referral process.

Topic 4: A suggested list of the most important appendices that could be added to the guidelines was discussed.

Topic 5: The best ways to encourage the adoption and use of the guidelines.

A questionnaire was distributed to participants at the end of the discussion and they were asked to rank their level of agreement about specific issues in the process of

guideline development. A five point Likert scale (1=strongly agree to 5=strongly disagree) was used to assess the level of agreement by calculating the mean scores for each statement.

1.9 RESULTS

The summary results from the workshop discussions were as follows:

1.9.1 Discussion topic ONE:

The guiding questions that all group agreed should be considered in the guidelines were:

- What are the recommended methods to assess and classify overweight and obesity?
- Which anthropometric measurements should be used?
- Which energy expenditure equations and weight should be used to calculate daily energy requirement?
- What are the appropriate goals for weight loss?
- What are the appropriate levels of energy restriction?
- What are the recommended strategies and approaches for weight loss?
- How best to achieve weight loss (diet therapy, physical activity and behavior therapy)?
- When should other methods of weight reduction such as drugs and surgery be recommended and how effective are these methods?
- What are the recommended methods to maintain weight loss?

Each group listed several specific questions within the above broad questions. The most common questions are:

- What is the best method to assess the degree of obesity and to monitor the progress of weight loss? (Body mass index, waist circumference, waist/hip ratio, skin fold thickness, bioelectrical impedance etc.)
- In calculating energy requirements, which should be used: actual, ideal or adjusted body weight?
- How to use the adjusted factors when you calculate resting energy expenditure (REE) (activity factors, stress factors, etc.)
- Are the current available prediction equations accurate in estimation of REE for Saudi people?

- Is the current common target for energy restricted diets (500 to 1000 cal deficit day) appropriate?
- Is the current practice of prescribing energy restricted diets (1000-1200 Cal/day for women; 1200-1500 Cal/day for men) appropriate?
- Is the current practice of targeting a weight loss (0.5- 1.0 kg/week) appropriate?
- What duration and intensity of physical activity are required to support weight loss?
- What lifestyle modifications can be shown to support weight loss?
- How to combine the three strategies of weight reduction? (energy restriction, physical activity and behavior & lifestyle modifications)
- What is the optimal meal pattern in terms of number and timing to support weight loss? Does missing breakfast matter?
- Is group education an effective intervention strategy and for whom? What is the evidence comparing effectiveness of group versus individual counselling?
- Is home delivered complete meal solution an effective strategy to assist weight loss? If so, for how long?
- What counselling strategies maximize compliance? When is it effective to threaten longer term healthy consequences of non-compliance?
- Is there any scientific support for use of common herbal remedies/drinks?
- How should dietitians attempt to manage adaptations of the body to weight loss (eg reduced REE)?
- What diet patterns/strategies will maximize satiety and make weight loss easier?
- Who should be involved in a multidisciplinary approach to managing overweight and obese patients? (eg dietitian, psychologist, social worker, physician, physiotherapist...)

1.9.2 Discussion Topic TWO:

Each group suggested a specific preferred format according to the examples that were distributed.

Four possible formats were identified:

- Literature review + Graded evidence statements + Conclusion + Graded practitioner recommendations
- Literature review + Graded recommendations

- Graded evidence statements + Dietetic practice recommendations
- Literature review + Graded evidence statement + graded recommendations

1.9.3 Discussion Topic THREE:

Differences from Western countries were discussed and summarized as follows:

- Difficulty promoting physical activity in Saudi Arabia because of issues related to weather, modesty for women
- Compliance decreases when diet restrictions conflict with social expectations.
- Very high fat diets usually provided in Saudi social occasions.
- Ramadan is often a time of weight gain (despite the day time fasting) because of consumption of high fat/high sugar sweet foods.
- Lack of patient referrals to dietitians.
- There is a lack of understanding of the barriers to compliance currently.

1.9.4 Discussion Topic Four:

Participants suggested a few appendices that can be added to the clinical practice guideline. These appendices include:

- Sample reduced caloric Saudi meals
- Food Exchange List including Saudi food
- Educational materials for obese subjects
- Tables showing exercise required to burn off energy from different food portions.
- Body Mass Index Table

1.9.5 Discussion topic FIVE:

Participants recommended the following ways to encourage the use of the guidelines including distribution, endorsement and training:

- Make the guideline as widely available as possible
- Use scientific journals and Media to distribute it to hospitals, health organizations and universities.
- Produce the guidelines for use in a range of formats, including on the internet and on computer disks

- Endorsement by medical and dietetics profession
- Training in use of guidelines is critical to successful implementation, including continuing evaluation of adoption and outcomes.

Table 1.1 shows the mean level of agreement with specific statements ranked by participants. The mean level of agreement (1.04 ± 0.28) was very strong when the participants were asked about the important of developing the clinical practice guidelines for nutritional management of obesity in Saudi Arabia. Participants also agreed about the importance of including an overall summary translated to Arabic (1.42 ± 0.78) and also indicated the importance of including full written literature review, practice recommendations, flow charges, and education tools (1.25 – 1.63).

Table 1.1: Mean level of agreement with specific statements ranked by participants (n=46)

Strongly agree =1, agree = 2, neither agree nor disagree = 3, disagree = 4, or strongly disagree = 5

Statements	Level of agreement (1-5) (Mean \pm SD)
There is a need for the establishment of clinical practice guidelines for nutritional management of obesity and overweight in Saudi Arabia	1.04 \pm 0.28
Ask respected dietetics and nutrition leaders to promote the guidelines	1.38 \pm 0.71
Guideline should include an overall summary	1.42 \pm 0.78
Use professional journals and magazines to inform people about guideline development and promote the completed guideline	1.54 \pm 0.88
Guideline summary should be translated to Arabic	1.63 \pm 0.97
Produce short summaries for use in a range of formats, including on the internet and on computer disks.	1.63 \pm 0.88
The full guideline should be translated to Arabic	1.71 \pm 1.08
The guideline should be endorsed by local clinical groups	1.71 \pm 0.91
<i>How important is it to include each of the following:</i>	
Practice recommendations	1.25 \pm 0.44
Assessment tools (eg. Equations, anthropometry, psychological questionnaire)	1.33 \pm 0.70
Education tools	1.50 \pm 0.72
Compliance and outcome measurement tools (wt loss, satisfaction, diet quality)	1.58 \pm 0.72
Full written literature review	1.58 \pm 0.93
Flow charts	1.63 \pm 0.65

1.10 DISCUSSION:

The way in which guidelines are established will undoubtedly affect their success. It is proposed that the methodology that has been described by the National Health and Medical Research Council in Australia (18) will be followed for the development of the Saudi guidelines in this project. A series of two further workshops will be conducted during guidelines development to review and refine the guidelines before they are finalized.

At this first workshop several questions were identified that need to be addressed when setting up the guidelines. They mainly focused on the estimation of REE. It was obvious that practitioners want to know how to assess REE accurately and the accuracy of the present predictive equations was questioned. To our knowledge there are no equations developed specifically for use with Middle Eastern people and the most commonly used current equations were derived from samples of normal weight subjects. Only two equations - those developed by Ireton-Jones *et al* (19) and Bernstein *et al.* (20) - were derived from samples of obese subjects. This issue will be investigated further in the next stages of this project.

Participants discussed the best formats of guidelines but there was no general agreement about this. This may be due to the limited use of the evidence based guidelines in daily practice. However, most of the groups agreed it would be important to include a literature review and graded evidence-based recommendations. Others preferred to include both graded evidence statements and graded recommendations.

The other ideas about topics for inclusion and the methods of dissemination of the guidelines will be considered in the next stages of this project. At the proposed second workshop, results of a literature review will be presented, which will summarise research in this area since the development of the US practice guidelines in 1997. The Grade of Recommendations, Assessment, Development and Evaluation (GRADE) system (21) will be used to evaluate the quality of evidence that is available to support nutrition practice recommendations and develop graded evidence-based recommendations. Drafts of the Saudi practice guidelines will be discussed at this

workshop, planned for early 2008, and it is anticipated that the final version will be presented at a final workshop in mid 2008.

PART C: PLAN OF THESIS

1.11 THESIS HYPOTHESES

The hypotheses to be tested are:

H1: Current dietetic practices in Saudi Arabia are substantially different to practice in Australia and are influenced by several factors including culture, available technology and professional history and development.

H2: Tools developed for classifying obesity and measuring REE in Western subjects can be applied accurately to Saudi subjects and are significant in the dietetic management of obesity.

H3: Evidence-based clinical practice guidelines for dietetic management from other countries can be adapted for use in Saudi Arabia and will be accepted and valued by Saudi dietitians.

1.12 STUDIES UNDERTAKEN

The present thesis included three main research projects. Based on the outcomes of these projects, a draft of evidence-based practice guidelines for the nutritional management of obesity in Saudi Arabia was prepared. The framework of this thesis is presented in Figure 1.2

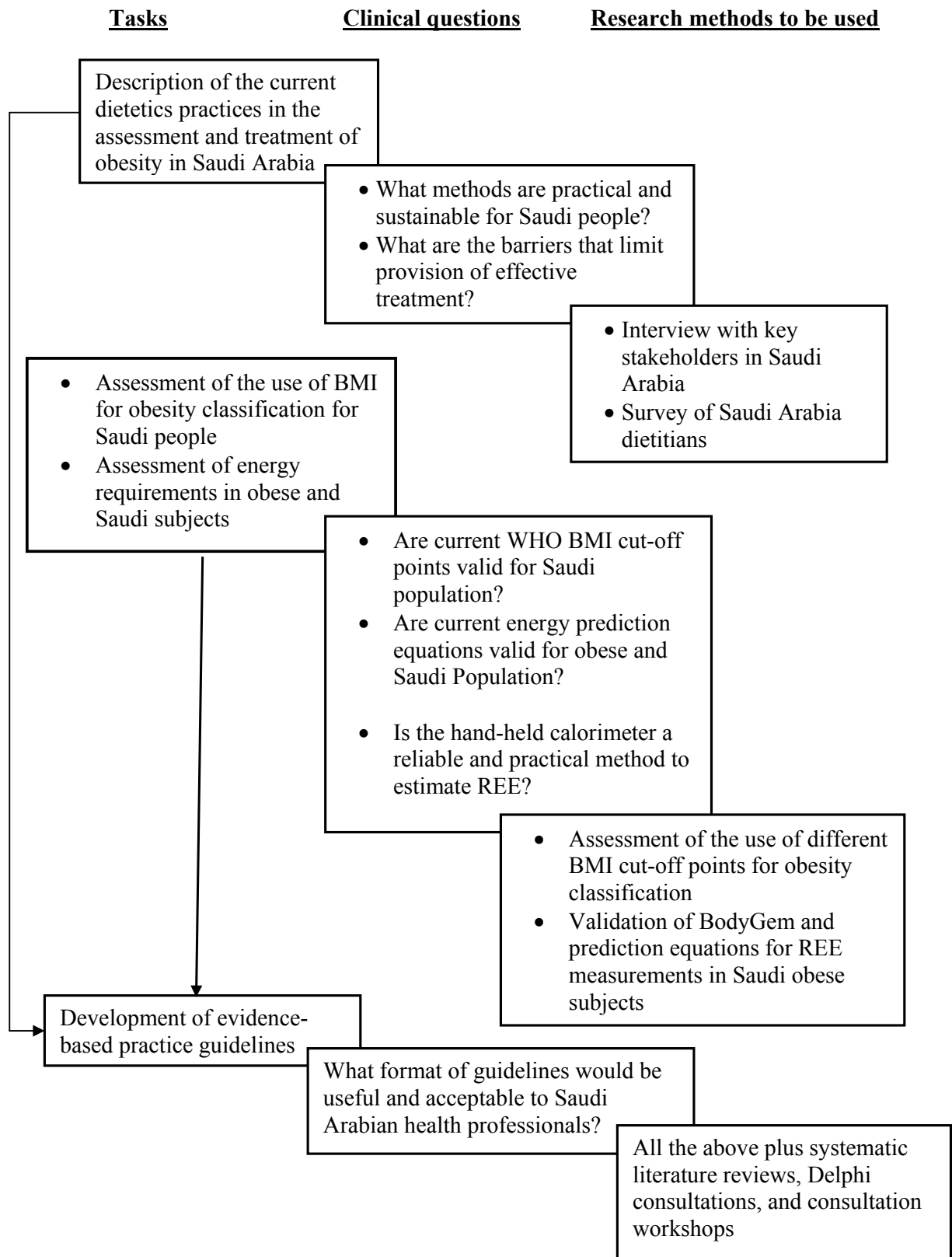
The first project focused on the description of the dietetic practices in the assessment and treatment of obesity in Saudi Arabia. This project covered several aspects including information about the practical and sustainable methods for the treatment of obesity for Saudi people and barriers that limit provision of effective treatment. The study was conducted through a survey of Saudi Arabia dietitians and the results compared with a similar survey conducted previously in Australia.

The second project focused on the validity of the most important practical tools used for the classification of obesity and the assessment of energy requirements for overweight and obese Saudi subjects. This project consisted of two studies:

- 1) an examination of the use of different BMI cut-off points for obesity classification in the Saudi population (through secondary analysis of data collected in a recent large national epidemiological survey of diabetes risk factors), and
- 2) studies of the accuracy and validity of the use of prediction equations and a popular hand-held calorimeter (BodyGem) for assessment of energy requirements.

The third project focused on the development of evidence-based statements for the assessment and treatment of obesity by dietitians in Saudi Arabia. Findings from the previous two projects were incorporated in this stage. Draft guidelines were developed, based on review of existing international guidelines, supplemented with systematic literature reviews, and refined through the use of Delphi technique consultations with Saudi experts and practitioners. This process also included two main consultation workshops conducted in Saudi Arabia. At the first workshop, the findings of the survey and the guidelines development process were discussed. The second workshop focused on the development of consensus statements when the scientific evidence is lacking or insufficient.

Figure 1.2: Framework for the PhD program of studies



CHAPTER 2

METHODOLOGY

CONTENTS:

- 2.1 Introduction
- 2.2 BMI and obesity classification
- 2.3 Methods for assessment of energy expenditure
- 2.4 Evidence based clinical practice guidelines

2.1 INTRODUCTION

This chapter includes general reviews of the types of methods used in this thesis and outlines the reasoning behind the study design and the analytical methods applied. More details about the specific design of each study are described in subsequent chapters. The main methods used in this thesis include the use of BMI for obesity classification, Calorimetry methodology for REE measurement, and methods used for the development of evidence based clinical practice guidelines.

2.2 BMI AND OBESITY CLASSIFICATION

2.2.1 Classification of obesity using different BMI cut-off points

Obesity and overweight are both defined as "excessive" accumulation of fat in the body where the former is a more severe state (22). Total body fat can be measured or calculated using several methods including dual-energy X-ray absorptiometry (DEXA), total body water and total body potassium. These techniques are expensive and cannot be used in normal clinical practice. Therefore, practitioners use simple methods to assess obesity and overweight such as Body Mass Index [$BMI = (\text{weight in kilograms}) \div (\text{height in meters})^2$], skin-fold thickness, waist circumference (WC) and waist-to-hip ratio. BMI is the most common tool for obesity classification in Saudi Arabia (23). The cut-off points for BMI classification were derived primarily in European populations and there is ongoing debate as to whether these cut points are appropriate for non-European populations (24).

In 1997, the World Health Organization (WHO) proposed cut-off points for classifying overweight and obesity (10, 25). Overweight is classified as $BMI \geq 25.0$ and obesity is

classified as BMI ≥ 30.0 . These cutoffs have been identified on the basis of the association between BMI and chronic diseases and mortality (25, 26). However, more recently ethnic differences have been considered and a few studies have been conducted to address this issue.

In Asia, it has been demonstrated that Asians have a higher percentage of body fat than Caucasians at the same BMI cut-off levels and the health risks associated with obesity occur at lower BMI cut-off level than Caucasians (27-34). There have been a few attempts to interpret the WHO BMI cut-offs in Asians and Pacific populations (24, 34-39). In 2000, the Regional Office for the Western Pacific Region of WHO with the International Association for the Study of Obesity (IASO) and the International Obesity Task Force (IOTF) defined overweight in Asians as BMI $> 23.0 \text{ kg/m}^2$ and obesity as BMI $> 25.0 \text{ kg/m}^2$ (24). In 2004, WHO did not propose a clear BMI cut-off for all Asians but they indicated that the cut-off points for observed risk varies from 22.0 kg/m^2 to 25.0 kg/m^2 in different Asian populations and these values varies from 26.0 kg/m^2 to 31.0 kg/m^2 for those at high risk. Due to the common use of BMI and the uncertainty about its appropriateness for Saudi population, the validity of BMI as a tool for obesity classification has been examined in this thesis.

2.2.2 Methods used to determine BMI cut-off points

2.2.2.1 Obesity-related health risks

It is well established that obesity is associated with increased morbidity and mortality and a well known risk factor for several health problems such as diabetes, hypertension and high cholesterol levels and cardiovascular diseases. The literature shows that most researchers have examined the association between BMI and different risk factors and diseases to determine the optimal BMI cut-off points (36, 39-44). However, some others have examined the association between percentage of body fat (% BF) and BMI to classify obesity (34, 45-49). Obesity is defined as BF $> 25\%$ in men, $> 35\%$ in women according to WHO criteria (50)

The number of obesity risk factors used in previous studies to classify obesity varies. Nguyen *et al.* (40, 41) relied on the association between hypertension in Asians to

determine the best anthropometric index for obesity classification. Similarly, Snehalatha C et al. (36) used the association between diabetes and stratified BMI. Al-Lawati J and Jousilahti P (43) defined the prevalence of cardiovascular disease (CVD) risk as the presence of at least two of the following three risk factors: hyperglycaemia, hypertension and dyslipidaemia, and examined the relationship of BMI to this. In a study of Hong Kong Chinese (51), the CVD risk was estimated using four risk factors including diabetes, hypertension, dyslipidaemia and albuminuria.

2.2.2.2 Analytical methods:

The data analysis is usually performed for men and women separately. The most common method used for assessing the association between risk factors and BMI is the receiver operator characteristic (ROC) curve analysis (52). The researchers select several cutoff points and determine the sensitivity and specificity at each point on the curve. They then graph the sensitivity (the true positive rate) on the Y-axis as a function of 1-specificity (the false positive rate) on the X-axis (Figure 2.1). An ideal test is one that reaches the upper left corner of the graph (100% true positives and no false positives). A worthless test follows the diagonal from the lower left to the upper right corners. The area under the curve (AUC) is ranged from 0.5 for a useless test to 1.0 for a perfect test.

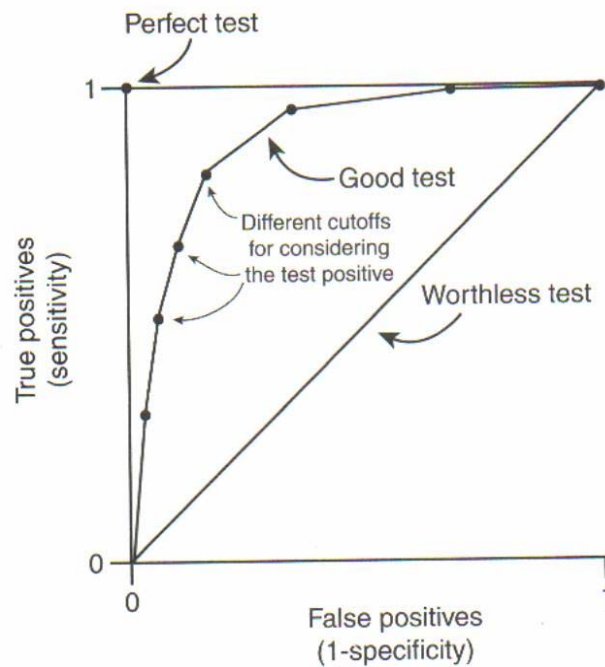


Figure 2.1 ROC curves for perfect, good and worthless tests

Researchers usually calculate sensitivity, specificity and AUC to examine the ability of different BMI cut-off points to detect the risk factors. Other diagnostic characteristics could be used such as positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (LR+), negative likelihood ratio (LR-), false positive rate (FP rate), false negative rate (FN rate) and misclassification rate. A brief description of each term is described below.

- Sensitivity is proportion of actual positives which are correctly identified as such (e.g. the percentage of sick people who are identified as having the condition)
- Specificity is the proportion of negatives which are correctly identified (e.g. the percentage of well people who are identified as not having the condition).
- PPV is the proportion of patients with positive test results who are correctly diagnosed.
- NPV value is the proportion of patients with negative test results who are correctly diagnosed.
- LR+ indicates how much the odds of the disease increase when a test is positive.
- LR- indicates how much the odds of the disease decrease when a test is negative.

- FP rate is the proportion of negative instances that are erroneously reported as being positive
- FN rate is the proportion of positive instances that are erroneously reported as negative
- Misclassification rate is the proportion of instances that are incorrectly diagnosed

The other method is the use of regression analysis to assess the risk (estimated by the odds ratio) of obesity related risk factors at different BMI categories. In this method BMI is commonly stratified in units (kg/m^2) with the use of $\text{BMI} < 20 \text{ kg/m}^2$ as the reference. Authors usually determine the optimal BMI cut-off points based on the best values of sensitivity and specificity and then show the odd ratios at these points using the regression analysis (24, 36)

In this thesis both methods have been used with interpretations of the results from each method. Moreover, the study attempted to identify obesity cut-offs based on the observed significant association between BMI and other risk factors of the metabolic syndrome.

2.3 METHODS FOR ASSESSMENT OF ENERGY EXPENDITURE

It is very important to accurately assess energy requirements for obese subjects as well as for other people, to avoid the problems associated with under or over-nutrition when developing dietary management plans. Clinicians need accurate tools to assess individual energy requirements which have a major role in planning obesity management. In this section the most common techniques used for energy expenditure assessment will be described.

2.3.1 Direct calorimetry

A direct calorimeter measures total heat loss from the body to the environment. Energy expenditure can be measured using this method by placing subjects in a tightly insulated environment, and the heat that is dissipated is detected by change in thermal gradients in the immediate environment (53). This method is considered the “gold standard” for the measurement of energy expenditure in the past. This technique measures heat loss and

not production, and because heat storage occurs in the body, the total heat loss will not be equivalent to heat production for periods less than 24 hours. Therefore, the method is considered inappropriate for short-term measurements (54).

2.3.2 Indirect calorimetry

The most widely used techniques are those that employ indirect calorimetry. The technique detects heat production through the measurement of oxygen consumption (VO_2) and carbon dioxide production (VCO_2) (53). Energy expenditure can be calculated by converting the amount of VO_2 and CO_2 to calories by application of developed equations such as Weir equation (55). Indirect calorimetry is considered today as the “gold standard” for measuring energy expenditure in clinical nutrition practice.

2.3.2.1 Indirect calorimetry: whole room calorimetry (WRC)

The WRC technology is an indirect calorimetry technique measures heat production from the rates of respiratory gas exchange associated with the oxidation of the major nutrients (carbohydrate, fat and protein). In the WRC the subject usually kept in a sealed chamber with a constant and measured supply of fresh air. The effect of subject's respiratory gas exchanges on the composition of the air inside the WRC enable technicians to measure O_2 produced and CO_2 consumed by subject. Samples of room air are analyzed continuously and comparison of the differences in O_2 and CO_2 concentrations in the in-going and out-going air enables the subject's respiratory exchange to be calculated and hence energy expenditure.

The UOW facility (Figure 2.2), which has been described in detail elsewhere (56), consists of two separate air-tight, ventilated and air-conditioned chambers (3 x 2.1 x 2.4 m), each with a bed, desk, chair, hand basin TV/VCR, computer, phone and toilet. Temperature is maintained at 20-24 °C and ventilated with fresh air measured by a solid-state gas sample drying system. O_2 concentration is measured using a paramagnetic oxygen analyzer and CO_2 is measured using an infrared analyzer. O_2 and CO_2 measurements are corrected to standard temperature, pressure, and dry from fresh air temperature, water, vapor pressure and barometric pressure measurements.

For REE measurements, the subject is usually asked to stay in the chamber for approximately two hours and measurement starts in the second hour while the subject is lying quietly on a bed. The first hour is sufficient to reach steady-state levels in the subject and gather accurate measurements in the WRC. The WRC gives the measurement for O₂ consumption and CO₂ production at 10 minute intervals. The measurements are considered only when the subject had reached a steady-state condition when respiratory quotient (RQ), O₂ consumption and CO₂ production are stable for at least 3 consecutive readings (coefficient variation (CV) < 10%). Otherwise, the test results are discarded.

The WRC technique is accurate, precise and provides direct energy measurement and a good environment for strictly controlled studies. However, the technique is very expensive and need complex mechanical engineering. Also the room environment represents artificial conditions for the subjects.



Figure 2.2 Human Whole Room Calorimeter in UOW

2.3.2.2 Indirect calorimetry: Ventilated hood systems

In these systems the air comes around subject's head while the subject sits or lies quietly. The system usually consists of pliable plastic or rigid Perspex hoods with latex or thin plastic aprons providing a rough seal around the neck or chest. The ventilation components are a pump, a flowmeter and a means of regulating the air flow. Samples of air, usually drawn from the hood, are taken directly to gas analyzers. One example of these ventilated hood system is DeltaTrac II metabolic monitor (SensorMedics Yorba Linds, CA). In this system, the subject head usually covered with a plastic tent or canopy and ventilated with a constant flow of about 40 L/min for adults. The system consists of a 4-L mixing chamber, a paramagnetic oxygen analyzer, infrared CO₂ analyzer, microprocessor and CRT display. The expired gases travel from the canopy to the mixing chamber where the gases are measured. The gases are then diluted with room air by the flow generator making the total flow through the system equal to the flow generator's output.

This system provides accurate and reliable data and can be operated easily compared to the WRC. However, this system is expensive and cannot be used in most daily clinical practice since it needs periodic checks by alcohol/butane burns.

2.3.2.3 Indirect calorimetry: hand-held calorimetry

Recently, researchers developed relatively new hand-held calorimetry devices that can be used even in the clinical and educational settings due their portability, low cost, small size and ease of use (57, 58). A hand-held calorimeter is a portable indirect calorimeter that can be held in the palm of the hand. This device can easily and quickly measures a person's REE and perform auto-calibration prior each measurement.

Subjects usually wear a nose clip and breathe into a disposable plastic mouth-piece for approximately 10 minutes. Normally, these devices are programmed to begin collecting data when the first breath is detected and continue until either a steady state or 10 minutes is reached. VCO₂ is not measured by these devices and a RQ of 0.85 is assumed (59). Figure 2.3 shows one commonly used device – the BodyGem (HealtheTech Inc., Golden, CO, USA)



Figure 2.3 BodyGem device and its mouthpiece and nose clip

2.3.2.4 Prediction equations

It is impractical to use methods such as the WRC or ventilated hood systems to measure total energy expenditure for 24 hours. However, since the REE constitutes 65-75% of the total energy expenditure (60), accurately estimating REE from prediction equations using simple variables such as weight, height, sex and age can provide clinicians with important information to set dietary prescriptions. Equations that have been developed from direct and indirect calorimetry measures have been adopted as the major method of determining energy needs in individuals. Although development of prediction equations extends back almost a century, new reports about their validity for different populations appear on a regular basis (61-75).

Energy expenditure by overweight and obese individuals is variable, and the best method to predict it is still controversial. The inaccuracy of the prediction equations for estimation of REE in obese individuals is attributed to the presence of large amounts of adipose tissue which has a low metabolic rate (20, 76).

Despite the important role of prediction equations in the management of obesity, no equation has been developed or validated for the Saudi population or even the Middle Eastern population in general. Therefore, one of the aims of this thesis focused on the

validation of the common equations for predicting REE in overweight and obese Saudi subjects due to the lack of existing research in this area.

2.4 EVIDENCE BASED CLINICAL PRACTICE GUIDELINES

2.4.1 Evidence-based medicine

Evidence based medicine (EBM) is the integration of best research evidence with clinical expertise and patient values (77). The concept of EBM has its origins in the 18th century. However, the concept was formally named in 1992 by the Evidence Based Medicine Working Group (USA) (78). Several decades ago, the assessment and treatment of patients were based primarily on the practitioners' experience, and the decision of experts served as the main guide for less experienced clinicians.

Today we have thousands of websites, journals, and textbooks available to provide data for making decisions. Conclusions can be drawn from research-based processes provided by several sources such as the Cochrane collaboration, which is a worldwide network of centers launched in 1995 (79). The Cochrane collaboration has become the most reliable source of evidence in health care. The major product of the Collaboration is the Cochrane Database of Systematic Reviews which is published quarterly as part of the Cochrane Library. Sources that provide systematic reviews of the effects of health care support the development of evidence based guidelines.

Despite the important role of the evidence based guidelines in health care, little is known about the use of these guidelines in Saudi Arabia. Several studies have demonstrated that clinical decisions in Saudi Arabia are not sufficiently evidence based (16, 80, 81). The major obstacles to the implementation of guidelines include: poor dissemination of guidelines (16, 82) and a low level of awareness among clinicians of journals, review publications, and databases (16).

2.4.2 Evidence-based Nutrition and Dietetics

EBM can be applied to all health professions including dietetic practices. Evidence-based practice assists dietitians and other health practitioners to improve research utilization in practice. Evidence based practice is a key component of “clinical guidelines’ which health professions are encouraged to develop. It has become an

important competency in nutrition and dietetics in most of developed countries. The dietetic associations have a major role in the development of clinical practice guidelines in many countries. In Australia, the Australian Centre of Evidence Based Nutrition and Dietetics was established in 2003 as a Collaborating Centre of Joanna Briggs Institute (JBI) (83). This centre aims to promote dietetics as a clinical science and to support evidence based nutrition practices across the disciplines. In Saudi Arabia, the newly formed dietetic association will possibly have a role in supporting evidence based nutrition practice.

2.4.3 Development of clinical practice guidelines

Clinical practice guidelines are “systematically developed statements for specific clinical circumstances” (9). These guidelines have been developed throughout the world to improve both the quality of care and patient outcomes (84). Clinicians can use the clinical guidelines as a tool for making care more consistent and efficient and for closing the gap between their usual practices and the scientific evidence. Several studies have demonstrated that the frequency with which procedures are performed for effective care varies significantly among clinicians even after case mix is controlled for (85). The main steps on clinical practice guidelines development are described below.

2.4.3.1 Identifying a clinical area to promote best practice

The first step in guideline development is to choose a particular topic with clear objectives. Reasons for selecting a particular topic can include the prevalence of condition or its associated burden, identification of large variation in treatment among practitioners, the likelihood of the effectiveness of the guidelines in influencing practice, or to keep practice up to date or evidence based (8, 18, 84). Most guidelines programs target primary and secondary care, and cover the prevention, diagnosis, and management of a wide range of clinical topics (7). Guidelines may not be needed if there are existing guidelines covering the same topic. However, previous guidelines can be assessed and updated on a regular basis.

2.4.3.2 Reviewing the scientific evidence

With the growth of evidence-based medicine in the 1990s, there has been a shift from using professional consensus to scientific evidence as the basis for clinical practice

guidelines (7). Methods for identifying the evidence range from highly formal, quantitative information synthesis such as meta-analysis of randomized clinical trials to subjective information synthesis from less rigorous sources such as observational studies (8, 86). Clinical practices guidelines usually include three sources of evidence:

- evidence based on the outcomes of systematic reviews
- evidence based on clinical experience, or
- evidence adopted from well established guidelines.

2.4.3.2.1 Steps in developing scientific evidence based on systematic review:

Previous well established obesity clinical practice guidelines have used systematic reviews to develop the evidence based statements. These methods have been explained in detail in the American Dietetic Association (ADA) Analysis Manual (87). The major common steps in the ADA's analysis and other guidelines are as follow:

- Formulation of the evidence analysis question. The question should be specific and applicable in every clinical practice. A clear question or well-defined issue surrounding an obesity-related intervention is the starting point of the review
- Search the literature for each question. This should involve several steps:
 - Search plan needs to be developed with inclusion and exclusion criteria
 - Search words need to be identified
 - Databases to search should be identified. The common databases to search for clinical nutritional research are Medline, Pubmed, CINAHL, EMBASE, Cochrane library and Science direct
 - Initial search should be conducted using the search words
 - Titles and abstracts need to be reviewed first and reviewers should determine weather a research article meet the inclusion criteria and is relevant to the research question
 - Gather articles and reports meeting the inclusion criteria and determine the study design and level of quality for each study
- Write the evidence summary. This step is a challenge since not all studies are the same in terms of their answers to the research questions. Some articles designed especially to answer the question while other articles may have an indirect relation to the question.

2.4.3.3 Grading the scientific evidence

Since the 1970s a growing number of organizations have used several systems to grade the quality of evidence and the strength of recommendations (88). In 1992, the US Agency for Health care and Research and Quality developed a grading system based on the study design only (89). Until recently, this system was widely used for grading guidelines recommendations (89). However, over time guideline developers and users realized three main weaknesses in this system (90). Firstly, the grading system was mainly designed to assess effectiveness, where randomized controlled trials are accepted as the best design for this purpose. However, randomized controlled trials cannot be used for all areas of medical practice due to ethical or practical issues. Secondly, guidelines developers often fail to assess the overall strength of the evidence and its applicability to the target population of the guidelines. Thirdly, guideline users may misinterpret the grade of recommendations as relating to its importance, rather than to the strength of the supporting evidence.

In 2001, the Scottish Intercollegiate Guidelines Network (SIGN) developed a revised system of determining level of evidence and grades of recommendations (89). Assessment of evidence in the SIGN system is based on study design in addition to consistency and methodological quality of individual studies. Grades of recommendations are based on the strength of supporting evidence, including its overall level, and the considered judgments of guideline developers.

In 2004, the Grades of Recommendations Assessment, Development and Evaluation (GRADE) working group updated SIGN and other grading systems (88). The level of evidence in the GRADE system is based on four elements; study design, study quality, consistency and directness. The system initially classifies evidence based on study design, then guideline developers decide whether the studies have serious limitations, inconsistency in the results, imprecise or sparse data or whether uncertainly about the directness is observed. In 2005, the GRADE working group updated their system for grading the quality of evidence and strength of recommendations (21).

The JBI in Australia currently assign a level of evidence to all conclusions drawn in JBI systematic reviews. This evidence is summarized under four major headings of

Feasibility, Appropriateness, Meaningfulness and Effectiveness – the “FAME” scale of evidence (91).

Recently, the American Dietetic Association (ADA) developed two quality criteria checklists to assign a quality rating to primary research and review articles (87). Both checklists include four relevance questions that address applicability to dietetic practice and ten validity questions that address scientific soundness (Appendix A). Under each validity question there is a list of sub-questions that identify important aspects of sound study design. These questions were developed particularly to assess nutrition research since they cover most elements usually used in such research. Therefore, this grading system has been used in this thesis to evaluate the scientific evidence.

2.4.3.4 Development of consensus statements

Clinical practice guidelines should be based on the best available evidence. However, the evidence is sometimes insufficient or lacking. In such situations, the development of guidelines will inevitably have to be based partly or largely on the opinions and experience of clinicians and others with knowledge of the subject at issue.

To create consensus statements and make effective decisions in situation where insufficient information exists, a method that creates expert consensus needs to be used. The Delphi technique is considered one of the best methods to creates consensus (92). Other common methods that have been used in the health field are the nominal group technique (NGT) and consensus development conference (92).

2.4.3.4.1 Delphi technique

The Delphi method was introduced in the 1950s by Olaf Helmer and Norman Dalkey (92, 93). This process is a structured communication which consists of questioning experts by means of successive questionnaires, in order to reveal convergence and any consensus there may be. The most important advantages of this technique are (92, 93):

- Participants who cannot come together physically can be involved in the process.
- Allows participants to remain anonymous, which means a decrease in mutual influence
- Inexpensive

- Participants send their contribution when they want to and only contribute to those aspects that they feel best able to contribute

Main stages of this consultation processes for developing of consensus statements include:

Step 1: Determination and formulation of questions

Participants are asked to participate in the preparation of the structure and content of an initial set of draft consensus statements. This can be achieved through interviews with experts and/or consultation workshops.

Step 2: Selection of Delphi experts

The type and number of participants have an effect on group judgment. Consensus development groups should be composed of experts in the appropriate area who have credibility with the target audience (92). Representatives from different expert groups such as clinicians who have clinical expertise and researchers who have scientific expertise need to be involved in the consensus process (92). The reliability of a composite judgment increases as the number of participants increases. Reliability seems to decline rapidly with less than six participants and improvements of reliability will be subject to diminishing returns with more than 12 participants (92). However, one study about the ratings of quality of medical care indicated that the reliability increased over the range from one to ten participants and then began level off. It required on average of 16 to 28 participants to provide judgment of the quality of care for a single case with a reliability of 0.95 (92).

Step 3: Formulation of a first questionnaire that is sent to the experts

The first questionnaire contains a reminder of the nature of the project. Participants are asked to rate their agreement level about a list of statements. They are also encouraged to modify, reject or add new statements to be included in the clinical practice guidelines.

Step 4: Analysis of the answers to the first questionnaire.

The answers are analyzed in order to determine the general tendency and the most extreme answers.

Step 5: Formulation of a second questionnaire that is sent to experts

Each expert is informed of the results of the first round and asked to provide new ratings of the statements and to justify them if they differ from the general tendency.

Step 6: Sending of a third questionnaire

This questionnaire is intended for those experts whose answers were "extreme". They are asked to criticise the arguments of those who support the opposite point of view. The comparison of opinions has a moderating influence and facilitates the appearance of convergence between the points of view. Sufficient convergence of opinions may appear with the second or third questionnaire. If that is not the case, the cycle continues.

2.4.3.4.2 Nominal group technique (NGT)

NGT is a structured method for group brainstorming that encourages contributions from all participants who want to make their decision quickly (for example, by a vote) but want everyone's opinions taken into account. It was introduced in the 1960s by Delbecq and Van de Ven in the context of committee decision making (94). The main stages of this consultation processes for developing of consensus statements include are:

Step 1: Introduction and explanation: the facilitator states the subject of the brainstorming and explain the purpose and procedure of the meeting. The statement needs to be clarified until every participant understands it.

Step 2: Silent generation of ideas: the facilitator provides participants with a list of statements and asks each participants to write his or her ideas independently and privately. This step takes approximately 10 minutes

Step 3: Sharing ideas: each participant in turn states aloud one idea. The facilitator writes each idea on a flipchart. The round robin process continues until all ideas recorded using the words spoken by the participant. No discussion is allowed at this step. This step takes approximately 30 minutes

Step 4: Group discussion: the facilitator should discuss each statement and ensure that each participant is allowed to be involved without spending too long time on a single statement or idea. This step takes approximately 30-45 minutes

Step 5: Prioritizing the ideas: the final step is prioritizing the presented ideas and statements so the meeting concludes having reached a specific outcomes using voting or list reduction.

For clinical practice guidelines development, the modified NGT has been commonly used. This method developed by the RAND Corporation during the 1970s and 1980s (92). This method called “modified Delphi” since participants express their opinions privately through mailed questionnaires. This modified Delphi involves three steps. The idea or statement initially are rated independently and privately by each participant without any discussion. Then the group meets and discuss the rating results. After discussion, each participant re-rates each idea or statement independently and privately. The median rating is used as the appropriateness score.

2.4.3.4.3 Consensus development conference

This method introduced in 1977 by the National Institute of Health (NIH) in the USA (92). In this method a group of around 10 experts meets to reach consensus on a selected subject. Procedures include an open meeting for participants that may last for 2 or 3 days. Evidence is presented by experts and several interested groups who are not members of the decision-making group. The latter then retire to consider the questions in the light of the evidence presented and attempt to reach consensus. All discussions in the conference are chaired.

2.4.3.5 Formulating a dissemination and implementation strategy

A strategy should be developed to ensure that the guidelines are disseminated and implemented properly. Guidelines should be presented in formats that easily understood

by audience. They can be summarized and published in professional journals, trade publications, institutional newsletters and in the popular media. Guidelines can also be published as brochures, posters, on computer disks and as video or audio tapes. For implementation, there is no single implementation strategy which is superior in all circumstances (18). However, the following strategies have been shown to be effective in changing clinicians' behavior or health outcomes or both (18): media marketing, the use of opinion leaders, endorsement by clinical groups, practice visits from influential experts, seminar and conferences and local involvement in evaluation. Also the use of the academic detailing method has been studied for over 25 years (95) and has been shown to be effective in changing clinicians' behavior (96).

2.4.3.6 Formulating an evaluation and revision strategy

Guidelines should be evaluated to know whether they make a difference to clinical practice and health outcomes and also to assess the effectiveness of their dissemination and implementation (18). Guidelines need to be revised routinely as the circumstances prone to rapid change. It has been recommended that revision should take place at least every 3 to 5 years (18)

CHAPTER 3

CURRENT DIETETIC PRACTICES OF OBESITY MANAGEMENT IN SAUDI ARABIA AND COMPARISON WITH AUSTRALIAN PRACTICES AND BEST PRACTICE CRITERIA

This chapter has been published in the following peer-reviewed paper:

Almajwal A, Williams P, Batterham M. Current dietetic practices of obesity management in Saudi Arabia and comparison with Australian practices and best practice criteria. Nutr & Diet. 2009;66:94-100

AA was responsible for the design of the study, distribution, collection and analysis of the data and preparation of the manuscript. PW assisted in editing the manuscript. MB assisted with the data analysis. All authors involved in critical discussions of study design and outcomes

CONTENTS:

- 3.1 Abstract
- 3.2 Introduction
- 3.3 Methods
- 3.4 Results
- 3.5 Discussion
- 3.6 Conclusion

3.1 ABSTRACT

Objective: To describe the dietetic practices of the treatment of obesity in Saudi Arabia and compare this with best practice criteria and the practice in Australia.

Methods: Anonymous questionnaires were completed by dietitians in Saudi Arabia. The topics included barriers to obesity management, demand and level of service and strategies and approaches used for weight management. Best practice scores were based on those used to assess Australian dietitians.

Results: 253 dietitians participated in the survey. Of these, 175 (69 %) were involved in the management of obesity. The best practice score for Australian dietitians was slightly greater than the scores of Saudi dietitians (median 43 vs 39). There was also a significant correlation between the best practice score and years of experience ($r = 0.26$, $p < 0.001$). The most common assessment approaches were assessment of BMI (87%) and exercise habits (81%) while the most common strategies for obesity management were; dietary total fat reduction (92%) and increase incidental daily activity (92%). The major barrier for establishment of a weight management clinic reported by 49% of participants was inadequate resources.

Conclusion: Saudi Arabian dietetic practice for the management of obesity does incorporate most best practice recommendations, but some specific elements are rarely used.

3.2 INTRODUCTION

Obesity has become a global epidemic and the prevalence of both overweight and obesity is still increasing in Saudi Arabia (1-4, 97). The latest survey conducted between 1995-2000 to study cardiovascular disease and its risk factors involved 17,232 male and female Saudi subjects aged 30-70 years (4). Results showed that the overall obesity prevalence (BMI > 30 kg/m²) was 35.6%. The prevalence of overweight (BMI: 25-30 kg/m²) was 36.9%, which makes 72.5% of Saudi population either overweight or obese.

It is well established that obesity is directly or indirectly associated with several diseases including type II diabetes, hypertension, dyslipidemia, coronary heart disease, stroke, gall bladder diseases, osteoarthritis, sleep apnoea and respiratory problems, and some type of cancer (98, 99). Therefore, obesity is a condition with significant economic costs and one that causes a great loss of quality of life. In Saudi Arabia, obesity has become a major cause of coronary artery diseases in the recent decades (2), apparently due to the sudden change in life style as a result of economic development, urbanization, and the tremendous increase in the socio-economic fortunes which has resulted in dietary changes and an increasingly sedentary life (100).

It is important that dietitians, as one of the major health professionals involved in obesity management, know the most effective approaches and strategies for the treatment of overweight and obesity. Dietitians are considered to be the most effective providers of weight management advice (101). In Saudi Arabia, dietetics is a relatively new profession and little published data is available about the practice of dietetics. There are only two universities that train clinical dietitians (King Saud University and King Abdulaziz University). At present there are no national obesity practice guidelines developed for use by doctors, dietitians or other health professionals. To address this issue, we have planned a larger project to develop clinical practice guidelines to be used by dietitians in Saudi Arabia.

This study aimed to describe the current dietetic practices for the treatment of obesity in Saudi Arabia and compare this with practice in Australia. It also aimed to provide baseline information to assist in the development and evaluation of the proposed new practice guidelines.

3.3 METHODS

3.3.1 Subjects

All dietitians in Saudi Arabia were invited to participate in the survey during the period from January to June 2007.

3.3.2 Recruitment and distribution

Because no complete lists of dietitians in Saudi Arabia are available, dietitians were recruited primarily by contacting employer organizations and asking for the survey to be promoted to all dietitians on staff. Both urban and rural areas were covered in the survey. The survey was designed to be available in a web-based form in addition to a paper-based version (Appendices B, C and D)

3.3.3 Survey development

To assist in developing the survey, a qualitative interview with 6 key stakeholders from different hospitals and universities was conducted over the phone, including academic staff, physicians, and expert dietitians in the area of obesity management.

Based on a review of the literature and suggestions received from participants of the qualitative interviews, a pilot questionnaire was developed in both Arabic and English languages. Some questions were drawn from previous similar surveys – such as those used by Campbell & Crawford and Collins in surveys of Australian dietitians, to enable comparison of obesity management in Saudi with Australia (102, 103). Thirty pilot questionnaires were distributed to dietitians with known expertise in obesity management. Twenty one responses were received along with comments on the pilot questionnaire for scope, length, clarity, and suitability. Copies of the final version of the survey are available from the first author (AA) (Appendices B and C). Translation was performed by AA and reviewed for accuracy by two academic staff from the English department in King Saud University, Saudi Arabia. All participants who completed at least the first two sections in the questionnaire were included in the survey.

The study was approved by the Human Research Ethics Committee (University of Wollongong / Illawarra area health services, Australia) (Appendix E) and permission to distribute the survey in Saudi Arabia by King Saud University staff was obtained based on the Australian ethics approval. All participants received a cover letter with

participant information (Appendices F and G) and consent implied by return of the questionnaire.

3.3.4. Survey format

The survey contained 36 questions which were divided into five sections.

3.3.4.1 Section one

Respondents provided demographic and professional information as shown in Table 3.1

3.3.4.2 Section two

This section consists of questions concerning barriers that prevent dietitians being involved in obesity management such as referral issues (in which physicians or other health care professionals are not referring obese patients to dietitians), lack of dietitians (a workforce shortage, a funding shortage or both), or other resource barriers (such as inadequate access to space, scales, food modules, etc).

3.3.4.3 Section three

Participants were asked to estimate the number of clients seen per week, report the source of referrals and resources available in their clinic, and whether the service had specific referral criteria and practice guidelines.

3.3.4.4 Section four

This section consisted of questions concerning dietitians' approaches to obesity assessment. Using a five-point Likert scale (1 = never; 5 = usually), participants were asked how frequently they performed each of 22 assessment and service provision activities (Table 3.2). These questions were drawn from a 1997 survey by Campbell and Crawford (102) in Australia with the addition of two questions related to assessment of educational level and calculation of Body Mass Index (BMI). For analysis purposes, the responses were collapsed into three categories (never/seldom; sometimes; often/usually).

3.3.4.5 Section five

This section consisted of questions concerning dietitians' approaches to obesity management. Using the same five point scale, participants were asked how frequently they used each of 17 possible weight management activities (Table 3.3). These questions were drawn from the surveys by Campbell and Crawford and Collins with three additional questions (102, 103).

Table 3.1 Demographic profile of survey respondents (n=253)

Percentage of surveyed participants	
Age (y)	
21-35	79
36-45	16
46- 55	5
Gender	
Male	34
Female	66
Sector of employment	
Hospitals of Ministry of Health	55
Other hospitals	37
Weight reduction centre or clinic	6
Academia	6
Other sectors	4
Professional qualifications	
Bachelor in Clinical Nutrition	50
Bachelor in Food and Nutrition	31
Master degree	10
PhD degree	3
Other	6
Years in Practice	
0- 5 years	65
6 – 15 years	27
> 15 years	8

3.3.5 Data analysis

The survey was analysed by SPSS software (version 15.0; SPSS Inc., Chicago, IL). The mean score of each weight management activity was calculated (Tables 3.2 and 3.3) with a maximum possible score of 2. Descriptive statistics were used to analyse the responses to each item and differences between scores of each item from the survey by Collins (103) and our findings were examined using Kruskal-Wallis test, as indicated for non-normal data. $P < 0.05$ was considered statistically significant.

A best practice score was calculated for each participant on the basis of the frequency with which they reported using 33 of the 39 recommended assessment management activities (Table 3.2 and 3.3). The six items that were not included in the score are those without comparable data in the Collins survey and these are noted in the footnotes to Tables 2 and 3. Using scores of 'never' or 'seldom' = 0, 'sometimes' = 1, 'often' or 'usually' = 2, the maximum score that could be achieved from the 33 activities included in the calculation was 63. Three items in Table 2 were calculated as follows; 'never', 'seldom', 'often', 'usually' = 0; 'sometimes'=1. The differences between best practice scores and categories of years of dietetic experience or number of patients seen by dietitians were examined using one-way ANOVA that is robust to violations of the normality assumptions (104). As the data are not normally distributed, both parametric and nonparametric methods were used and the results were identical.

3.4 RESULTS

3.4.1 Subjects

A total of 253 dietitians participated in the study. Of these, 175 (69 %) were involved in the management of overweight and obesity. Fifteen participants were excluded due to incomplete questionnaire responses. Table 3.1 contains demographic and employment characteristics of the sample population.

3.4.2 Barriers to obesity management

Participants who reported that they did not have a nutrition clinic at their service (20%) were asked to list the barriers for establishment of a weight management clinic. Forty-nine percent reported that inadequate resources (space, tools, etc) was the major barrier, 40% reported that the service administration had not established a clinic yet, 25% reported referral issues and 23% reported lack of dietitians. Similarly, participants who did not provide consultations to hospital patients (19%) were asked to list the barriers. The majority (61%) reported that hospital policy did not require dietitians to manage obesity, 35% reported lack of dietitians, 27% reported referral related issues, and 22% reported resource problems.

3.4.3 Demand and level of service

A total of 175 participants (69%) reported that they manage obese patients. None of these participants reported the use of local clinical practice guidelines for the management of overweight and obesity. However, sixty-one percent of participants who manage obesity reported that they use some international guidelines such as the American practice guidelines (11).

Forty two percent of participants who manage obesity see 5-10 obese patients every week, with 25% managing 11-20 patients, followed by 21% with less than 5 patients every week. Only 11% manage more than 20 obese patients per week.

Seventy-seven percent of participants who manage obesity reported that they have basic scales in their services and 36% reported that they have scales that measure weight and body fat percentage. Sixty percent reported that they have food models in their clinics. Obesity services sometimes included other health professionals (52%). Of those, team members included a physician (92%), physiotherapist (38%) and social worker (31%)

3.4.4 Strategies and approaches for obesity assessment and dietary treatment

Some questions were included about the assessment of energy intake. Most dietitians (86%) use the Harris Benedict equations to assess resting energy expenditure (REE) with 5% using World Health Organization equations, followed by 3% using Owen equations, 3% using Schofield equations, 1% using Mifflin equations and only 2% using other different equations. None of participants use Ireton-Jones equations or Bernstein equations.

Participants were also asked about other factors that they consider when they calculate the REE. For overweight patients ($BMI = 25-30 \text{ kg/m}^2$), 57% of participants indicated that they consider the Ideal Body Weight in calculating REE, 32% consider the Actual Body Weight, followed by 12% consider the Adjusted Body Weight. For obese patients ($BMI > 30 \text{ kg/m}^2$), 64% consider the Adjusted Body Weight (105), 22% consider the Ideal Body Weight and 14% consider the Actual Body Weight. Most participants (62%) also indicated that they reduce the daily energy requirements by 1255-2092 kJ (300-500 kcal), 24% indicated that they reduce 2092-4184 kJ (500 – 1000 kcal) a day and 14% indicated that they do not have any specific plan. Twenty nine percent of participants reported that they do not have a specific time period to achieve their goals with 26% reporting that they achieve their goals from 3-6 months, 9% reported 1-3 months, 18% reported more than 6 months and 18% reported that they consider other factors such as patient readiness to lose weight and the amount of excess weight.

The approaches of the majority of services (94%) incorporated diet, exercise and behavior modification. None of the participants reported the use of diet only. Specific dietary strategies were selected for participants on the basis of dietitian experience (49%), based on a program prepared by the service with specific energy level (49%), patient preference (11%) or as requested by medical referral (15%). Tables 3.2 and 3.3 show comparison of the use of specific strategies for weight management by dietitians in Saudi Arabia in 2007 and Australia in 2002

Table 3.2 Comparison of the assessment approaches and service provision for weight management by dietitians in Saudi Arabia in 2007 and Australia in 2002 (103).

Strategy	SAUDI ARABIA				AUSTRALIA
	Never Seldom (%) n = 175	Sometimes (%) n = 175	Often usually (%) n = 175	Score (Mean \pm SD) [‡] n= 172	Score (Mean \pm SD) [‡] n = 254
Assessment of exercise habits	1	18	81	1.80 \pm 0.43	2.00 \pm 0.00*
Assessment of weight history	4	27	69	1.65 \pm 0.56	1.97 \pm 0.27*
See client on one to one basis [§]	6	19	75	0.19 \pm 0.39	0.07 \pm 0.26*
Assessment of readiness for change	7	34	59	1.52 \pm 0.62	1.80 \pm 0.49*
Assessment of client's expectations of weight loss/ management	5	44	51	1.46 \pm 0.59	1.85 \pm 0.44*
Assessment of client's values and beliefs regarding the ability to lose weight	10	37	53	1.43 \pm 0.67	1.72 \pm 0.59*
Assessment of home environment for supportive structure of weight management/loss	9	47	44	1.35 \pm 0.64	1.74 \pm 0.58*
Assessment of the client's definition of successful outcomes in weight management	9	43	48	1.39 \pm 0.65	1.61 \pm 0.65*
Assessment of the weight history of the client's family	23	51	26	1.03 \pm 0.70	1.27 \pm 0.73*
Assessment of the clients preferred style of consultation/ method of intervention	18	43	39	1.21 \pm 0.73	1.34 \pm 0.80
Assessment of client's progress for more than 6 month	11	39	49	1.37 \pm 0.68	1.24 \pm 0.77
Offering more than one weight management strategy	17	46	37	1.20 \pm 0.71	1.31 \pm 0.72
Accompanied by significant other	19	52	29	1.10 \pm 0.69	1.34 \pm 0.72*
Assessment of expected number of consultations clients need with you	28	41	31	1.03 \pm 0.77	1.08 \pm 0.84
Assessment of client's anticipation of regaining weight loss	19	48	33	1.14 \pm 0.71	1.18 \pm 0.79
Providing preventive advice to individuals and families	14	37	49	1.35 \pm 0.72	NA ^{††}
Referral to another member of health care team	42	46	12	0.70 \pm 0.67	0.96 \pm 0.68*
See client in group format [§]	73	25	2	0.25 \pm 0.43	0.23 \pm 0.42
See client in combined one to one counseling/group format [§]	61	29	10	0.29 \pm 0.46	0.16 \pm 0.37*
Review client's progress more than two years.	49	39	13	0.65 \pm 0.70	0.48 \pm 0.69*
Calculation of BMI [¶]	2	11	87	1.85 \pm 0.42	NA ^{††}
Assessment of education level [¶]	15	65	21	1.06 \pm 0.55	NA ^{††}

[‡] SD: Standard Deviation

[‡] Never/Seldom = 0; Sometimes = 1; Usually/often = 2

[§] Item was calculated as follows for the purpose of calculating the best practice score: 'never', 'seldom', 'often', 'usually' = 0; 'sometimes'=1. All other items were scored as follows: 'never' or 'seldom' = 0, 'sometimes' = 1, 'often' or 'usually' = 2

[¶] Item was not included in the calculation of best practice score

^{††} NA: Not available in survey by Collins and not included in the overall best practice score

* Significant differences ($P < 0.05$)

Strategy	Never Seldom (%) n=172	Some- times (%) n=172	Often Usually (%) N=172	Score (Mean \pm SD) [†] N= 172	Score (Mean \pm SD) [†] n = 262
General advice to do more exercise [§]	0	8	92	1.00 \pm 0.00	1.02 \pm 0.01
Pedometer or other exercise monitoring device [¶]	37	38	25	0.88 \pm 0.78	NA ^{††}
Practical advice regarding shopping and cooking to achieve dietary goals	6	30	64	1.58 \pm 0.60	1.93 \pm 0.30*
Specific advice regarding opportunities for increasing incidental daily activity	3	27	69	1.65 \pm 0.53	1.92 \pm 0.32*
Specific advice to reduce total fat intake	1	7	92	1.91 \pm 0.32	1.90 \pm 0.36
Specific advice re incorporating low intensity, long duration exercise such as walking into present lifestyle	1	14	85	1.84 \pm 0.40	1.89 \pm 0.37
Planning for follow up in the short term	8	31	62	1.55 \pm 0.64	1.81 \pm 0.48*
Specific advice regarding ways of incorporating other forms of exercise into daily living	5	43	52	1.47 \pm 0.59	1.76 \pm 0.51*
Behavior modification techniques	1	25	74	1.73 \pm 0.47	1.68 \pm 0.59
Specific advice to eat fewer kilojoules [§]	2	24	73	1.00 \pm 0.13	1.30 \pm 0.45*
Keeping a food diary	24	52	24	1.00 \pm 0.69	1.18 \pm 0.77*
Planning for follow up in the long term	15	41	44	1.29 \pm 0.71	1.12 \pm 0.77*
Keeping a hunger awareness diary	43	37	20	0.77 \pm 0.76	0.68 \pm 0.74
Keeping a weight diary [¶]	23	42	35	1.12 \pm 0.76	0.31 \pm 0.64*
Joining of a commercial or community-based "slimming group" [¶]	41	36	23	0.82 \pm 0.78	0.42 \pm 0.62*
Advice to use medications [¶]	84	13	3	-	NA ^{††}
Surgical intervention [¶]	67	31	2	-	NA ^{††}

Table 3.3 Comparison of the use of recommended strategies for weight management used by dietitians in Saudi Arabia in 2007

and Australia in 2002 (103).

[†] SD: Standard Deviation

[‡] Never/Seldom = 0; Sometimes = 1; Usually/often = 2

[§] Item was calculated as follows for the purpose of calculating the best practice score: 'never' or 'seldom' = 2, 'sometimes' = 1, 'often' or 'usually' = 1. All other items were scored as follows: 'never' or 'seldom' = 0, 'sometimes' = 1, 'often' or 'usually' = 2

[¶] Item was not included in the calculation of best practice score

^{††} NA: Not available in the survey by Collins and not included in the overall best practice score

* Significant differences ($P < 0.05$)

3.4.5 Best practice in weight management

The Best Practice Score was calculated by adding together the scores from Table 3.2 and Table 3.3. The possible maximum score was 63. The median best practice score for Saudi dietitians was 39. The best practice score for Australian dietitians was slightly greater than the scores of Saudi dietitians (median 43 vs 39). Using ANOVA there was a significant increase in the mean Best Practice Score as the years in practice increased (0-5 y = 35.0; 6-15 y = 39.7; > 15 y = 40.6; $F = 7.2$; $P < 0.001$). When the best practice score was analysed by the number of patients seen by dietitians, there was no significant association.

3.5 DISCUSSION

This is the first study to describe the current dietetic practice for the management of overweight and obesity in Saudi Arabia. There are few similar studies conducted anywhere worldwide and therefore published Australian practice has been used for comparison purposes.

Since there are no recent statistics on the number of dietitians in Saudi Arabia, we could not calculate the survey response rate. However, the majority of dietitians are employed in the Ministry of Health (MOH). Unpublished data from the MOH show that the number of dietitians in their hospitals was 218 in 2007. The number of survey participants from the MOH was 130, making the response rate of MOH dietitians 70%. The majority of participants (41%) were from the central area due to the large number of hospitals in this area. In contrast only 22 % of participants were from both Southern and Northern areas due to the limited number of hospitals in these areas. Since dietetics is a relatively a new profession in Saudi Arabia we found dietitians had less experience and were younger in comparison to dietitians in Australia (103).

This survey examined the barriers of obesity management in Saudi Arabia and it was surprising that 61% of dietitians who do not give nutritional consultation for hospital patients reported that hospital policy did not require dietitians to manage obesity. Also 49% of dietitians who do not have obesity clinic in their services reported that inadequate resources was the major barrier and 40% reported that the health administration had not established a clinic yet.

These findings indicate an urgent need for developing and implementing a clear policy explaining the importance and role of dietitians in the health services in Saudi Arabia and finding ways to overcome the limited involvement of dietitians in managing obesity either with inpatients or in out patients' clinics. It seems too that more effort is required to develop policies and care pathways whereby physicians and other health professionals refer obese patients to dietitians more routinely, and the role of the multi-disciplinary team including dietitians and physicians in the management of obesity needs to be clearly identified.

The median best practice score for all dietitians was 39 (out of 63). Similar surveys reported on obesity management practices of Australian dietitians by Campbell and Crawford in 1997 and Collins in 2002 showed that scores were 46 and 43, respectively

(102, 103). The best practice score for Australian dietitians was slightly greater than the scores of Saudi dietitians. This is likely to be due to the lesser experience of the Saudi dietitians. However, both scores were relatively low compared to the maximum total scores that could be achieved. There were significant differences in several activities between practices in Saudi Arabia and Australia (Table 3.2 and 3.3). Saudi dietitians do not place emphasis on the assessment of client's home environment or family weight nor do they routinely include significant others in the client consultation. This could be explained by the high values placed on the privacy of Saudi families. Saudi dietitians also do not place emphasis on the assessment of exercise habits, weight history, and readiness for change. Australian dietitians place an emphasis on providing practical advice regarding shopping and incidental daily activities.

As found in the Australian studies, the best practice score was positively correlated with the number of years practicing as a dietitian (102, 103). There was no significant correlation between the best practice score and the number of clients usually seen by the dietitian. As illustrated in Table 3.2 and 3.3, a large range of assessment approaches and strategies were employed with varying frequency. Most dietitians reported that they usually assess exercise habits, weight history, readiness for change, and see clients on a one-to-one basis. In contrast, most dietitians reported that they seldom see clients in a group format or refer clients to another member of health care team. Most dietitians also reported that they usually advise client about behavior modification techniques in addition to diet and exercise, specifically dietary total fat reduction, advice to shopping, incidental daily activity and to eat fewer kilojoules. Several other approaches and strategies (Table 3.2 and 3.3) were employed with varying frequency among dietitians.

These findings indicate that Saudi dietetic practice does incorporate most of the best practice elements identified in the literature. However, approximately two thirds of dietitians reported relying on the use of international dietetic practice guidelines, which suggests the need for the establishment and endorsement of local obesity clinical practice guidelines similar to those developed in other countries such as the USA, Australia, Canada and Scotland (11-14).

Approximately 86% of dietitians reported the use of Harris-Benedict equation in the assessment of energy requirements. Several validation studies have demonstrated that it overestimates energy requirements, particularly among overweight and obese people

(106, 107). It was surprising that none of participants used either of those equations developed by Ireton-Jones *et al.* or Bernstein *et al.* which were derived from samples of obese subjects (19, 20). However, energy expenditure of the overweight and obese is variable, and the best method to predict it is still controversial. Also it is unclear whether prediction equations derived from one population can be applied in different populations. Several studies have shown that ethnicity, climate and genes have an influence on metabolic rate (72, 108-112). These findings support the need for further research to validate the use REE equations in the Saudi population and to examine factors that affect their accuracy. To address this deficit, we have commenced a project to validate the use of such equations with Saudi subjects.

3.6 CONCLUSION

This study indicates that Saudi dietitians use a variety of approaches and strategies for obesity management and employ most of the recommended best practice elements. However, the development of local evidence-based practice guideline might assist in making the care more consistent and efficient. The findings also suggest that efforts are needed to improve the recognition of the value of weight management services and the role and needs of dietitians in Saudi Arabia needs to be clearly identified.

CHAPTER 4

PERFORMANCE OF BODY MASS INDEX IN PREDICTING DIABETES AND HYPERTENSION IN THE EASTERN PROVINCE OF SAUDI ARABI

This chapter has been accepted for publication in the following peer-reviewed journal:

Almajwal A, AL-Baghli N, Batterham M, Williams P, AL-Turki K, AL-Ghamdi A. Performance of Body Mass Index in predicting diabetes and hypertension in the Eastern province of Saudi Arabia. Ann Saudi Med 2009;29(6):437-445

AA was responsible for the design of the study and preparation of the manuscript. PW assisted in editing the manuscript. NA and MB assisted with the data analysis. AA, PW and MB were involved in critical discussions of study design and outcomes. NA, KA and Al-Ghamdi A were involved in the original survey.

CONTENTS:

- 4.1 Abstract
- 4.2 Introduction
- 4.3 Methods
- 4.4 Results
- 4.5 Discussion

4.1 ABSTRACT

BACKGROUND AND OBJECTIVES: BMI is the most widely used measure to define obesity and predict its complications such as diabetes and hypertension, but its accuracy and usefulness for such purposes in Saudi subjects is unknown. This study aimed to assess the validity of standard BMI cut-point values in a Saudi population in defining metabolic risk factors.

SUBJECTS/ METHODS: 197,681 adults participated in a cross-sectional study to detect diabetes and hypertension in the Saudi Eastern province in 2004/2005, with blood pressure, fasting blood sugar, height and weight measurements taken. Sensitivities, specificities, areas under the curves, predictive values, likelihood ratios, false positive, false negatives and total misclassification ratios were calculated for various BMI values determined from ROC curves, and the observed significance of association between metabolic risk factors and BMI was assessed using regression analysis.

RESULTS: For the definition of overweight, ROC curve analysis suggested optimal BMI cut-offs of 28.50 to 29.50 in men and 30.50 to 31.50 in women, but the levels of sensitivity and specificity were too low to be of clinical value and the overall misclassification was unacceptably high across all the selected BMI values (> 0.80). The relationship between BMI and presence of diabetes and/or hypertension was not improved when a BMI of 25 was used. Using regression analyses, the odds ratios for hypertension and/or diabetes increased progressively significantly from BMI values as low as 21-23 with no improvement in the diagnostic performance of BMI at these cutoffs.

CONCLUSION: In a large sample from the Eastern region of Saudi Arabia, there was an increased risk of diabetes and hypertension relative to BMI starting at BMI as low as 21 but overall, there was no cutoff BMI level with high predictive value for the development of these chronic diseases including the WHO definition of obesity at BMI ≥ 30

4.2 INTRODUCTION

Body Mass Index (BMI) is widely used as a method to classify underweight, overweight and obesity. Around three quarters of Saudi dietitians use this tool as outcome measure to assess the success in weight loss (23). BMI is defined as the weight in kilograms divided by the square of the height in meters (kg/m^2). In 1997, the World Health Organization (WHO) proposed cut-off points for classifying overweight and obesity (10, 113). Overweight is classified as $\text{BMI} \geq 25.0$ and obesity is classified as $\text{BMI} \geq 30.0$. These cutoffs have been identified on the basis of the association between BMI and chronic diseases and mortality (26, 113). Since these criteria were derived from European populations their appropriateness for Non-European populations including the Saudi population, is unclear, and the recent WHO monograph on obesity acknowledged the ‘need for different standards that are “culturally specific” (113).

It has been demonstrated that Asians have a higher percentage of body fat than Caucasians at the same BMI cut-off levels and the health risks associated with obesity occur at lower BMI cut-off level than Caucasians (27-34). There have been a few attempts to investigate the applicability of the WHO BMI cut-offs in Asians and Pacific populations (24, 34-39). In 2000, the Regional Office for the Western Pacific Region of WHO with the International Association for the Study of Obesity (IASO) and the International Obesity Task Force (IOTF) defined overweight in Asians as $\text{BMI} > 23.0$ and obesity as $\text{BMI} > 25.0$ (24). In 2004, WHO did not propose a clear BMI cut-off for all Asians but they indicated that the cut-off points for observed risk varies between BMI of 22.0 to 25.0 in different Asian populations and these values varies between BMI 26.0 to 31.0 for the high risk cut-off.

Even though BMI has been used extensively in research and clinical practice, there are only few studies examining its diagnostic accuracy and no study has examined this in a large, non-Caucasian adult population. Therefore, the present study aimed to assess the ability of BMI to diagnose obesity relative to metabolic risk factors and to determine the optimal BMI cut-off points that could be used to classify obesity in a Saudi population.

4.3 METHODS

This study used data from a large survey conducted in the Eastern Province of Saudi Arabia during the period from August 2004 to February 2005. The survey was conducted by the Saudi Government Ministry of Health. The aim of the survey was the early detection of diabetes and hypertension and a detailed description of the study design and data collection procedures has been published elsewhere (114). Briefly, all Saudi residents in the Eastern province aged 30 years and above were invited to participate in the survey. Pregnant women and non-Saudi people were excluded from the survey. For recruitment, a media campaign was organized in each sector using written material and audiovisual media. In addition, posters were put up on billboards along the streets and public places in the Eastern Province. The estimated target population of Saudi residents in the Eastern province aged ≥ 30 years old was 650,000 individuals (115). A total of 197,681 Saudis responded to the campaign's invitation (30.4%) and 195,851 of them had assessments of height and weight, and presence of diabetes and/or hypertension and were included in the analysis of the present project. The survey through this convenience sample was conducted through more than 300 examination posts run by trained nurses and technicians distributed in the eastern province of Saudi Arabia, including all primary health care centers (PHCCs), governmental hospitals, and several private health places, and other venues, in addition to mobile teams who visited the target population in places of work that had more than 30 employees.

Weight was approximated to the nearest 0.5 kilogram using standardized beam weight scales (Detecto scale, Cardinal Scale Mfg Co., USA) and recorded to the lowest unit without footwear and with only light clothes on. Height was measured to the nearest centimetre with the subjects barefoot and standing with the feet together, ensuring the nape, back, calves, and with the ankles pressed against the measuring tape, which is part of the weighing scale. The BMI was calculated as weight in kilograms divided by height in meters squared (kg/m^2), and standard WHO cut-off values of a BMI 25 and 30 were used to define the prevalence of overweight and obesity, respectively.

Blood pressure was measured two times with the subject at rest in a sitting position. The average of the two measurements was accepted if the difference between the values was less than 5 mmHg. Measurement was taken using standardized mercury sphygmomanometers (Diplomat Presameter 660-360 manufactured by Riester GMBH, Germany) with an appropriate cuff inflated to a pressure approximately 30 mmHg greater than systolic and subject's arm at the level of the heart. The screening test for hypertension was considered positive if the systolic and diastolic blood pressure was ≥ 140 and/or ≥ 90 mmHg, respectively (116). The diagnosis of hypertension was made if positive screening was confirmed on a subsequent day, or if there was a history of previous diagnosis, irrespective of the blood pressure reading. Participants who did not come for the confirmatory test were diagnosed as having hypertension if screening test of systolic and diastolic blood pressure was ≥ 180 and/or ≥ 110 mmHg, respectively. These relatively high values were chosen to avoid over diagnosing hypertension in participants who might be in rush or anxious from the results of the evaluation

Whole blood glucose concentration was measured for all participants using uniform portable glucometer machines with a Medisafe Reader (Terumo Co., Tokyo, Japan), based on reflectance photometry, where the glucose was catalytically oxidized by the glucose oxidase and peroxides enzymes with a color change reaction. A screening test was considered to be positive for hyperglycemia if capillary fasting blood glucose (CFBG) was ≥ 100 mg/dl (≥ 5.6 mmol/l) after at least 8 hours of fast or the Capillary random blood glucose (CRBG) was ≥ 140 mg/dl (≥ 7.8 mmol/l) taken without consideration to the time of the last meal (117). A CFBG of 100-125 mg/dl (5.6-6.9 mmol/l) and a CRBG of 140-199 mg/dl (7.8-11 mmol/l) were considered to be consistent with impaired fasting glucose (IFG) and impaired glucose tolerance (IGT), respectively. Initial screening test was considered to be consistent with the diagnosis of diabetes if the CFBG was ≥ 126 mg/dl (≥ 7.0 mmol/l) or the CRBG was ≥ 200 mg/dl (≥ 11.0 mmol/l). Diabetes mellitus was diagnosed either by a positive history of diabetes or through the screening test. All subjects who had been screened positive for hyperglycemia without a history of diabetes were asked to come in fasting for ≥ 8 hours, on the following day, at the central laboratory, for confirmation of the results by venous blood testing through the measurement of fasting plasma glucose (FPG). Confirmatory

FPG was considered to be diagnostic for diabetes if it was ≥ 126 mg/dl (≥ 7.0 mmol/l). Participants who did not come for the confirmatory test were diagnosed as having diabetes if screening test of CFBG was ≥ 200 mg/dl (11.0 mmol/l) or CRBG was ≥ 270 mg/dl (15.0 mmol/l)

Data were analyzed with SPSS software (version 17.0; SPSS Inc., Chicago, IL). All results are presented as mean \pm S.D. or percentage, where applicable. Data analysis was performed in men and women separately. BMI was stratified in units of 0.5 for both men and women. A BMI ≤ 19.9 was considered as the reference to be consistent with other similar studies (36, 43). Logistic regression analysis was used to examine the independent relationship between the stratified BMI and the odds ratio of having diabetes, hypertension, both diabetes and hypertension and either diabetes or hypertension. P -value < 0.001 was considered to be significant.

The optimal sensitivity and specificity using different BMI cut-off values to predict the presence of diabetes and/or hypertension were examined by receiver operating characteristic curve (ROC) analysis. A greater area under the curve (AUC) indicates better predictive capability. An AUC = 0.5 indicates that the test performs no better than chance, and an AUC = 1.0 indicates perfect discrimination. An ideal test is one that reaches the upper left corner of the graph (100% true positives and no false positives). To determine the optimal BMI cutoff points, we computed and searched for the shortest distance between any point on the curve and the top left corner on the y-axis. Distance was estimated at each one-half unit of BMI according to the equation (44, 118):

$$\text{Distance in ROC curve} = \sqrt{(1-\text{sensitivity})^2 + (1-\text{specificity})^2}$$

Additional criteria were also used to select cut-offs, including the greater sum of sensitivity and specificity, the smallest misclassification rate, and the significant associations between BMI and risk factors based on the logistic regression. Diagnostic performance of BMI in predicting diabetes and hypertension was assessed by calculating AUC, sensitivity, specificity, predictive values (PPV and NPV), likelihood ratios (LR+ and LR-), false positive (FP), false negative (FN) and total misclassification rate.

4.4 RESULTS

A total of 195,851 participants (99,946 men and 95,905 women) were included in the analysis. Table 4.1 shows study population characteristics. The overall mean BMI of participants was 29.69 ± 6.00 . The mean weight and height for men were 80.45 ± 15.94 kg and 1.67 ± 0.07 m and for women were 73.29 ± 16.1 kg and 1.54 ± 0.07 m, respectively. The overall prevalence of obesity (BMI ≥ 30), overweight (BMI 25-29.9), diabetes and hypertension were 43.8, 35.1, 17.2 and 15.6%, respectively. Results of the initial screening test for participants with no previous diagnosis of diabetes or hypertension showed that 10.9% of participants had IFG, IGT or diabetes and 9% had hypertension. Analysis also showed that 59.3% of participants with diabetes and 46% of participants with hypertension had another confirmatory test. This means 4.4% and 4.9% of the total sample did not have the confirmatory test for the diagnosis of diabetes and hypertension. However, $> 70\%$ of participants who did not come for the confirmatory test for diabetes had IFG or IGT. For hypertension, 53.0 % of participants had diastolic blood pressure ranged from 140 to 150 mmHg and 77.3% of participants had diastolic blood pressure ranged from 90 to 100 mmHg

Table 4.1 Population characteristics (n = 195,851)

	Men	Women	Both genders
Weight (kg)	80.45 ± 15.94	73.29 ± 16.1	76.95 ± 16.43
Height (m)	1.67 ± 0.07	1.54 ± 0.07	1.61 ± 0.10
BMI (kg/m ²)	28.67 ± 5.26	30.75 ± 6.51	29.69 ± 6.00
Obese (%)	36.1	51.8	43.8
Overweight (%)	40.3	29.7	35.1
Diabetes (%)	15.9	18.6	17.2
Hypertension (%)	13.1	18.1	15.6

Table 4.2 displays details of the diagnostic performance of BMI in detecting diabetes and/or hypertension using optimal BMI cut-off values based on the shortest distance in ROC curve. Values ranged from 28.50 to 29.50 in men and from 30.50 to 31.50 in women. The AUC ranged from 0.566 to 0.625 in men and from 0.618 to 0.645 in

women (Figure 4.1). These values were statistically significantly higher than that would be expected by chance alone ($P < 0.001$).

The corresponding sensitivities and specificities in men ranged from 0.55 to 0.59 and 0.54 to 0.62 respectively, and in women were ranged from 0.58 to 0.63 and 0.58 to 0.62, respectively. LRs were close to 1.0 in both men and women. Positive likelihood ratio (LR+) ranged from 1.21 to 1.55 and negative likelihood ratio (LR-) ranged from 0.66 to 0.82. The positive predictive values (PPV) were small ranging from 0.08 to 0.25; on other hand, negative predictive values (NPV) were high ranging from 0.87 to 0.96. False positive (FP) and false negative (FN) rates were close to each other and ranged from 0.38 to 0.46 and from 0.37 to 0.45, respectively. The overall misclassification was unacceptably high across all the selected BMI values (> 0.80). These cut-offs were selected based on the shortest distance in the ROC curves. However, when other criteria applied, including the greater sum of sensitivity and specificity, and the smallest misclassification rate, the results were very similar (data not shown).

Table 4.3 shows the odds ratios of the association between diabetes and hypertension and BMI in men and women. A significant positive association was observed with BMI values starting at 21 to 23 and increasing progressively with higher BMI values for both genders. Table 4.4 displays the predictive value of BMI in detecting diabetes and/or hypertension using BMI cut-off values based on the lowest significant association between BMI and the risk factors from the logistic regression analysis. The diagnostic performance of BMI was also assessed using a BMI of 25 (the value recommended by WHO to identify overweight), but the results showed poor performance (data not shown).

Table 4.2 Diagnostic performance of BMI in detecting diabetes and/or hypertension using optimal BMI cut-off values based on the shortest distance in ROC curves in Saudi adults, Eastern province, 2004, (n = 195,851)

Risk factors	Gender	N	AUC (95% CI)	Cut-offs Kg/m ²	Sensitivity	Specificity	PPV	NPV	LR +	LR -	FP rate	FN rate	Misclassification Rate
Diabetes	Men	99946	0.566 (0.561-0.571)	28.50	0.55	0.54	0.19	0.87	1.21	0.82	0.46	0.45	0.91
	Women	95905	0.618 (0.614-0.622)	31.50	0.58	0.61	0.25	0.86	1.48	0.69	0.39	0.42	0.81
Hypertension	Men	99946	0.625 (0.62-0.63)	29.00	0.59	0.58	0.18	0.91	1.42	0.70	0.42	0.41	0.83
	Women	95905	0.645 (0.641-0.650)	31.50	0.60	0.62	0.25	0.87	1.55	0.66	0.39	0.41	0.80
Diabetes or Hypertension	Men	99946	0.594 (0.590-0.598)	28.50	0.58	0.56	0.13	0.92	1.30	0.76	0.44	0.42	0.86
	Women	95905	0.640 (0.636-0.643)	30.50	0.63	0.58	0.17	0.92	1.47	0.65	0.43	0.37	0.80
Diabetes and Hypertension	Men	99946	0.618 (0.611-0.625)	29.50	0.55	0.62	0.08	0.96	1.44	0.73	0.38	0.45	0.83
	Women	95905	0.643 (0.637-0.649)	31.50	0.61	0.59	0.12	0.94	1.55	0.66	0.41	0.39	0.80

AUC, area under the curve; PPV, positive predictive value; NPV, negative predictive value; LR+, positive likelihood ratio; LR-, negative likelihood ratio; FP rate, false positive rate; FN rate, false negative rate

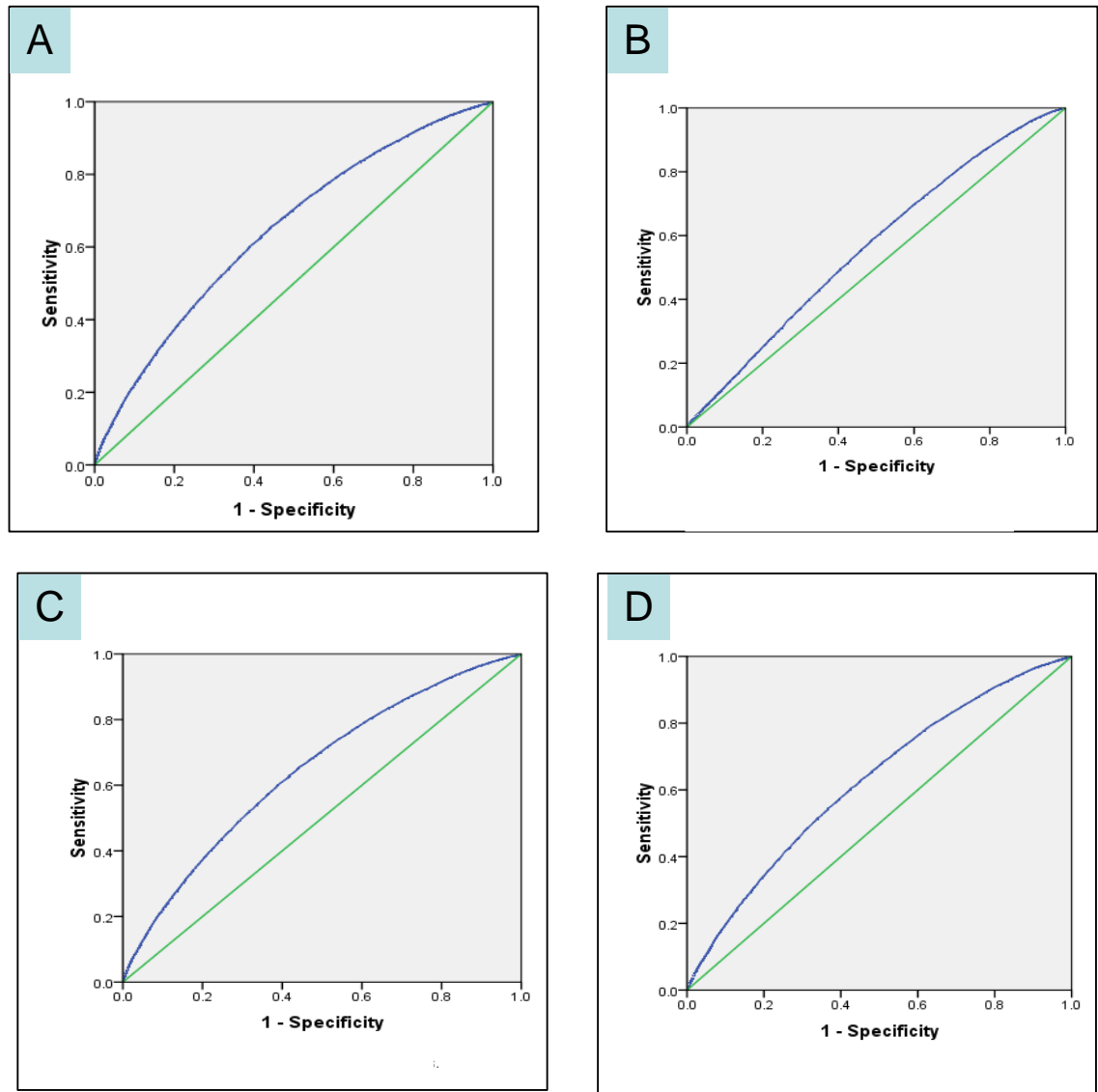


Figure 4.1: ROC curve showing the performance of BMI in predicting diabetes and hypertension (A: diabetes in women, AUC = 0.618 (95% CI 0.614 to 0.622); B: diabetes in men, AUC = 0.566 (95% CI 0.561 to 0.571); C: hypertension in women, AUC = 0.645 (95% CI 0.641 to 0.650); D: hypertension in men, AUC = 0.625 (95% CI 0.620 to 0.630))

Table 4.3 Risk of diabetes and/or hypertension associated with increasing BMI in Saudi adults, Eastern province, 2004, based on regression analysis (n = 195,851)

BMI	Diabetes Odds Ratio (95 % CI)		Hypertension Odds Ratio (95 % CI)		Diabetes & Hypertension Odds Ratio (95 % CI)		Diabetes or Hypertension Odds Ratio (95 % CI)	
	Men	Women	Men	Women	Men	Women	Men	Women
21	1.43* (1.16-1.78)	1.28 (0.98-1.67)	1.15 (0.89-1.48)	1.05 (0.82-1.34)	1.47 (0.93-2.30)	1.64 (1.09-2.45)	1.30* (1.08-1.55)	1.05 (0.86-1.29)
22	1.67* (1.38-2.03)	1.63* (1.29-2.05)	1.11 (0.88-1.41)	1.22 (0.98-1.50)	1.59 (1.06-2.40)	1.59 (1.10-2.32)	1.41* (1.20-1.66)	1.37* (1.15-1.63)
23	1.99* (1.67-2.38)	2.00* (1.63-2.47)	1.53* (1.25-1.87)	1.34* (1.10-1.62)	2.21* (1.53-3.17)	2.23* (1.59-3.11)	1.76* (1.53-2.04)	1.53* (1.30-1.79)
24	2.22* (1.88-2.63)	1.99* (1.63-2.44)	1.69* (1.40-2.05)	1.55* (1.29-1.86)	2.47* (1.74-3.49)	2.14* (1.55-2.97)	1.98* (1.72-2.27)	1.70* (1.46-1.97)
25	2.43* (2.07-2.86)	2.71* (2.24-3.28)	2.00* (1.66-2.38)	1.80* (1.51-2.13)	3.02* (2.16-4.21)	2.86* (2.10-3.89)	2.20* (1.93-2.51)	2.12* (1.84-2.45)
26	2.80* (2.39-3.28)	2.85* (2.34-3.44)	2.08* (1.74-2.49)	1.84* (1.55-2.19)	3.26* (2.35-4.53)	2.79* (2.06-3.79)	2.47* (2.17-2.81)	2.25* (1.95-2.59)
27	2.76* (2.36-3.23)	2.85* (2.36-3.44)	2.45* (2.06-2.92)	2.03* (1.72-2.40)	3.69* (2.67-5.12)	3.56* (2.64-4.79)	2.59* (2.28-2.95)	2.51* (2.19-2.88)
28	3.01* (2.57-3.51)	3.37* (2.80-4.05)	2.72* (2.29-3.24)	2.27* (1.93-2.67)	4.54* (3.29-6.26)	4.27* (3.19-5.71)	2.78* (2.45-3.16)	2.85* (2.49-3.27)
29	3.25* (2.78-3.80)	3.94* (3.29-4.73)	2.90* (2.43-3.45)	2.54* (2.16-2.99)	4.31* (3.11-5.95)	4.32* (3.23-5.79)	3.11* (2.74-3.54)	3.39* (2.96-3.88)
30	3.35* (2.87-3.92)	4.50* (3.76-5.39)	3.07* (2.58-3.65)	2.80* (2.39-3.29)	4.77* (3.46-6.59)	4.66* (3.48-6.22)	3.20* (2.82-3.64)	3.68* (3.22-4.20)
31	3.46* (2.96-4.05)	4.73* (3.96-5.66)	3.60* (3.02-4.28)	3.00* (2.56-3.52)	5.89* (4.28-8.12)	5.23* (3.92-6.99)	3.40* (3.00-3.87)	3.79* (3.324-3.4)

* Odds of disease significant (p < 0.001) when compared with BMI < 20 as a reference group

Table 4.4 Diagnostic performance of BMI in detecting diabetes and/or hypertension using optimal BMI cut-off values based on the significant association using logistic regression in Saudi adults, Eastern province, 2004, (n = 195,851)

Risk factors	Gender	N	AUC (95% CI)	Cut-offs kg/m ²	Sensitivity	Specificity	PPV	NPV	LR +	LR -	FP rate	FN rate	Misclassification rate
Diabetes	Men	99946	0.566 (0.561-0.571)	21	0.98	0.06	0.16	0.94	1.04	0.33	0.94	0.02	0.96
	Women	95905	0.618 (0.614-0.622)	22	0.98	0.08	0.20	0.95	1.07	0.25	0.92	0.02	0.94
Hypertension	Men	99946	0.625 (0.62-0.63)	23	0.95	0.13	0.14	0.95	1.09	0.38	0.87	0.05	0.92
	Women	95905	0.645 (0.641-0.650)	23	0.96	0.12	0.19	0.93	1.09	0.33	0.88	0.04	0.92
Diabetes or Hypertension	Men	99946	0.594 (0.590-0.598)	21	0.98	0.06	0.11	0.96	1.04	0.33	0.94	0.02	0.96
	Women	95905	0.640 (0.636-0.643)	22	0.97	0.09	0.13	0.95	1.07	0.33	0.91	0.03	0.94
Diabetes and Hypertension	Men	99946	0.618 (0.611-0.625)	23	0.96	0.12	0.06	0.98	1.09	0.33	0.88	0.04	0.92
	Women	95905	0.643 (0.637-0.649)	23	0.97	0.11	0.09	0.98	1.09	0.33	0.89	0.03	0.92

AUC, area under the curve; PPV, positive predictive value; NPV, negative predictive value; LR+, positive likelihood ratio; LR-, negative likelihood ratio; FP rate, false positive rate; FN rate, false negative rate

4.5 DISCUSSION:

This is the first population-based study to assess the ability of BMI to diagnose obesity and to determine the optimal BMI cut-off points for a Saudi population based on the prevalence of diabetes and hypertension. BMI has been shown to be associated with cardiovascular diseases such as diabetes and hypertension in Caucasians (119-121). These relations, which have been used in many studies to assess the accuracy of BMI in diagnosing obesity, have also been demonstrated in Middle East people including Saudis (2, 122, 123). The use of a reliable tool with optimal cut-off points for obesity diagnosis is very important to establish consequent public health policies, treatment protocols and to determine the correct prevalence of obesity for each population.

ROC curve analysis, using the endpoints of presence of diabetes or hypertension showed that the optimal BMI cut-off points for overweight were ranged 28.50 to 29.50 for men and from 30.50 to 31.50 for women depending on the risk factor being studied. These values are higher than the suggested values by WHO, particularly in women. One possible reason for the high value for women is the short stature in this group with a mean height of 1.54 m. Lara-Esqueda *et al.*(124) conducted a large cross-sectional study (n=119, 975) to assess the ability of the BMI to predict obesity-associated morbidity in Mexican participants with normal or short stature. The results showed that the BMI value with the best diagnostic proficiency ranged from 27 to 29 in normal stature women and from 28 to 29 in short stature women. The authors concluded that the proficiency of BMI as a diagnostic test is poor in short stature participants. However, lowering the BMI threshold did not improve the ability of BMI to predict diabetes and hypertension in that study and neither did it in our study as well.

The overall performance of the ROC curve can be quantified by estimating the AUC which ranged from 0.57 to 0.65 (Table 4.4). An area of 1.0 is perfect and an area < 0.5 is considered non-informative. Our results indicated that the ROC analysis was close to a non-informative test (Figure 4.1). To avoid misleading conclusion, several other diagnostic characteristics of BMI as a tool for obesity diagnosis were calculated.

ROC curve analysis showed that the corresponding sensitivities and specificities were poor (< 0.63 and < 0.62 , respectively). This indicates that the percentage of people identified as having the risk factors and the percentage of people who were identified as not being at risk were less than 63% of total population. Both positive likelihood ratio (LR+) and negative likelihood ratio (LR-) were close to 1.0, indicating to a minimal increase in the likelihood of the presence of the risk factor if the test is positive and a minimal decrease in the likelihood if the test is negative. Positive predictive values (PPVs) were small and ranged from 0.08-0.25. This indicates that the proportion of overweight and obese people who were classified correctly as overweight or obese was $< 25\%$. On other hand, the proportion of non-overweight or non-obese people who were classified correctly ranged from 86% to 96% as indicated by the negative predictive values (NPVs). The FP and FN rates were high and close to each other in both women and men. The overall misclassification was very high and exceeded 80% of the total population across all the selected BMI cut-off points.

Throughout this paper the technical statistical term “diagnostic performance” has been used to characterize the relationship between BMI and presence of diabetes or hypertension. This does not mean that BMI is used a diagnostic clinical test for these conditions. However clinicians will generally be more concerned about false negatives, when patients at risk may be overlooked for treatment. By using BMI as a tool for assessing the metabolic risks of being overweight or obese, these findings suggest 37 to 45% of people with risk factors would be incorrectly identified as healthy, as indicated by the FN rate. The percentage varies depending on the risk factors being studied. This finding is also supported by the high values of specificities and NPVs and the values of LR-. The use of the higher BMI cut-off values suggested by the ROC analysis (Table 4.2) would misclassify large percentages of people with risk factors as being healthy who might then miss the opportunity of treatment.

To reduce the large chance of such misclassification, we attempted to identify cut-offs based on the observed significant association between BMI and risk factors. Regression analysis showed that the risk of diabetes and/or hypertension was significantly increased at BMI values as low as 21-23 and increased progressively as BMI increased. Applying

this criterion to identify the cut-off values resulted in improvements in sensitivity, NPV, LR-, FN and worsening in specificity, PPV, LR+, FP and the overall misclassification rate. Using these lower BMI cut-offs resulted in a very small FN rate ranging from 0.02 to 0.05. Therefore, most of people with risk factors were correctly identified as at risk. This finding may suggest obesity management should be considered even at a quite low BMI values in the Saudi population.

This is not the first study to suggest the presence of significantly increased risk of co-morbidities at BMI values less than 25. In a Chinese population in Hong Kong, diabetes and hypertension was also reported to increase from a BMI value of 22 onwards (51). However, the use of such low cut-offs would lead to large misclassification of healthy people as being at risk, as indicted by the high values of sensitivities and FP rates. This fact that could cause unnecessary and costly diagnostic testing. Overall the total misclassification rate was unacceptably high, even with the use of different BMI cut off points and different selection criteria, and even with the use of the recommended value by WHO (BMI=25). These findings illustrate the significant limitations in using BMI alone for obesity diagnosis in Saudi Arabian population.

To our knowledge, only one study has assessed the optimal BMI cut-off points on a sample from Arab populations of the Middle East, and was conducted with 1420 Omani adult subjects (42, 43). The authors analyzed that study using two different definitions of cardiovascular disease (CVD) risk. When CVD risk was identified as the presence of at least two out of three risk factors (hyperglycemia, hypertension and dyslipidemia), the optimal BMI cut-off points for men and women were 23.2 and 26.8, respectively (43). Using the Framingham risk score, the optimal cut-off points for men and women were 22.6 and 22.9, respectively. (42) The use of the first definition resulted in moderate sensitivity (71.0) and poor specificity (53.7) with AUC of 0.65 in men and poor sensitivity (46.8) and moderate specificity (76.5) with AUC of 0.66 in women. Using the Framingham risk score resulted in good sensitivity (80.3), very poor specificity (37.3) and AUC of 0.60 in men, and good sensitivity (84.2), poor specificity (45.1) and AUC of 0.64 in women. Both methods indicated that waist to hip ratio (WHR) and waist circumference (WC) were better surrogates to detect CVD risk

compared to BMI. One major limitation of that study was the small sample size, which may limit the generalizability of the findings to other Middle Eastern populations. Unfortunately, other diagnostic characteristics of BMI as a tool for obesity diagnosis were not calculated.

Most of the other previous studies that have been conducted in non-Caucasian populations did not assess the misclassification rate. (36, 41-44, 47, 48, 51, 125) However, one study conducted in Asian Indians also indicated a high overall misclassification rate particularly in women (49). Those authors concluded that the BMI did not accurately predict overweight in that population.

Several reasons may explain the weakness of BMI as a tool to classify obesity in this large Saudi Arabian sample. First, BMI does not reflect fatness uniformly in all population and different ethnic groups (31, 49, 126, 127). The previous Omani study indicated that WHR and WC better predict CVD risk than BMI.(42, 43). This may suggest the importance of including a measure of abdominal obesity in classifying obesity in Middle East populations such as those in Oman and Saudi Arabia. Second, the short stature of Saudi women could be limiting the usefulness of BMI in this population.

Strengths and limitations of this study should be recognized. The very large number of participants provided sufficient cases at each single unit of BMI to assess the significance of association between each BMI unit and the presence of diabetes or hypertension. In contrast, the cross-sectional nature of the survey and the absence of measurements of other relevant obesity related co-morbidities, such as hypercholesterolemia and hypertriglyceridemia, could be considered as limitations in this study. The sample was a convenience non-random sample. However, it is fairly representative of the target population. When we compared the sub-classification of respondents with the latest census done in the eastern province regarding to age and sex, the characteristics of the study sample were similar (115). The relatively low response rate of participants coming for the confirmatory diagnostic test and the reliance on a single screening test using capillary blood glucose may have had an effect on the low performance of BMI in predicting diabetes and hypertension in this study. Also the

relatively high values chosen for the definition of diabetes and hypertension for participants who did not come for the confirmatory test may have had a similar negative effect on the performance of BMI. However, > 70% of participants who did not come for the confirmatory test for diabetes had IFG or IGT based on CFBS and CRBS. The situation was similar for hypertension, therefore, most of participants who were diagnosed as not having the conditions were not based on the high values chosen for the definition of diabetes and hypertension. Whether similar conclusions would be reached had this study been done on a random sample with avoidance of the above-mentioned limitations or not remains to be seen in future studies. Similarly, it is not clear if such conclusion would be obtained in a national sample covering other regions of Saudi Arabia.

In conclusion, the diagnostic usefulness of BMI alone in defining obesity is limited in this large population of Saudi adults in the Eastern Province, for both men and women. Future studies incorporating other measures such as WC, WHR, body fat composition, or a combination of tools, need to be conducted to determine the best method to classify obesity accurately in the Saudi population. It seems likely however that limiting management of obesity to those individuals with a $BMI \geq 30$ may mean that many Saudis at risk of serious co-morbidities could be missing necessary interventions. Due to the inadequate performance of BMI as a predictive tool for health risk, dietitians in Saudi Arabia may need to consider additional direct assessment of some risk factors as part of their initial nutritional assessment, particularly blood pressure and blood glucose. This has implications for the future training and skill development of dietitians in Saudi Arabia.

CHAPTER 5

VALIDITY OF THE BODYGEM™ CALORIMETER AND PREDICTION EQUATIONS FOR THE ASSESSMENT OF RESTING ENERGY EXPENDITURE IN OVERWEIGHT AND OBESE SAUDI MALES

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AA was responsible for study design and analysis, participants recruitment, technical works and preparation of the manuscript. PW assisted in editing the manuscript. MB assisted with the data analysis. All authors involved in critical discussions of study design and outcomes.

CONTENTS:

- 5.1 Abstract
- 5.2 Introduction
- 5.3 Methods and Materials
- 5.4 Results
- 5.5 Discussion

5.1 ABSTRACT

Objective: To assess the validity and reliability of resting energy expenditure (REE) in a sample of overweight and obese Saudi males, measured with the BodyGem device (BG) and using the Whole Room Calorimetry (WRC) as a reference; and to evaluate the accuracy of predictive equations.

Research Methods & procedures: 38 subjects (mean \pm SD, age 26.79 \pm 3.65 years, BMI, 31.0 \pm 4.8) were recruited. REE was measured with the WRC and BG and also calculated using 7 prediction equations. Accuracy was defined as $\pm 10\%$ of the measured REE by WRC. Differences $> \pm 250$ kcal were considered clinically unacceptable. Mean differences, bias, percent of bias, accurate estimation, underestimation and overestimation were calculated.

Results: Repeated measures with the BG were not significantly different (accurate prediction: 81.6%; Bias: 21.05 \pm 110.28 kcal/d; bias %; 1.10 \pm 6.33, $p > 0.24$) with limits of agreement ranging from + 241.61 to – 199.50 kcal and clinically acceptable. Mean REE measured by BG was significantly less than WRC values (accurate prediction: 47.4%; Bias: - 173 \pm 262 kcal/d; bias %; 11.0 \pm 14.63, $p < 0.05$) and with wide limits of agreement that would be clinically unacceptable. Harris-Benedict, Schofield and WHO were the most accurate equations, able to estimate REE within 10% of the measured REE, but none of these equations seem appropriate to predict the REE of individuals in this population.

Conclusion: There was poor agreement between the REE measured by WRC compared to BG or predictive equations. However, the BG assessed REE accurately in 47.4% of the subjects on an individual level.

5.2 INTRODUCTION

Obesity has become a global epidemic and the prevalence of both overweight and obesity is still increasing in Saudi Arabia (2-4, 97). Weight-reduction programs usually aim to establish an achievable goal for weight reduction and an achievable goal for daily food intake. Successful weight loss requires sustained negative energy balance, or the maintenance of a daily dietary intake with fewer calories than are expended. Therefore, clinical practitioners may need to assess individuals' total energy expenditure (TEE). TEE is divided into three main components: REE, the thermic effect of food, and energy expended in physical activity. REE represents the majority (60-75%) of TEE in sedentary people (128), thus accurate assessment of REE is an important factor in determining the appropriate energy intake target for overweight and obese individuals.

The accurate assessment of REE requires sophisticated techniques such as the use of Whole Room Calorimetry (WRC) and metabolic carts. Indirect calorimetry with WRC is often considered the "gold standard" for determining REE. However, the equipment is expensive and the technique requires highly skilled personnel. Therefore, this technique is impractical for most clinical and community settings.

Recently, researchers have developed relatively new hand held calorimetry devices. These devices can be used in the clinical and educational settings due their portability, low cost, small size and ease of use. To date there is only a limited number of studies that have validated the use of these devices (59, 129-138) and the results have been inconsistent (57). Furthermore, despite the potential value of these devices in energy assessment and obesity management, none of the previous studies was designed to evaluate their use with obese subjects. Given the limitations on the availability of indirect calorimetry and the uncertainty about the accuracy of the handheld calorimeter devices (57), clinicians usually use predictive equations to assess energy requirements.

Predictive equations have generally been developed in healthy people. For some equations, overweight and obese people were included, but their relative contribution to the final equation often remains unclear. It is unclear whether predictive equations derived from one population can be applied to a different population, and many studies

showed that the race has an influence on metabolic rate (72, 73, 108, 139, 140). There is also no doubt that obesity is influenced by genetics. Many genes have been identified to effect obesity (110, 111, 141, 142) after the first investigation of the leptin gene (143). The effect of gene can also be race specific. Nicklas et al. (144) reported that REE increases linearly with plasma leptin concentration in obese postmenopausal African-American women, but in Caucasian women REE is not related to circulating leptin levels. Most of the predictive equations have been derived from American and European populations. However, despite the important role of these equations in the management of obesity, no equation has been developed or validated for the Saudi population. Therefore, this study focused on the validation of these equations in overweight and obese Saudi subjects due to the lack of existing research in this area.

The goals of this study were to assess the validity of the BodyGemTM (BG) and predictive equations for estimating REE in overweight and obese Saudi subjects and to provide clinicians with recommendations regarding the use of these techniques.

5.3 METHODS AND MATERIALS

5.3.1 Participants:

A total of 38 overweight or obese Saudi male participants aged 20 to 34 years were eligible and recruited for the study. Characteristics of the sample are shown in Table 5.1. The study was conducted at the University of Wollongong (UOW) in Australia. Participants were recruited by email advertisements through the Saudi Students Association in UOW (Appendix H). A phone interview was used to screen applicants (Appendix I). Informed consent was obtained from each participant (Appendix J & K). Apparently healthy participants with BMI ≥ 25 kg/m² and aged more than 18 years were included in the study. Participants were not on any particular diet and had maintained a steady weight for the previous 3 months (varying ± 3 kg from the initial weight). Participants with diabetes or major illness or chronic diseases that effect REE were excluded. Ethics approval for the study was given by the UOW Human Research Ethics Committee (Appendix L).

Table 5.1 Subjects characteristics (n=38)

Variables	Mean \pm SD	Range
Age (y)	26.79 \pm 3.65	20-34
Height (cm)	1.72 \pm 0.07	1.61-1.96
Weight (kg)	92.01 \pm 18.05	66.30 – 174.00
BMI (kg/m ²)	31.03 \pm 4.79	25.10-50.00
Body fat (%)	28.76 \pm 5.29	19.00-41.00

5.3.2 Anthropometry

Body weight, height and percent body fat were measured with subjects in an upright position in minimal clothing and without shoes using scales with a bioelectrical impedance component (Tanita TBF-622, Tanita Corporation, Arlington Heights, IL 60005 USA) and a stadiometer.

5.3.3 Measurements of REE

5.3.3.1 WRC method

REE was measured on two mornings, one measure with the WRC and two measures with the same BG device (HealtheTech Inc., Golden, CO, USA) separated by approximately a one week period. The protocol for measurements required that participants had been fasting and kept off smoking, coffee and tea for at least 10 hours. Furthermore, the subjects had to refrain from drinking alcohol or doing any physical activity in the 24 hours preceding the morning of the measurements

The WRC technology was used as a reference method for REE measurements. The UOW facility, which has been described in detail elsewhere (56), consists of two separate air-tight, ventilated and air-conditioned chambers (3 x 2.1 x 2.4 m), each with a bed, desk, chair, hand basin TV/VCR, computer, phone and toilet. Temperature was maintained at 20-24 °C and ventilated with fresh air measured by a solid-state gas sample drying system (Peltier dryer, Maastricht Instruments, Netherlands). Oxygen concentration was measured using a paramagnetic oxygen analyzer (Stable System Inc., PA-IB, Las Vegas, NV, USA) and carbon dioxide was measured using an infrared analyzer (Stable System Inc., Las Vegas, NV, USA). Oxygen (O₂) and carbon dioxide (CO₂) measurements were corrected to standard temperature, pressure, and dry from fresh air temperature, water, vapor pressure and barometric pressure measurements. Data were collected by means of a data acquisition system, connected to a computer to store and analyze the data. The differential O₂ and CO₂ analyzers were manually calibrated against fresh air for zero readings. O₂ and CO₂ span were calibrated by diluting the fresh air supply to the analyzer sample inlet. Analyzers were calibrated at the beginning of each study day. Rates of oxygen consumption (VO₂) and carbon dioxide production (VCO₂) are calculated from the measured inflow and outflow (FO₂ and FCO₂) according to Schoffelen et al. (145) with minor modifications. Measurement noise in the raw data was reduced by smoothing with cubic spline functions. The room was also calibrated approximately every 3 weeks by means of the methanol burning test. VO₂ and VCO₂ consumption were converted to REE using the abbreviated Weir (55) formula:

$$\text{REE} = \text{VO}_2 (3.941) + \text{VCO}_2 (1.106),$$

where REE is measured in kcal/day and VO_2 and VCO_2 in L/d.

For REE measurements, each subject was asked to stay in the chamber for approximately two hours and measurement was started in the second hour while the subject was lying quietly on a bed. The first hour was sufficient to reach steady-state levels in the subject and accurate measurements in the WRC. The WRC gives the measurement for O_2 consumption and CO_2 production at 10-minute intervals. The measurements were considered only when the subjects had reached a steady-state condition when respiratory quotient (RQ), O_2 consumption and CO_2 production were stable for at least 3 consecutive readings (coefficient variation (CV) < 10%). Otherwise, the test results were discarded.

5.3.3.2 BG method

Measurement of REE using the BG was taken immediately after the measurement of REE in the WRC while the subject was still lying down on the bed. Subjects were asked to wear a nose clip and to breathe into a disposable plastic mouth-piece for approximately 10 minutes. Normally, BG devices are programmed to begin collecting data when the first breath is detected and continue until either a steady state or 10 minutes is reached. VCO_2 is not measured by BG devices and an RQ of 0.85 is assumed. These devices are autocalibrated prior to each measurement. For the second REE measurements with the BG, participants were asked to rest for 25 minutes before measurements were taken. This time period was sufficient to reach steady-state levels in subjects.

Since the BG does not display the measured oxygen consumption, the Weir equation and the assumed 0.85 RQ value was used to calculate VO_2 and the following equation was derived:

$$\text{VO}_2 \text{ (L/d)} = \text{REE (kcal)} / 4.8811$$

To assess the source of error in BG, REE was estimated using the mean measured oxygen by BG and the actual (measured by WRC) and fixed (0.85) RQs. Also REE was estimated using mean oxygen measured by WRC and BG and the actual RQ. The following equation was used (55):

$$\text{REE (kcal/d)} = (3.941 * \text{VO}_2) + (0.85 * 1.106 * \text{VO}_2)$$

Where VO_2 is measured in L/d

5.3.4 Prediction of REE

A set of seven prediction equations was used to calculate REE for each subject (20, 106, 146-150) (Table 5.2). These equations are commonly used in clinical practice particularly in Saudi Arabia (23, 61). REE was calculated using actual body weight. For the Harris-Benedict equation only, all subjects with a BMI more than 30 had an adjusted weight substituted in the equation: Adjusted weight (kg) = [(actual weight – ideal weight) * 0.25] + ideal weight (68). Since the Harris-Benedict equation is the most commonly used equation by Saudi dietitians (23), REE was calculated by 3 different versions of that formula that are in common use clinically in Saudi Arabia: using the actual body weight, the adjusted body weight, and with adjustment of the REE by a factor of 1.1.

Table 5.2 Energy predictive equations for men

- **Harris Benedict equation, 1919 (106):**

$$\text{REE (kcal/d)} = 66 + 13.7 \times \text{weight (kg)} + 5 \times \text{height (cm)} - 6.8 \times \text{age (y)}$$

- **Owen equations, 1987 (148):**

$$\text{REE (kcal/d)} = 879 + 10.2 \times \text{weight (kg)}$$

- **Schofield equations, 1985 (146):**

- weight only:

$$18-30 \text{ y } \text{REE (MJ/d)} = 0.063 \times \text{weight (kg)} + 2.896$$

$$31-60 \text{ y } \text{REE (MJ/d)} = 0.048 \times \text{weight (kg)} + 3.653$$

- weight and height:

$$18-30 \text{ y } \text{REE (MJ/d)} = 0.063 \times \text{weight (kg)} - 0.042 \times \text{height (m)} + 2.953$$

$$31-60 \text{ y } \text{REE (MJ/d)} = 0.048 \times \text{weight (kg)} - 0.011 \times \text{height (m)} + 3.670$$

- **Mifflin equations, 1990 (148):**

$$\text{REE (kcal/d)} = 9.99 \times \text{weight (kg)} + 6.25 \times \text{height (cm)} - 4.92 \times \text{age (y)} + 5$$

- **World Health Organization (WHO) equations, 1985 (147):**

- Weight only:

$$18-30 \text{ y } \text{REE (kcal/d)} = 15.3 \times \text{weight (kg)} + 679$$

$$31-60 \text{ y } \text{REE (kcal/d)} = 11.6 \times \text{weight (kg)} + 879$$

- Weight and height:

$$18-30 \text{ y } \text{REE (kcal/d)} = 15.4 \times \text{weight (kg)} - 27 \times \text{height (cm)} + 717$$

$$31-60 \text{ y } \text{REE (kcal/d)} = 11.3 \times \text{weight (kg)} + 16 \times \text{height (cm)} + 901$$

- **Ireton-Jones equation for obese, 1989 (149):**

$$\text{REE (kcal/d)} = 606 \times 1 + 9 \times \text{weight (kg)} - 12 \times \text{age (y)} + 1444$$

- **Bernstein equation, 1983 (20):**

$$\text{REE (kcal/d)} = 11.02 \times \text{weight (kg)} + 10.23 \times \text{height (cm)} - 5.8 \times \text{age (y)} - 1032$$

5.3.5 Data analysis

The data are reported as mean \pm SD. The level of bias between the REE measured by WRC and REE measured by BG or predicted by equations was evaluated using Bland-Altman limits of agreement analysis (differences between the two techniques are plotted against the averages of the two techniques) (52). A priori, an error of greater than 250 kcal from REE measured by WRC was considered clinically unacceptable (133). The paired t test was used to determine the statistically significant differences between REE measured by WRC and REE measured by BG or predicted from the applied equations. Regression analysis was performed to examine whether there were relationships between the accuracy of BG and other factors such as age, BMI and body fat.

The percentage of participants that had an REE estimated within $\pm 10\%$ of the REE measured by WRC was considered a measure of accuracy on an individual level. Pearson's correlation was used to compare measured REE by WRC to BG and each predictive equation. A one sample t test was used to compare the measured RQ with the fixed (0.85) RQ used by BG. *P* values < 0.05 were considered statistically significant. Statistical analysis were performed using SPSS (Version 15.0, 2006, SPSS Inc., Chicago, IL). Estimation between 90% and 110% of the REE measured by WRC was considered an accurate estimation, estimation $< 90\%$ of the measured REE was classified as underestimation, and estimation $> 110\%$ of the measured REE was classified as an overestimation.

5.4 RESULTS

5.4.1 Subjects

Thirty eight Saudi male participants completed the study. Three subjects did not repeat the measurement of BG due discomfort caused by the device in the first visit. Sample characteristics are presented in Table 5.1. The mean age was 26.79 ± 3.65 years and BMI was 31.03 ± 4.79 kg/m². Results are presented for the whole study group, since the subgroups (overweight vs obese subjects) did not show significant differences in terms of the accuracy of the BodyGem and predictions equations.

5.4.2 Reliability of BG

Paired t tests and Bland-Altman analysis indicated that BG is a reliable device for measurement of REE, with good between-test reproducibility. The mean REE values for the two measurements of BG were not statistically different from each other (1907 ± 381 vs 1886 ± 394 kcal/day) ($P > 0.24$) (Table 5.3). The mean difference between the two readings was 21.01 ± 110.28 kcal, with limits of agreement ranged from $+ 241.61$ to $- 199.50$ kcal (Figure 5.1). These values were within the 250 kcal margin of acceptable error. The correlation coefficients of the two BG REE measurements were statistical significant ($r = 0.96$, $P < 0.01$). When individual BG REE values were compared to each other, 81.6% were within the acceptable 10% difference.

5.4.3 Validity of BG

Mean REE and oxygen consumption were significantly different between WRC and BG, with a mean difference of 173 ± 262 kcal/d and 20.00 ± 41.94 ml/min, respectively. Limits of agreement of REE ranged from 697 to $- 351$ kcal. These values were clinically unacceptable. Bland-Altman plots did not show any specific trend (Figure 5.2). However, BG underestimated REE and VO₂ by 11.0 ± 14.63 and $9.07 \pm 16.36\%$, respectively. Mean RQ measured by WRC (0.81 ± 0.15) was significantly lower than the fixed RQ (0.85) used to calculate REE by BG.

To assess the source of errors in BG, REE was calculated using the oxygen uptake as measured by BG (269.82 ml/min) and the actual (0.81) or fixed (0.85) RQ values and this result in an estimated REE of 1896 and 1879 kcal/d, respectively. The use of the

fixed RQ (0.85) in the modified Weir equation introduced a mean error of 1.0% or 18 kcal/d. Similarly, REE was calculated using the actual RQ (0.81) and the measured oxygen by WRC (289.82 ml/min) and BG (269.82 ml/min) and this result in an estimated REE of 2019 and 1879 kcal/d, respectively. Therefore, measurement of VO_2 by BG introduced a mean error of 7.4% or 140 kcal/d.

Accuracy of BG was not affected by the subjects' physical measurements. Logistic regression analysis did not show any significant relationships between the accuracy of BG and other factors such as age, weight, height, BMI and % body fat.

Table 5.3 Accuracy of REE, VO₂ and RQ measured by WRC and BG

	BG1 (n=38)	BG2 (n=35)
REE (kcal/d)	1907±380.61	1886±393.78
Bias	21.05±110.28	
% Bias	1.10±6.33	
	Mean BG	WRC
REE (kcal/d)	1896±383	2069±336 *
Bias	173±262	
% Bias	11.0±14.63	
	Mean BG	WRC
VO₂ (ml/min)	269.82±54.47	289.82±52.10 *
Bias	20.00±41.94	
% Bias	9.07±16.36	
	Mean BG	WRC
RQ	0.85 (fixed value)	0.81±0.15 **
Bias	- 0.37	
% Bias	- 4.71	

Data are means ± S.D

Bias = measured by WRC – measured by BG

% Bias = (measured by WRC – measured by BG * 100)/measured by BG

* Significantly different from BG, $P < 0.05$ (P value from paired t test)

** Significantly different from BG, $P < 0.05$ (P value from one sample t test)

5.4.4 Predictive equations

All the equations were highly correlated with the measured REE by WRC. Paired t test indicated that Schofield, WHO and Harris-Benedict equations were the most accurate equations in the study sample (Table 5.4). The mean numerical bias and the mean percentage bias estimates for Schofield (wt), Schofield (wt & ht), WHO (wt), WHO (wt & ht) and Harris-Benedict were 20 ± 22 kcal (underestimation: $1.0 \pm 10.4\%$), 28 ± 22 kcal (underestimation: $1.0 \pm 10.4\%$), 13 ± 22 kcal (underestimation: $1.0 \pm 10.3\%$), 15 ± 21 kcal (underestimation: $1.0 \pm 10.2\%$) and 60 ± 197 kcal (underestimation: $3.0 \pm 9.9\%$), respectively. The accuracy of the predictions were 60.5%, 65.8%, 63.2%, 65.8% and 68.4%, respectively.

The Harris-Benedict equation showed the highest percentage of accurate prediction (68.4%) but with higher percentages of underestimation (28.9%) and bias (3%) compared to Schofield and WHO equations. When adjusted body weight was used and a factor of 1.1 was multiplied to the equation, the percentage of accurate prediction decreased (39.5 and 47.4%, respectively).

The five other equations were not accurate according to the paired t test. However, the Owen and Mifflin equations showed prediction accuracies of 60.5% and 63.2%, respectively. Both equations underestimated REE in all subjects. On the other hand, the Ireton equation for obese people overestimated REE for all subjects with a very low accurate prediction percentage (13%). The Bernstein equation was the least accurate equation and underpredicted REE in all subjects. In general, all predictive equations tend to underestimate REE in this study sample except the Harris-Benedict (with 1.1x adjustment) and the Bernstein equations.

To avoid misleading conclusions, an additional evaluation of the accuracy using the Bland-Altman analysis and the two SD limit of agreement was used. According to the numerical and bias percentage, the lowest values were shown by the WHO (wt) equation; however, the extent of error could be between + 450 kcal and – 425 kcal daily. The Harris-Benedict equation had the highest accurate prediction percentage, but the error range was + 454 kcal to – 335 kcal/day. The errors across all equations were more

than the 250 kcal maximum stated a priori (Figure 5.3). Upon visual examination of the Bland-Altman plots, there appeared to be more variation as the mean REE increased.

Table 5.4 Accuracy of REE measured by BG and REE predicted from prediction equations

Tools	REE (kcal/d)	Bias	Bias %	Accurate estimation	Underestimation (%)	Overestimation (%)	r
WRC	2069±336	-	-	-	-	-	-
BG	1896±383*	173±262	- 11.0 ± 14.63	47.4	47.4	5.3	0.74
HB	2010±267	60±197	- 3.0 ± 9.9	68.4	28.9	2.6	0.81
HB*1.1	2211±294*	-141±198	+ 6.9 ± 9.0	47.4	5.3	47.4	0.81
HB (ABW)	1827±150*	243±278	- 13.0 ± 14.7	39.5	57.9	2.6	0.57
Owen	1818±184*	252±227	- 14.0 ± 12.1	60.5	39.5	0.0	0.77
Schofield, wt	2050±232	20±219	- 1.0 ± 10.4	60.5	18.4	21.1	0.76
Schofield, wt & ht	2042±231	28±219	- 1.0 ± 10.4	65.8	18.4	15.8	0.76
Mifflin	1867±207*	203±204	- 11.0 ± 10.6	63.2	36.8	0.0	0.82
WHO, wt	2057±235	13±218	- 1.0 ± 10.3	63.2	15.8	21.1	0.76
WHO, wt & ht	2055±222	15±214	- 1.0 ± 10.2	65.8	15.8	18.4	0.78
Ireton	2557±161*	-487±227	+ 19.0 ± 9.1	13.2	0.0	86.8	0.81
Bernstein	1585±246*	485±193	- 31.0 ± 12.8	0.0	100	0.00	0.82

Bias: REE measured by WRC – REE measured by BG or predicted by applied equations

Bias %: [(REE measured by WRC – REE measured by BG or predicted by equations) * 100] / REE measured by BG or predicted by equations

Accurate estimation: percentage of all subjects whose REE was within 90% to 110% of measured REE by WRC

Underestimation: percentage of all subjects whose REE was less than 90% of measured REE by WRC

Overestimation: percentage of all subjects whose REE was more than 110% of measured REE by WRC

* Statistically difference between REE measured by WRC and REE measured by BG or predicted by equations on a two-tailed paired *t*-test (*P* < 0.05)

r: Pearson's Correlation Coefficient between REE measured by WRC and REE measured by BG or predicted by applied equation

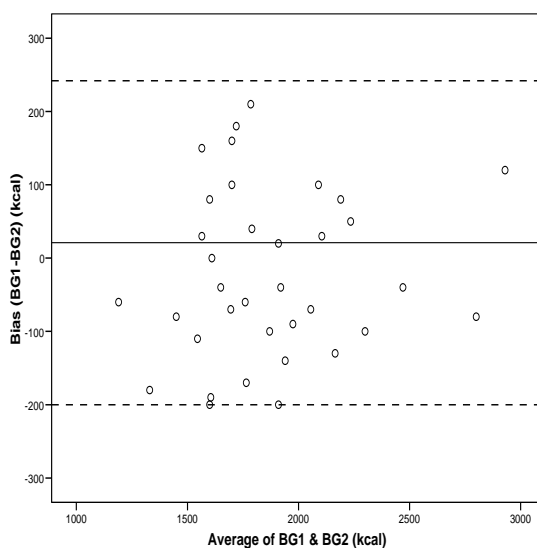


Figure 5.1 Bland-Altman plot of differences in REE measures between two BG measurements with the same device in overweight and obese Saudi males (n=35). Solid line indicates mean difference between the two measures and dashed lines indicate mean \pm 2 standard deviation (s.d.) (limits of agreement)

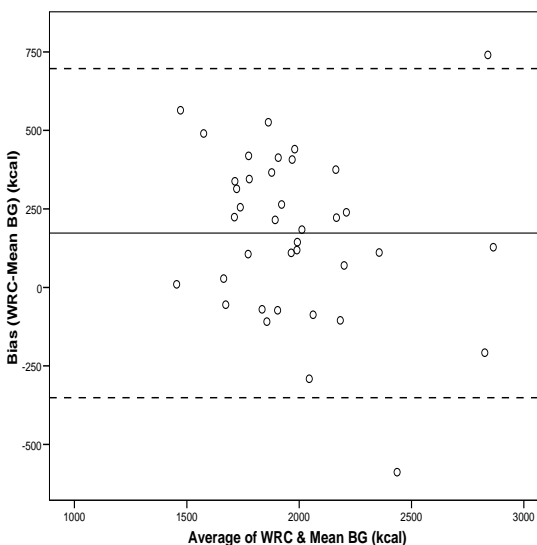


Figure 5.2 Bland-Altman plot of differences in REE measures between one WRC measure and the mean of two BG measurements in overweight and obese Saudi males (n=38). Solid line indicates mean difference between the two measures and dashed lines indicate mean \pm 2 standard deviation (s.d.) (limits of agreement)

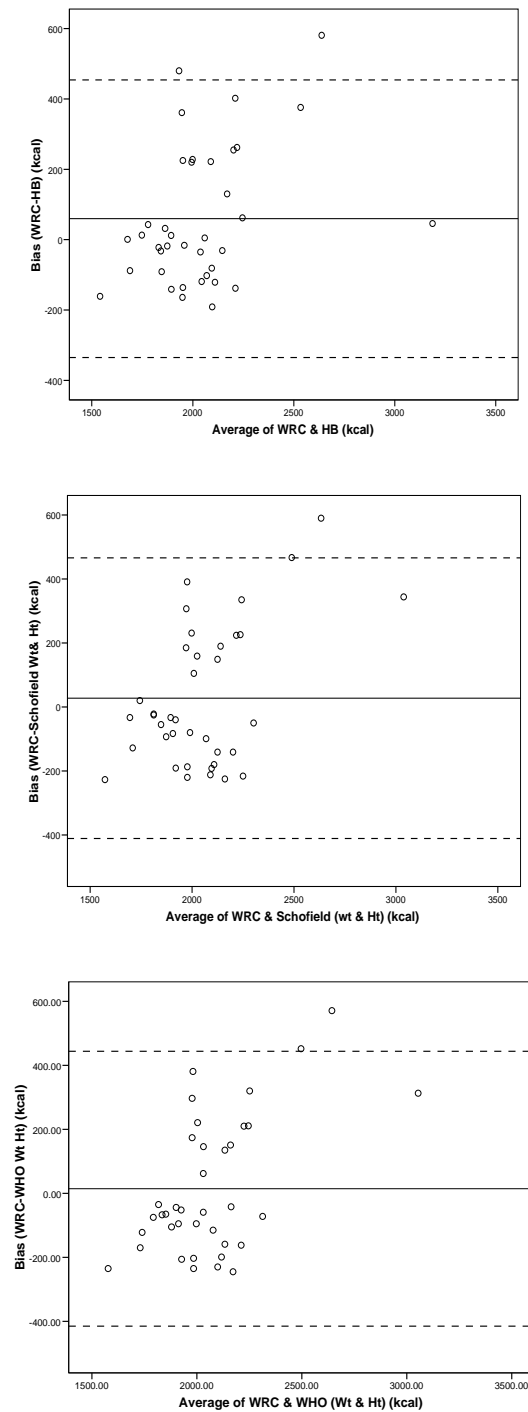


Figure 5.3 Bland-Altman plot of differences in REE measures between WRC measure and 3 predictive equations (HB, WHO, Schofield) in overweight and obese Saudi males (n=38). Solid line indicates mean difference between the two measures and dashed lines indicate mean \pm 2 standard deviation (s.d.) (limits of agreement)

5.5 DISCUSSION

There has been limited research conducted to assess the validity of the handheld indirect calorimeters in samples of overweight and obese subjects. To our knowledge this is the first study designed to assess the accuracy of predictive equations in a sample from a Middle Eastern population.

The results of this study showed that the mean bias between REE measured twice by BG was neither statistically nor clinically different. Therefore, the device can be considered to be reliable (ie consistent) in the measurement of REE. However, mean measurements of REE with the BG differed significantly, both statistically and clinically, from the mean REE measured with the WRC. BG underestimated REE by 11% (about 173 kcal/d).

Five studies have investigated the use of BG for REE measurements (129, 130, 137, 151, 152). All these studies demonstrated within instrument reliability. For validity, Herring (152) found that two of three BG devices used in her study gave consistently lower values (12% and 9%) compared to the metabolic carts. The third BG device provided an accurate measurement for REE. Similarly, Blanton *et al.* (151) found that the BG device significantly underestimated REE by about 95 kcal compared to the metabolic carts. On the other hand, two studies reported that BG significantly overestimated REE compared to metabolic carts (130, 137). Both authors adjusted their findings, considering the extra energy expenditure due to holding the device by subjects during the measurements. After adjustment for the additional energy demand, the difference become non-significant and therefore authors concluded that the BG provides valid and reliable measurements of REE after adjustment. Only one study reported that BG is an accurate and reliable device for measuring REE without any adjustment (129).

Findings from the present study support the conclusion reported in a recent review about the accuracy of hand-held calorimeters (57). The authors indicated that the majority of studies with BG devices reported significant differences between the BG devices and standard metabolic carts.

Studies that evaluated other portable hand-held calorimeters such as MedGem (129, 131-136, 153-155), Fitmate (156), VO2000 calorimeter (157) and MOXUS modular VO₂ system (138) have also provided inconsistent results. For MedGem, 4 out of 10 (132-135) studies have reported that the device is not valid for the measurement of REE. Of these, 3 studies indicated that the devices significantly underestimated REE compared to the metabolic carts. These findings do not support the adjustment for the increase in REE that have been suggested by others due to an increased energy demand required to hold the device in position (130, 137). A systematic review conducted by McDoniel indicated that the hand-held calorimeters are reliable and valid for the measurement of REE (58). However, the conclusion of accuracy was based only on four studies in which the Douglas-bag system was used as the reference method.

Several possible reasons might explain these differences in studies of the measurement of REE by BG and WRC. Firstly, each technique uses different equations to calculate REE. The WRC measures both VO₂ and VCO₂, whereas the BG measures only VO₂ and assumes that the RQ of the subject is 0.85. However, in this study REE was calculated using the measured VO₂ by BG and RQ measured by WRC. The results showed that the difference in REE due to the assumption of the fixed RQ is relatively small (1.0% or 18 kcal/d). Similarly, Rubenbauer *et al.*(59) and Nieman *et al.* (129) found that measured RQ introduced differences of only 0.4% and 1.2% in REE, respectively. Furthermore, an error introduced from the measurement of VO₂ was assessed. Results showed that error was relatively large (7.4% or 140 kcal/d).

Secondly, each technique measures REE over periods of different duration. The BG runs the test for 10 minutes or until a steady breathing state reached. The measurements taken by WRC lasted for approximately 1 hour which gave more time for subject to reach a steady state. Thirdly, each technique uses different collection systems and gas analysis, which may raise concerns about the quality of each system in the measurement of gases.

In the present study, REE was calculated using different predictive equations (Table 5.2). For groups, the mean REE predicted by Schofield, WHO and Harris-Benedict

equations was not significantly different from mean REE measured by WRC. The mean bias and bias percent were relatively small. For individuals, the limits of agreement of measurements of REE from the WRC compared to predictive equations were well outside clinically acceptable levels in all evaluated equations.

The HB equation was the most accurate of the predictive equations evaluated in this study. Accurate prediction by Schofield (wt & ht) (65.8%) and WHO (wt & ht) (65.8%) equations were also very close to the HB equation (68.4%) value. The results indicated that the HB equation tends to underestimate REE in most of subjects whose REE was inaccurately predicted, whereas Schofield and WHO equations tend to give near equal proportions of under- and overestimation. The Mifflin and Owen equations were less accurate and both equations tend to underestimate REE in overweight and obese people, as has been reported by others (61). When equations developed in obese populations were used (the Bernstein and Ireton equations), measured REE was significantly different from the predicted REE. The Bernstein equation underestimated REE and the Ireton equation overestimated REE. These findings are consistent with previous reports (158).

The evaluated predictive equations, developed primarily with European and American subjects, might not be appropriate for Saudi or Middle East populations, and may underestimate energy needs in this group. Several studies have shown that ethnicity has an influence on metabolic rate (72, 73, 108, 139, 140). Consequently, there is a need to develop an equation that can accurately predict REE for this ethnic group.

There are several limitations to the present study. First, the study was limited to men. Investigation of the accuracy of REE is needed for both genders. Secondly, the sample included young subjects (<35y) only. Thirdly, the study included only overweight and obese Saudi subjects. This is the group in which the measurement of REE is likely to be of most relevance, however, the use of healthy normal weight subjects for comparison would provide additional useful data and could possibly produce different results.

In conclusion, indirect calorimetry using metabolic carts or WRC remains the gold standard for assessment of REE in overweight and obese Saudi males (53, 66). Based on the present findings, the HB, Schofield and WHO equations tend to predict REE more accurately than the BG device. However, their accuracy was not clinically acceptable on an individual level. Therefore, the use of both BG devices and predictive equations is questionable and more research is needed in this area.

5.6 ACKNOWLEDGEMENTS

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CHAPTER 6

DEVELOPMENT OF EVIDENCE BASED CLINICAL PRACTICE GUIDELINES

CONTENTS

- 6.1 Introduction
- 6.2 Methodology
- 6.3 Results
 - 6.3.1 Adaptation of existing evidence based statements
 - 6.3.2 Development of new evidence based statements
 - 6.3.3 Development of new consensus statements

6.1 INTRODUCTION

In the last few years, obesity evidence based clinical practice guidelines have been published by several scientific societies and health care services in USA, UK, Canada and Australia (10-14, 159). These published clinical practice guidelines have been developed for local use. However, most healthcare organizations do not have the resources and skills to develop their own guidelines from scratch (160). To our knowledge, there are no current clinical practice guidelines for any of nutrition areas in Saudi Arabia, including the dietetic management of patients presenting with problems of overweight or obesity. Therefore, this project aimed to develop such guidelines to help in the management of this common health problem in Saudi Arabia.

The development process of the clinical practice guidelines for nutritional management of obesity in Saudi Arabia was based on 3 main approaches. The first approach was the adaptation of evidence based statements from well established guidelines in other countries. The second approach was the development of new evidence-based statements, based on targeted systematic literature reviews, which was used when evidence was lacking or uncertain from existing guidelines. The third approach was the development of consensus statements, which was used when there was inadequate published research on which to base evidence-based statements. This last approach was

particularly relevant for issues related to practical implementation in the Saudi cultural context, and the statements were developed by a mixture of workshops and a Delphi consultation process with key experts in Saudi Arabia. Finally, the level of evidence for some guideline statements were supported by the results of specific studies undertaken as part of this thesis.

The following table summarizes the main elements and the three approaches used in developing these guidelines:

Table 6.1 Main elements and approaches used for the development of the clinical practice guidelines

ELEMENT	APPROACH USED
Effect of calcium, PUFA and fiber intakes on weight loss	Systematic mini-reviews
Effect of low glycemic index diet on weight loss	
Effect of meal frequency and breakfast meal on weight loss	
Validity of BMI for obesity classification in Saudi population	Additional studies in this thesis (Chapters 3 & 4)
The most accurate prediction equation for the assessment of REE in overweight and obese Saudis	
Behaviour modifications techniques for obese Saudi clients	Consultation workshops and Delphi techniques
Specific dietary counseling strategies	
Obesity management in Ramadan	
Physical activity for Saudi people	
A list of 14 evidence based statements presented in Table 6.2	Adaptation of existing guidelines

6.2 METHODOLOGY

A review of the literature suggests that the majority of clinical guideline development processes have used a combination of expert judgment and scientific evidence due to the limited data on interventions and outcomes in many areas of health care (161). The overall process of developing the guidelines in this thesis is shown in Figure 6.1

The above methods have been used to develop three different types of statements: adopted statements that were developed through searching a set of well established guidelines, evidence based statements that were developed through systematic mini-reviews and consensus statements that were developed through interviews, workshops and Delphi consultations.

A guideline panel started the development of this clinical practice guidelines assisted by many experts through interviews, consultation workshops and Delphi consultations. The main panel is comprised of 3 members. One member was the PhD candidate who is a certified clinical dietitian in Saudi Arabia. The other two members were academic staff in the University of Wollongong in Australia, who supervised this research; both have expertise in clinical nutrition and research methodology in nutrition and one has specific expertise in statistical methods in nutrition research, statistical methods in clinical trials and evidence synthesis.

Other Saudi experts were involved in developing these guidelines through interviews, consultation workshops or Delphi consultations with academic staff in nutrition, dietitians, nutritionists, physicians and government health representatives.

The methods used to develop each type of statements are described below

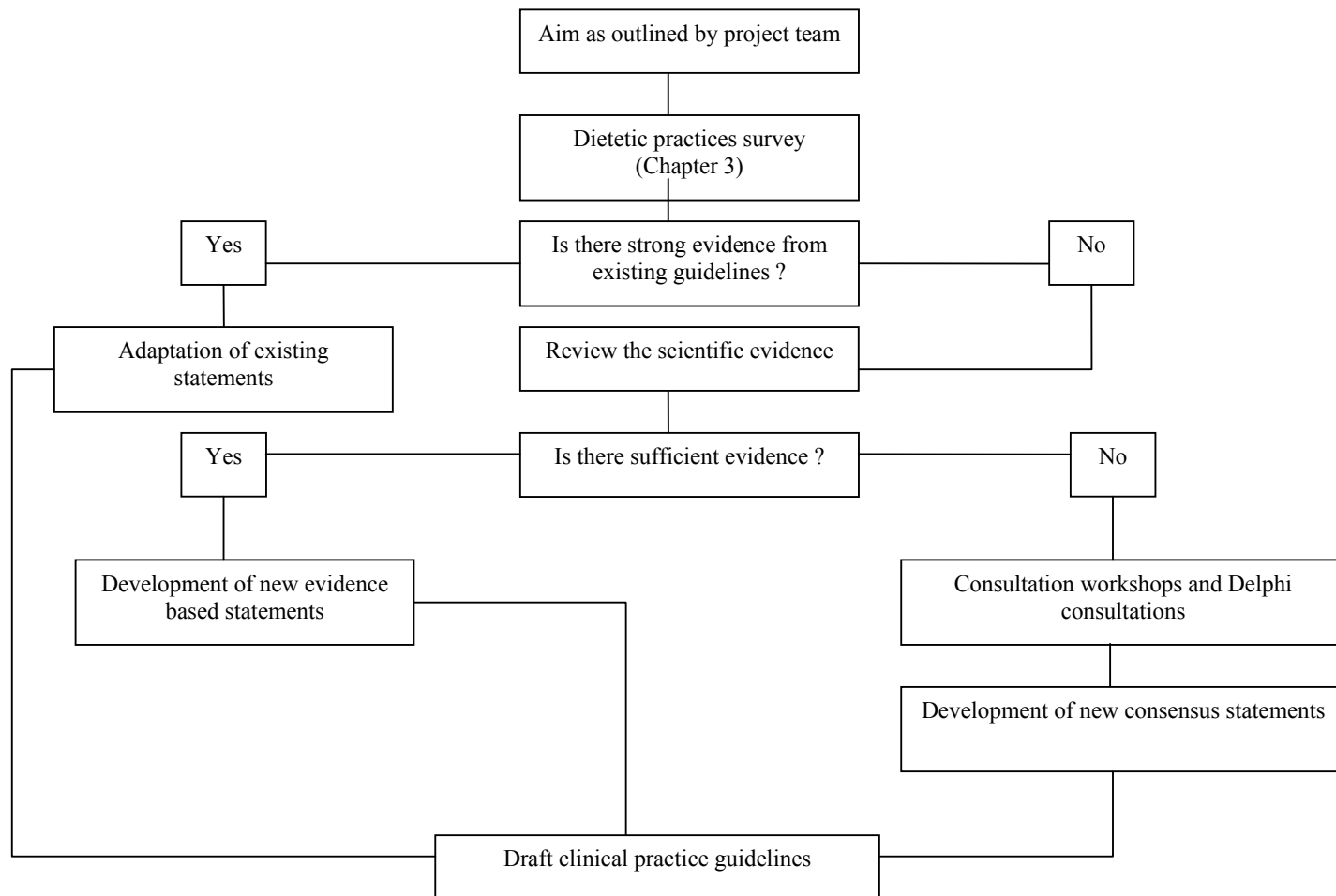


Figure 6.1 Steps in Guideline Development

6.2.1 Adaptation of existing evidence based statements:

Several obesity existing nutrition clinical practice guidelines were reviewed for possible adaptation. Three well established guidelines were chosen for the adaptation process. The selected guidelines were:

1. Guidelines developed by the National Heart, Lung and Blood Institution (NHLBI), USA, 1997 (10)
2. Guidelines developed by the Dietitians Association of Australia (DAA), Australia, 2005 (159)
3. Guidelines developed by the American Dietetic Association (ADA), USA, 2007 (11).

Statements to be included in the adaptation process needed to be supported with strong and clear evidence and had to be applicable with the Saudi population. Statements that presented knowledge that could not be applied in the Saudi population due to cultural, genetic or other factors were excluded. However, one statement about the use of BMI for obesity classification was adapted and supported by a study conducted by the candidate to assess the validity of standard BMI cut-point values in the Saudi population (Chapter 4)

6.2.2 Development of new evidence based statements:

6.2.2.1 Selected topics:

The guideline panel decided to include 6 topics in the present guidelines. The selected topics were either not included in the existing guidelines or there was recent published research that might change the level of evidence presented in other guidelines. These topics were:

- Effect of calcium intake on weight loss
- Effect of PUFA intake on weight loss
- Effect of fiber intake on weight loss
- Effect of low glycemic index diet intake on weight loss
- Effect of meal frequency and breakfast meal on weight loss
- Determination of REE

In addition, the development of statements considered results from the study conducted by the candidate about the validity of the use of prediction equations and hand-held calorimetry for REE assessment in overweight and obese Saudi subjects (Chapter 5). Since evidence is lacking in this area, this study was used to support the conducted review and the level of evidence allocations.

6.2.2.2 Steps in developing scientific evidence based on systematic review:

- Formulation of evidence analysis questions to cover the selected topics
- Identification of inclusion and exclusion criteria.
 - Inclusion criteria used to select papers for their analysis were:
 - Age: adults (20 years and above)
 - Health status: any
 - Study designs: RCTs, cohort studies, cross sectional studies, meta-analysis or systematic review and review articles
 - Year range: until January 2009
 - Language: limited to articles in English

- Exclusion criteria used to select papers for their analysis were:
 - Non-original research papers
 - Studies done exclusively on children or adolescents, pregnant women or athletes
- Identification of search words: specific search words for each topic will be described later in the reviews section (6.3.2)
- Identification of databases: this project searched the following databases:
 - Pubmed (1966- present)
 - Medline (1966-present)
 - *The Cochrane Library* (1991-present)
 - CINAHL (1981- present)
 - Science direct (1995-present)
 - Proquest (various dates)
- Articles that met the criteria were collected and assessed using specific quality criteria (Appendix A)
- A summary of each article including authors, study design, study sample, methods, results and conclusions was developed
- A summary of all articles including the number of studies, study design, level of evidence, conclusions and the overall level of evidence was created
- A summary of the literature review and evidence based statements for each topic were given, along with an overall rating of the evidence, using the following ratings: High, Medium, Low and Not Supportive.

The level of evidence for each article was assessed using a quality criteria developed by the ADA (87). The content of criteria list is based on the quality constructs and domains identified in the Agency for Healthcare Research and Quality (AHRQ) report on

Systems to Rate the Strength of Scientific Evidence (2002) (87). The criteria included four relevance questions that address applicability to dietetic practice and ten validity questions that address scientific soundness (Appendix A). Under each validity question there is a list of sub-questions that identify important aspects of sound study design.

The overall evidence for the conclusion and the developed statement was assigned by the candidate based on the definition of each evidence grade defined by the ADA. These definitions are described by the ADA as following (87):

High: the evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power.

Medium: the evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the questions addressed, but the results have been confirmed in separate studies and consistent with minor exceptions at most

Low: the evidence consists of results from a limited number of studies of weak design for answering the questions addressed. Evidence from studies of strong design is either unavailable because no studies of strong design have been done or because the studies that have been done are inconclusive due to lack of generalizability, bias, research design flaws, or inadequacy sample sizes

Expert Opinion: the support of conclusion consists solely of the statement of informed medical commentators based on their clinical experience, unsubstantiated by the results of any research studies

Not Supportive: there is no evidence available that directly supports or refutes the conclusion

6.2.3 Development of new consensus statements:

6.2.3.1 Selected topics:

Consensus statements were developed when the evidence was lacking or insufficient. Topics and statements were selected through interview with experts, consultation workshops and finalized using Delphi techniques. Topics include:

- Behaviour modifications techniques for obese Saudi clients
- Specific dietary counselling strategies
- Obesity management in Ramadan
- Goal setting for the management of obesity
- Physical activity for Saudi people

6.2.3.2 Interview with experts

The consensus process started with phone interviews with 5 academic staff and experienced clinical dietitians in Saudi Arabia. In this interview the nature and the proposed methods of the project were described. Participants were encouraged to comment on the project methodology and the suggested topics for the consensus process. Following this, a series of consultation workshops were held to explore the issues further.

6.2.3.3 Consultation workshops

Aim:

To discuss possible consensus statements and recommendations for obesity management in some areas where there is insufficient evidence for the development of evidence based statements.

Methods:

Five small consultation workshops were conducted in different hospitals in Saudi Arabia in April 2008. Initial statements were presented for discussion in the workshops. These statements were generated through previous interviews with experts and by searching some articles written by well known experts in the local newspapers or suggested by the guideline expert panel. Participants were encouraged to discuss and

modify these statements and add new statements. Suggested statements were then included in a Delphi consultation to produce final consensus statements.

Workshops were conducted in the following hospitals:

- King Faisal Specialist Hospital & Research Centre
- King Khalid University Hospital
- Security Forces Hospital
- Prince Abdulaziz Bin Musaad Specialist Hospital
- Alowaiqelah General Hospital

Participants:

Dietitians and physicians in Saudi Arabia (Saudi and non-Saudi) who are experts and interested in this topic were invited to participate in these workshops. Clinicians with more than 5 years experience were preferred. Experts not available for the workshops were invited to participate in a separate individual consultation interview.

6.2.3.4 Delphi consultations

Staff team

A staff team was formed to initiate these consultations and consisted of all members of the guideline expert panel. The team was responsible for approving the selection of statements and participants. The candidate was responsible for the planning, construction and distribution of the questionnaires, the analysis of the responses and the formulation of the feedback reports.

Selection of participants

The participants had to be experts in nutrition clinical practices, particularly obesity management, and included physicians, academic staff and dietitians. A participant group of 20 experts who represent the above-mentioned three key disciplines in the field of nutrition in Saudi Arabia was formed (Appendix M). The study was approved by the Human Research Ethics Committee (University of Wollongong / Illawarra area health services, Australia) (Appendix N). All participants received an invitation letter with

participant information (Appendices O and P) and consent implied by return of the questionnaire. Participants also received invitation emails to participate in each Delphi round (Appendix Q)

Procedures

The Delphi rounds included structured questions regarding the agreement of participants about a list of statements. The answer options used a 5-point Likert scales (strongly agree, agree, neutral, disagree, strongly disagree). Participants were encouraged to provide reasons for their choices and to modify the statements if required or to add new statements. After each round, the candidate provided feedback to inform the participants about the arguments and opinions of other participants. The overall process of the Delphi consultations is shown in Figure 6.2

Analysis

The mean score for each statement was presented on the 5-point Likert scales [strongly agree (4 points), agree (3 points), neutral (2 points), disagree (1 point) and strongly disagree (0 points)] as a percentage of the maximum obtainable score. A cut-off point of 75% was chosen for including the statement in the clinical practice guidelines. For example: a mean score of 2.0 is 50% of the maximum achievable score. The mean score was calculated as the total scores given by participants to each statement divided by the total number of participants. Two to three Delphi rounds were considered sufficient to reach consensus (162).

Delphi-1:

Participants were asked how strongly they agreed with the inclusion of each statement in the draft clinical practice guidelines. Statements with agreement scores $> 75\%$ were entered into the set of accepted clinical practice guidelines. In the case of agreement score of 50 to 75%, statements were changed with the aid of participants' comments and included in Delphi-2. Statements with agreement scores $< 50\%$ were excluded (Figure 6.2). Participants were also encouraged to suggest alternative wording and to add new statements to be included in Delphi-2.

Delphi-2:

The candidate reworded the initial items based on opinions and arguments given in Delphi-1, and presented them in Delphi-2. The candidate had only an editorial role in modifying the statements. Participants were asked again how strongly they agreed about inclusion of the reworded statements in the final list of statements. Statements with agreement score $> 75\%$ were entered into the set of accepted clinical practice guidelines and other statements were excluded (Figure 6.2.) After Delphi-2, the candidate drafted a feedback report and distributed it to participants.

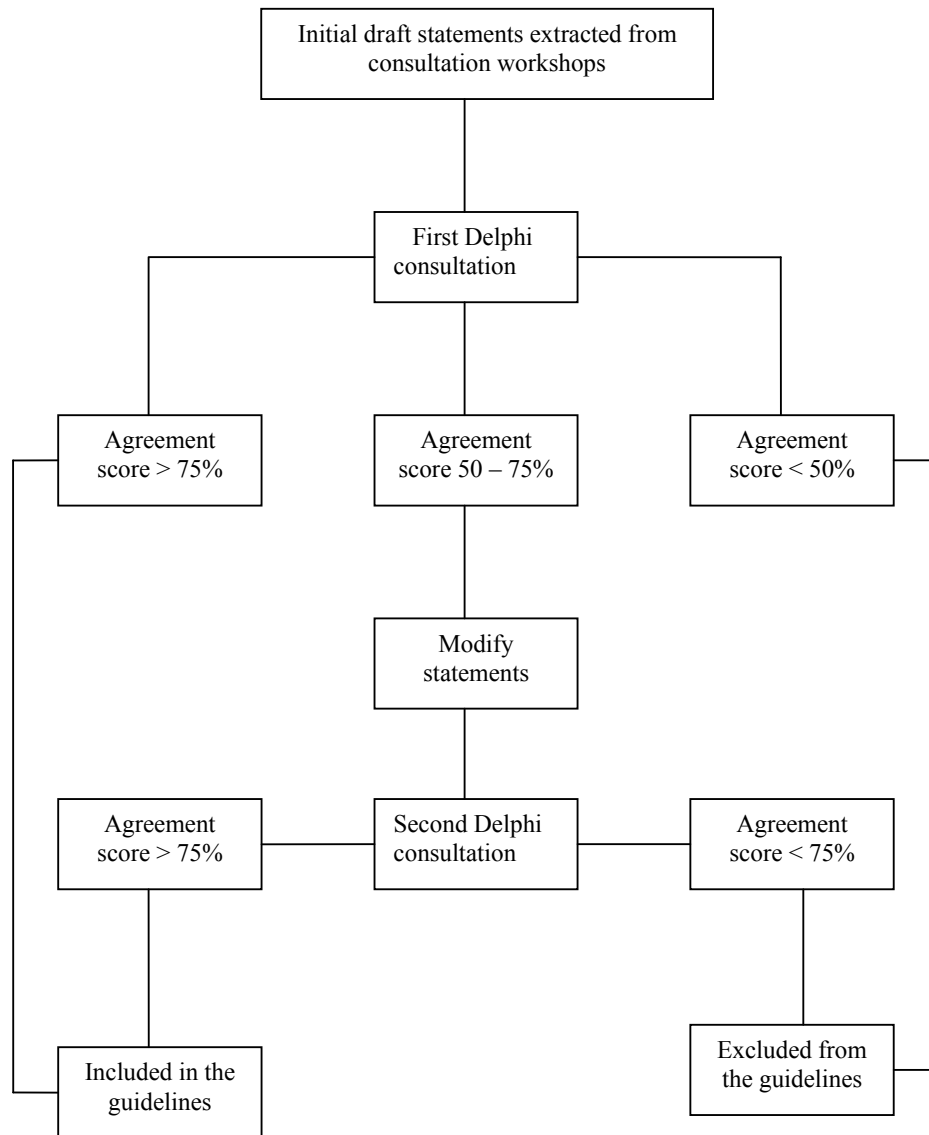


Figure 6.2 Delphi technique procedures

6.3 RESULTS

6.3.1 Adaptation of existing evidence-based statements

The guideline panel reviewed the three sets of identified guidelines:

- Guidelines developed by the National Heart, Lung and Blood Institution (NHLBI), USA, 1997 (10)
- Guidelines developed by the Dietitians Association of Australia (DAA), Australia, 2005 (159)
- Guidelines developed by the American Dietetic Association (ADA), USA, 2007 (11).

The guideline panel agreed to adopt 14 relevant statements, that had strong scientific support. These statements are presented in Table 6.2.

Table 6.2 Statements adopted from existing obesity guidelines*

Evidence based statement	Level of evidence
Comprehensive weight Management Program	
The combination therapy of diet, physical activity and behavioral therapy is more successful than using any one intervention alone	Strong, Imperative; ADA ^a A; NHLBI ^b
Selected Dietary Approaches	
The main requirement of a dietary approach to weight loss is a reduction in total energy intake	Strong, Imperative; ADA ^a A; NHLBI
Reducing fat as part of a low-calorie diet is a practical way to reduce calories	A; NHLBI ^b A; DAA ^c
Reducing dietary fat and/or carbohydrates is a practical way to create a caloric deficit of 500-1000 kcals (2092-4184 kJ) below energy estimated needs and should results in a weight loss of 1-2 lbs (0.454-0.907 kg) per week	Strong, Imperative; ADA ^a
Low fat <i>ad libitum</i> diets can results in long-term weight loss	A; DAA ^c
Goals for weight loss	
Diet therapy should last at least 6 months or until weight loss goals are achieved with implementation of a weight maintenance program after that time	Strong, Conditional; ADA ^a
Initial goal should be to reduce weight by 10% from baseline.	Strong, Imperative; ADA ^a A; NHLBI ^b
Weight loss should be about 1 to 2 lb/week (0.454-0.907 kg) for a period of 6 months	Strong, Imperative; ADA ^a B; NHLBI ^b
A loss between 5 and 10% of original weight can produce significant improvement in cardiovascular and metabolic health	A; DAA ^c
A long term weight loss of grater than 10% provides further health benefit but is less commonly achieved	A; DAA ^c

^a ADA: American Dietetic Association

^b NHLBI: National Heart, Lung and Blood Institute

^c DAA: Dietitian Association of Australia

Table 6.2 Statements adopted from existing obesity guidelines (cont.)

Evidence based statement	Level of evidence
Physical Activity	
At least 30 minutes/day of moderate intensity physical activity. Physical activity contributes to weight loss, may decrease abdominal fat, and may help with maintenance of weight loss.	Strong, Imperative; ADA ^a A; DAA ^c B; NHLBI ^b
The combination of a reduced calorie diet and increased physical activity is recommended	Strong, Imperative; ADA ^a A; NHLBI ^b
In the absence of dietary change, moderate to vigorous exercises (3-5 hours a week) produces modest weight loss of about 2 kilograms over one year. If combined with energy restriction, leads to further 3-6 kilograms of weight loss with a grater loss of abdominal fat than <i>ad libitum</i> low-fat diets or exercise alone over one year	A; DAA ^c
Obesity Assessment**	
Practitioners should use the BMI to assess overweight and obesity. Body weight alone can be used to follow weight loss, and to determine efficacy of therapy	C; NHLBI ^b Fair; ADA ^a

^a ADA: American Dietetic Association

^b NHLBI: National Heart, Lung and Blood Institute

^c DAA: Dietitian Association of Australia

* Existing guidelines used different terms for the evidence categories, which are also different from categories used in this thesis (Section 6.2.2.2). Therefore, in the final draft guidelines (Appendix V), equivalent terminologies were used (e.g Strong and A level = High level)

**** Note:**

Optimal BMI cutoffs for the definition of overweight and obesity are identified on the basis of the association between BMI and chronic diseases such as diabetes and hypertension. The studies in Chapter 4 showed that, in a large sample from the Eastern region of Saudi Arabia, there was an increased risk of diabetes and hypertension relative to BMI starting at BMI as low as 21 but overall, there was no distinct cutoff BMI level with high predictive value for the development of these chronic diseases including the WHO definition of obesity at BMI of 30. This indicates that the diagnostic usefulness of BMI alone in defining obesity is limited in this large population of Saudi adults. Therefore, the grading of the level of evidence for this recommendation was moved down one grade to a Low level until more data are available for the Saudi population.

6.3.2 Development of new evidence based statements

6.3.2.1 Effect of Calcium/dairy diet on body weight in adults

Research question:

How effective is a high calcium or dairy diet intake on weight loss in adults?

Date of the literature review:

January 2008

Search words:

Calcium, dairy products, body weight and weight loss

Possible Mechanism:

The increase in calcitriol (1,25-dihydroxyvitamin D) in response to low-calcium diets stimulates adipocyte Ca^{2+} influx and, as a consequence, stimulates lipogenesis, suppresses lipolysis, and increases lipid accumulation, and hereby promotes adiposity. High calcium diets suppress calcitriol levels, which result in reduced lipogenesis, increases in lipolysis and markedly accelerate fat loss (163-166)

Evidence-based statement:

Increased intakes of calcium or dairy products are associated with weight loss.

Level of evidence: Low

Literature review reported by the ADA before July 2005:

- Diets with low intakes of calcium and dairy are associated with increased body weight, body fat, BMI and waist circumference. These findings reported from one medium-quality RCT (167), one medium-quality cohort study (168), three cross sectional studies (1 high and 2 medium-quality) (166, 169, 170), and one medium-quality meta-analysis (171).
- Calcium intake at recommended levels showed no associations with body weight from one high-quality cohort study (172)

- Calcium intakes above recommended levels showed conflicting results. Four neutral-quality RCTs (173-176) have shown a loss of body weight and body fat while one positive-quality RCT (177) did not report any significant differences.

Literature review not covered by the ADA:

- One high-quality meta-analysis of 13 RCTs (178) did not show any association between the increased consumption of either Ca supplements or dairy products and body weight
- One medium-quality non-systematic review of 26 RCTs (179), 9 studies of dairy products supplementation and 17 studies of calcium supplements (only two studies included in the above meta-analysis), reported that only one study found greater weight loss in the calcium supplemented group.
- One low-quality short review (180) included adult and children concluded that data from cross-sectional studies supported the hypothesis that high calcium or dairy diets are associated with lower fat accumulation. However, prospective studies and RCTs have shown inconsistent findings.
- One high-quality cross sectional study (181) reported that milk intake is slightly but significantly inversely related with BMI in men and young women.
- Three medium-quality prospective (182-184) studies examined the effect of Ca on body weight and showed inconsistent results. One study showed a significant effect of Ca on 10-year weight change in women group only (183). One study did not report any association between calcium and dairy intakes and 12-year weight change in US men(184). The last study reported that dietary calcium is inversely associated with BMI and body fat in American Indians (182).

Comments:

Most studies reviewed were neither designed nor powered to detect an impact of increased calcium or dairy intake on body weight. Most of the analyses were cross sectional analysis from retrospective data in which the cause and effect can not be established. Further well designed studies are needed to better assess the effect

**Table 6.3 Evidence Summary: Higher Calcium or dairy intake and weight loss in adults
(Studies grouped by study design and date order)**

Primary Research							
Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Cifuentes M, 2004(173)	RCT	Medium	73 overweight postmenopausal women	Interventions: 1.8 gm/d (Ca citrate group) with normal diet or restricted diet vs placebo	6 weeks	In the high calcium group, the rate of weight loss was directly associated with the estimated daily absorbed calcium ($P < 0.05$)	Supportive: Weight loss is associated with an increased demands for calcium intake
Zemel MB, 2004(176)	RCT	Medium	41 obese young adults	Interventions: - Control diet: 500 kcal/day deficit with 0-1 servings of dairy products/day, 400-500 mg Ca/day and a daily placebo supplements - a calcium-supplemented diet identical to control but with placebo replaced by 800 mg Ca (as calcium carbonate) to bring total dietary calcium intake to 1200-1300 mg - a high-dairy diet (placebo supplemented) providing a 500 kcal/day deficit and containing 3 dairy servings to bring total calcium intake to 1200-1300 mg/day	24 weeks	- Participants on the low-calcium control diet lost $6.4 \pm 2.5\%$ of their body weight, which was increased by 26% (to $8.6 \pm 1.1\%$) on high-calcium diet and by 70% (to $10.9 \pm 1.6\%$) on the high-dairy diet ($P < 0.01$). - Participants lost $8.1 \pm 2.3\%$ of their body fat on the low-calcium control diet, which was increased to $11.6 \pm 2.2\%$ on the high-calcium diet and $14.1 \pm 2.4\%$ fat loss on the high-dairy diet ($P < 0.01$). -Participants on the low-calcium control diet had significantly higher fat mass than the other 2 groups ($P < 0.05$) and this group also lost the least amount of body fat during energy restriction.	Supportive: Increasing dietary and supplemental calcium intakes result in weight and fat loss.

Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Thompson WG, 2005 (177)	RCT	High	90 obese men and women aged 25-70 years	Interventions: 3 diets providing a calorie deficit of 500 Kcals/day Diet 1: 30% fat, 20% protein, 50% carbohydrate with 2 dairy serving Diet 2: the same as diet 1 with 4 dairy serving Diet 3: the same as diet 2 with an increased amount of fiber and a reduction in glycemic index	48 weeks	- A diet with 1400 mg calcium did not result in greater weight loss or fat loss than the standard diet - A diet with 1400 mg calcium, high fiber and fewer high glycemic index foods did not result in greater weight loss or fat loss than the standard diet	Not supportive: There is no significant association between high dairy diets and weight loss.
Zemel MB, 2005 (174)	RCT	Medium	38 obese adults aged 18-50 years	Interventions: - balanced deficit diet (-500 kcal/d) with < 1 serving of dairy products/d and 400-500 mg calcium/d - Yogurt diet (3-6 oz servings of Yoplait Light/d and 1100 mg Ca/d	12 weeks	- Participants on balanced control diet lost 4.99±0.5 kg body weight, 2.75±0.73 kg body fat, 1.74 kg trunk fat and 0.58±1.04 cm in waist circumference (P < 0.05) - Participants on yogurt diet lost 6.63±0.6 kg body weight, 4.43±0.47 kg body fat, 3.15 kg trunk fat and 3.99±0.48 cm in waist circumference (P < 0.05)	Supportive: Increased yogurt intake is inversely associated with body weight, total adiposity and central adiposity.
Zemel MB, 2005 (175)	RCT	Medium	75 obese African-American Adults	Interventions: - Weight maintenance diet: low calcium (500 mg/d) and low dairy (< 1 serving/d) or high dairy (1200 mg Ca/d with 3 dairy servings) - weight loss diet: same as above but with deficit of 500 kcal/d	24 weeks	- Participants on weight maintenance and high dairy diets lost body fat (2.16 kg, P < 0.01), trunk fat (1.03 kg, P < 0.01) whereas there were no significant changes in the low dairy group - Participants on weight loss and high dairy diets lost body weight and fat 2-fold higher (P < 0.01) than participants on low dairy diet	Supportive: Increased dairy intake is inversely associated with body fat and weight in obese African Americans

Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Lin Y-C, 2000 (167)	Cohort study	Medium	54 normal weight women aged 18-31 years	This cohort study is part of RCT in which mean intakes of nutrients of interest were determined from three-day diet records completed at baseline and every six months for two years. The change in total body weight and body composition from baseline to two years was also determined.	2 years	Total and dairy calcium intake were inversely associated with change in body weight ($r = -0.35$, $P < 0.05$)	Supportive: High calcium intake is associated with weight loss in young women
Pereira MA, 2002 (168)	Cohort Study	Medium	5115 black and white men and women aged 18-30 at baseline	This is a 15 year population-based prospective study. The current analysis included the first 10 years and 5 clinic examinations. General linear regression models were used to compare incidence of insulin resistance syndrome (IRS) across dietary intake categories. IRS defined as the presence of 2 or more of the 4 components: obesity, abnormal glucose homeostasis, elevated blood pressure and dyslipidemia.	10 years	- IRS in overweight participants decreased by $> 50\%$ from lowest to highest categories of dairy intake ($P = 0.03$) - No association was observed in normal weight participants.	Supportive: High dairy intake have a strong inverse association with IRS in overweight young adults
Venti CA, 2005 (172)	Cohort Study	High	- 65 Pima Indian adults (mean age 33 ± 8 years) - 78 Pima Indian Children (mean age 10.4 ± 0.3 years)	Data were collected from two prospective cohort studies: eating behavior study and childhood obesity study. Food intake in adults was assessed using the Block 1998 Food Questionnaire; food intake in children was assessed using a 24-hour recall.	Adults study: 4 years Children study: NA	There were no significant associations between calcium intake and body weight ($r=0.05$, $P=0.71$; $r=0.04$, $P=0.73$), body fat ($r=0.16$, $P=0.19$; $r=0.12$, $P=0.42$), or body mass index ($r=0.01$, $P=0.97$; $r=0.04$, $P=0.77$) in either adults or children, respectively.	Not supportive: There was no association between calcium intake and adiposity in Pima Indian adults and children

Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Gonzalez AJ, 2006 (183)	Cohort study	Medium	10,591 men and women aged 53-57 years	Retrospective data was used to assess the relationship between calcium intake and weight change over an 8- to 12-year period among middle-aged adults. Linear regression was used to examine associations of 10-year weight change and calcium intake.	8 to 12 years	<ul style="list-style-type: none"> - Calcium intake was associated with 10-year weight change in women only - Women with current calcium supplement dose > 500 mg/day had a 10 year weight gain of 5.1 kg (95% CI 4.7 to 5.5) compared to 6.9 kg (95% CI 6.5 to 7.4) among nonusers (P = 0.001) - Dietary calcium alone had no significant effect on weight change 	Supportive: Calcium supplementation support weight maintenance but dietary calcium alone has no effect.
Swapnil NR, 2006 (184)	Cohort study	Medium	51,529 men aged 40-75 years	Data were collected from the Health Professionals Follow-up Study, a prospective cohort of men. Data on lifestyle factors and diet were updated biennially with self administered questionnaires. Multivariate linear regression was used to examine the association between calcium intake and weight.	12 years	<ul style="list-style-type: none"> - Baseline or change in intake of total calcium was not significantly associated with weight change. - No association was found with dietary, dairy, or supplemental calcium intake when evaluated separately 	Not supportive: An increase in calcium intake or dairy consumption is not associated with lower long-term weight gain in men.
Eilat-Adar S, 2007 (182)	Cohort study	Medium	2975 American Indians from Strong Heart Study (SHS) compared to 2755 individuals from NHANES III. Both groups aged 47-79 years	Data were collected from two prospective cohort studies: SHS and NHANES III. Dietary data were collected using a 24-h dietary recall	SHS: 3 years NHANES III: 6 years	<ul style="list-style-type: none"> - After adjustment for potential confounders, BMI and % body fat were lower by 0.80 kg/m² (95% CI: -1.53 to -0.08, p = 0.046) and 1.28% (95% CI: -2.10 to -0.47, p = 0.011) in SHS participants with higher (≥ 873 mg/d in the 5th quintile) vs lower Ca intake (< 313 mg/d in the 1st quintile) - No association between Ca intake and BMI or % body fat was observed in NHANES III 	Supportive: This study support an association between Ca intake and obesity in American Indians and may be useful in developing approaches for nutritional interventions aimed at weight control

Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Zemel MB, 2000(166)	Cross sectional study	High	7114 men (mean age 43.5 ±0.44) and 380 women (mean age 28.7±0.4)	Cross sectional survey of adult subjects. Dietary consumption was measured in servings/month. Multiple logistic regression analysis was used.	The regression model for men and women indicated an inverse relationship between calcium and dairy intakes and body fat (multiple $R^2 = 0.20$; $P = 0.0009$ for men, $R^2 = 0.40$; $P = 0.0006$ for women)	Supportive: Increased calcium and dairy intakes is inversely associated with body fat
Lovejoy JC, 2001(170)	Cross sectional study	Medium	97 white and 52 African American women (mean age 47.4±0.2 years)	Data were collected from the Health Transitions Study. Dietary intake was assessed by 4-day food record.	Body fat was inversely associated with fiber and calcium intake and positively correlated with total, saturated, and monounsaturated fat intakes ($P < 0.05$)	Supportive: Calcium intake is inversely associated with body fat in African American women
Jacqmain M, 2003(169)	Cross Sectional Study	Medium	470 men and women aged 20-65 years	Data were collected from the Quebec Family Study Sample who regularly used vitamin or mineral supplements. Participants were divided into 3 groups based on calcium intake.	- In women: calcium intake was inversely correlated with % body fat ($r = -0.19$), fat mass ($r = -0.17$, $P < 0.05$), BMI ($r = -0.07$), and waist circumference ($r = -0.07$) - In men: there were no significant differences	Supportive: Calcium intake is inversely associated with body weight and fat mass but these findings observed in women only.
Marques-Vidal P, 2006(181)	Cross sectional study	High	17,771 men and 19,742 women aged > 18 years	Data were collected from the Portuguese Health Interview Survey. Average daily milk intake was calculated by a frequency questionnaire that also assessed the average volume of one serving	- In men, milk intake was inversely related to BMI ($r = -0.10$, $P < 0.001$), whereas the relationship in women was weaker ($r = -0.06$, $P < 0.001$). - In women younger than 55 y, milk intake decreased with increased BMI categories (291±9, 271±10 and 269±11 ml/day for normal, overweight and obese subjects, respectively, $P < 0.001$), whereas no relationship was found in the older group.	Supportive: Increased calcium intake is inversely associated with BMI in men and premenopausal women but no associated observed older women.

Evidence Summary: Higher Calcium or dairy intake and weight loss in adults

Review Articles						
Author	Review design	Quality rating	Number and types of studies	Interventions	Results	Conclusion
Davies KM, 2000 (171)	Meta-Analysis	Medium	1 RCT 2 Cohort studies 2 Cross sectional studies Total sample size: 780 adult women	Calcium supplements in the RCT	- Significant negative associations between calcium intake and weight were found, and the odds ratio for being overweight was 2.25 for young women in the lower half of the calcium intakes of their respective study groups ($p < 0.02$) - Estimates of the relationship indicate that a 1000-mg calcium intake difference is associated with an 8-kg difference in mean body weight and that calcium intake explains approximately 3% of the variance in body weight.	Supportive: There is significant negative correlations between calcium intake and weight
Barr SI, 2003 (179)	Non-systematic review	Medium	9 RCTs of dairy products supplementation 17 RCTs of Ca supplementation	Calcium supplements or dairy products	Only one study found greater weight loss in Ca supplemented group. Two studies conducted in older adults observed significantly greater weight gain in the dairy product groups. In the remaining studies no significant changes were observed	Not supportive: The data available from this review did not provide support for an effect of dairy product or calcium supplementation in reducing body weight or fat mass.
Barba G, 2006(180)	Non-systematic review	Low	8 RCTs 5 Cohort studies 7 Cross sectional studies	Calcium supplements or dairy products	- Data from cross-sectional epidemiological studies support the hypothesis that a dairy food-rich diet is associated with lower fat accumulation in adults and children - Prospective studies and RCTs have yielded inconsistent results	Not supportive: Data from this review do not support the hypothesis that a causal relationship exists between high dairy food intake and/or high dietary calcium intake
Trowman R, 2006 (178)	Meta-analysis	High	13 RCTs Total samples size: 1127 men and women	Calcium supplements or dairy products	There was no association between the increased consumption of either Ca supplements or dairy products and weight loss after adjusting for differences in baseline weights between the control and intervention groups ($P=0.19$ and 0.85 , respectively).	Not supportive: Calcium supplementation is not associated with weight loss

Table 6.4 Calcium and body weight: type, quality and number of supportive and non supportive studies*

Study type	Study quality	Number of supportive studies	Number of non supportive studies
Review articles	High	0	1
	Medium	1	1
	Low	0	1
RCTs	High	0	1
	Medium	4	0
Cohort studies	High	0	1
	Medium	4	1
Cross-sectional studies	High	2	0
	Medium	2	0
Total		13	6

* Review articles and high quality RCTs do not support the hypothesis

6.3.2.2 Effect of Polyunsaturated fatty acids and Monounsaturated fatty acids on body weight in adults

Research question:

How effective is increased intakes of polyunsaturated fatty acids (PUFA) and monounsaturated fatty acids (MUFA) on body weight in adults?

Date of literature review:

August 2008

Search words:

polyunsaturated fatty acids (PUFA), monounsaturated fatty acids (MUFA) and body weight loss

Possible Mechanisms:

- Unsaturated fatty acids increase lipid catabolism via enhancing fatty acid oxidation and/or peroxidation (185-189)
- Unsaturated fatty acids decrease lipid synthesis through inhibiting stearyl-CoA desaturase and/or fatty acid synthase (190, 191)
- Unsaturated fatty acids increase intracellular lipolysis (192, 193)
- Unsaturated fatty acids have an impact on the level of some hormones that are essential for body fat control such as leptin (192, 194, 195) and adiponectin (195, 196)
- Unsaturated fatty acids increase energy expenditure (197, 198) and/or decrease energy intake (199-201)

Evidence-based statement:

Increased intakes of PUFA are associated with weight loss

Level of evidence: Medium

Evidence-based statement:

Increased intakes of MUFA are associated with weight loss.

Level of evidence: Not supportive

Literature review:

- Four RCTs (3 high-quality and 1 medium-quality) (188, 201-203) and 1 high-quality cross sectional study (204) demonstrated that high PUFA intake is associated with weight loss or lower BMI.
- Two high-quality RCTs (205, 206), 1 medium-quality cohort study (207) and 3 high-quality cross-sectional studies did not show any significant association between high intake of PUFA and weight loss or BMI.
- Three RCTs (1 high-quality, 2 medium-quality) (189, 208, 209) demonstrated that high MUFA intake is associated with weight loss or lower BMI.
- Three RCTs (2 high-quality, 1 medium quality) (206, 210, 211) , 2 medium-quality cohort studies (207, 212) and 3 high quality-cross-sectional studies (213-215) did not show any significant association between high intake of MUFA and weight loss or BMI

Comments:

This review summarized all the studies reported in the literature that reported a positive, a negative, or an absence of association between PUFA or MUFA intake and weight or body fat changes. However, studies that described outcomes as oxidation rate, energy expenditure, energy intake or thermogenesis are not included in this review

Table 6.5 Evidence Summary: PUFA and weight loss in adult
(Studies grouped by study design and date order)

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Kratz M <i>et al.</i> , 2008 (205)	RCT	High	16 women and 10 men with a BMI between 28 And 33 kg/m ²	Participants were randomly assigned to consume a diet rich in n-3 PUFAs (3.5% of energy intake) or a control diet (0.5% of energy intake from n-3 PUFAs). For the first 2 wk, these diets were consumed under isocaloric conditions; then followed a 12-wk period of ad libitum consumption	14 weeks	During the 12 weeks when subjects consumed these diets ad libitum, body weight decreased by a mean of 3.1±3.8 kg in the control group and by 2.2±3.6 kg in the n-3PUFA group. This change was significant overall but did not differ significantly between the 2 groups (P = 0.541). Body fat mass decreased by 2.6±3.5 kg in the control group and by 1.8±2.9 kg in the n-3 PUFA group, changes were significant overall but did not differ significantly between treatment groups (P= 0.583)	Not supportive: There was no significant relationship between increased PUFA intake and weight loss
Akuamoah-Boateng L <i>et al.</i> , 2007 (206)	RCT	High	129 adults with a mean BMI of 22.09±2.58 kg/m ²	Participants were randomized into a control group and 3 intervention groups; peanut oil (rich in MUFA), olive oil (rich in MUFA), and safflower oil (rich in PUFA)	8 weeks	At week 8, there was a significant increase in weight relative to baseline in all 3 oil intervention groups (P<0.05), but not among controls	Not supportive: Higher intake of diet high in PUFA was associated with weight gain.
Kabir M <i>et al.</i> , 2007 (202)	RCT	High	27 adults women with type 2 diabetes	Participants were randomly allocated in a double-blind parallel design to 2 months of 3 g/d of either fish oil (1.8 g n-3 PUFAs) or placebo (paraffin oil).	2 months	Total fat mass (P=0.019) and subcutaneous adipocyte diameter (P = 0.0018) were lower in the fish oil group compared to the placebo group. Body weight was unchanged	Supportive: Increased intake of PUFA significantly decreases total fat mass and subcutaneous adipocyte diameter

Evidence Summary: PUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Thorsdottir I <i>et al.</i> , 2007 (203)	RCT	High	324 men and women aged 20–40 years with BMI between 27.5 and 32.5 kg/m ²	Participants were randomly assigned to one of four energy restricted diets: 1-Control: sunflower oil capsules, no seafood (rich in MUFA and PUFA) 2-Lean fish: 3x150 g portions of cod/week (rich in PUFA) 3-Fatty fish: 3x150 g portions of salmon/week (rich in PUFA) 4-Fish oil: DHA/EPA capsules, no seafood (rich in PUFA)	4 weeks	Weight loss and decrease in waist circumference was significantly greater in the groups receiving fish or fish oil (cod, salmon or fish oil) when compared with the control group ($P<0.05$), but in male subjects only	Supportive: Diet rich in PUFA introduces more weight loss compared to diet contains a combination of MUFA and PUFA
Summers LK <i>et al.</i> , 2002 (201)	RCT	High	17 participants- 6 subjects with Type II diabetes, 6 non-obese and 5 obese subjects without diabetes	Participants were randomized to follow diet rich in SFA or in PUFA for two 5-week periods using a crossover design. Based on the diet history, items providing most of the fat intake were identified and participants were given advice on substitutions which would achieve the most effective change in the type of fat consumed	5 weeks for each diet	There was no change in body weight between the two groups after the completion of the study. However, subcutaneous fat area was decreased in the obese ($p = 0.01$) and non-obese ($p = 0.03$) non-diabetic groups following the PUFA diet compared with the SFA diet. When participants were split into two groups according to sex, only female subjects showed a significant decrease in the subcutaneous fat area on the PUFA diet compared with the SFA diet ($p = 0.001$)	Supportive: Increased intake of PUFA was associated with a decrease in subcutaneous fat area.

Evidence Summary: PUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Couet C <i>et al.</i> , 1997 (188)	RCT	Medium	Six healthy young adults with BMI of $21 \pm 1.6 \text{ kg/m}^2$	Participants were fed a control diet <i>ad libitum</i> (during a period of 3 weeks and, 10-12 weeks later, the same were 6 g/d of visible fat were replaced by 6 g/d fish oil (rich source of PUFA) for another 3 weeks	3 weeks for each diet	Body fat mass decreased with fish oil diet (-0.88 ± 0.16 vs -0.3 ± 0.34 kg; fish oil vs control; $p < 0.05$)	Supportive: High PUFA diet (fish oil) reduces body fat mass.
Abbey M <i>et al.</i> , 1994 (207)	RCT	Medium	20 Australian adult men	Week 1- 2: Background diet; 18% of energy from fat as nuts and 18% from other sources Week 3-5: reference diet; PUFA: MUFA:SFA = 0.5:1:1 to match the Australian diet Week 6-8: MUFA diet; background diet + 84 g raw almond (46 g fat) Week 8-11 PUFA diet; background diet + 68 g walnuts (46 g fat)	11 weeks	There were no significant changes in body weight throughout the study. Mean body weights were 86.1 ± 2.8 kg at the beginning of the study and 85.8 ± 2.9 , 85.4 ± 2.9 kg after the reference and PUFA diets periods, respectively.	Not supportive: Increased PUFA intake is not associated with body weight
Trichopoulou A <i>et al.</i> , 2002	Cross-sectional study	High	27,862 health men and women aged 25-82 years	The study was carried out in the Greece cohort as part of a larger study carried out in several European countries. Information on usual food intake was collected through an interviewer-administered semi-quantitative food frequency questionnaire	-	There is evidence of a positive, statistically significant, but weak association between PUFA and BMI	Not supportive: The association between PUFA intake and BMI tends to be positive. Therefore, the increase intake of PUFA may not decrease BMI

Evidence Summary: PUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Brunner EJ <i>et al.</i> , 2001(204)	Cross-sectional study	High	4497 men and 1865 women aged 39 ± 62 years in the Whitehall II study	This is a cross-sectional analysis of the Whitehall II longitudinal study of British Civil Servants Food intakes was assessed by a semi-quantitative food frequency questionnaire	-	- In men, higher intakes of both PUFA and carbohydrates were linked to lower waist - hip ratio - In women, a positive association of PUFA intake with body mass index and waist - hip ratio (0.47 kg/m ² , P <0.05 and 0.006, P <0.05, respectively) were observed.	Supportive: Small positive effect on waist-hip ratio was observed in men who consumed higher PUFA.
Gonzalez CA <i>et al.</i> , 2000	Cross-sectional study	High	23,289 women and 1,437 men aged 29-69 years	The study was carried out in the Spanish cohort as part of a larger study carried out in several European countries. Information on usual food intake was collected by interviewers by means of a dietary history questionnaire	-	The association between PUFA and BMI was very weak, accounting for less than 1% of variance	Not supportive: No significant association between PUFA intake and BMI
Doucet <i>et al.</i> , 1998	Cross-sectional study	High	128 adults men with BMI 28.1±0.4 kg/m ²	Participants were from Phase 2, Generation 2 of the Quebec Family Study. Food intake was assessed by a three-day dietary record. A comparison of body fatness was also performed between consumers of high (4th quartile) and low amounts (1st quartile) of total dietary fat intake (TFI), SFA, MUFA and PUFA	-	There was no any significant relationship between PUFA intake and adiposity. BMI values in higher and lower quartiles were identical.	Not supportive: High PUFA intake is not associated with body weight

Table 6.6 Evidence Summary: MUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Akuamoah-Boateng L <i>et al.</i> , 2007	RCT	High	129 participants with a mean BMI of 22.09±2.58 kg/m ²	Participants were randomized into a control group and 3 intervention groups; peanut oil (rich in MUFA), olive oil (rich in MUFA), and safflower oil (rich in PUFA)	8 weeks	At week 8, there was a significant increase in weight relative to baseline in all 3 oil intervention groups (P<0.05), but not among controls	Not supportive: Higher intake of diet high in MUFA was not associated with weight loss.
Pieterse Z <i>et al.</i> , 2005 (210)	RCT	High	55 adults men and women with BMI 32±3.9 kg/m ²	Subjects were paired and randomly assigned to one of two groups. The experimental group consumed 200g/d of avocado (rich source of MUFA). The control group excluded avocado from their diet. The inclusion of avocado substituted for 30 g of other dietary sources of mixed fat. Diets for both group were isoenergetic and energy restricted and provided total energy intakes of 30% fat, 55% carbohydrates, and 15% protein	6 weeks	There were significant decreases BMI, body mass and percentage of body fat in both groups after treatment but the changes were similar in both groups.	Not supportive: Increased MUFA intake is not associated with body weight
Clifton <i>et al.</i> , 2004 (208)	RCT	Medium	70 adults women with BMI > 27 kg/m ²	Participants were matched by BMI and age, blocked into 2 groups and randomly assigned to one of two different diets: Diet 1 (high in MUFA diet): 6000 kJ, 35% fat, 20% MUFA, and 6% SFA Diet 2 (very low-fat diet): 6000 kJ, 12% fat, 4% MUFA and 4% SFA	12 weeks	Weight loss (9.5 ± 2.4 vs 9.4±3.4 kg, very low-fat diet vs high MUFA diet) and total fat loss (6.1 ± 2.4 vs 6.3±2.7 kg, very low-fat diet vs high MUFA diet) did not differ in the two groups	Supportive: The high MUFA diets (35%) caused weight loss as much as the very low-fat diets (12%)

Evidence Summary: MUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Piers LS <i>et al.</i> , 2003 (216)	RCT	High	8 overweight or obese adults men with BMI 25.5-31.3 kg/m ²	This is a randomized crossover study. Participants provided two different diets followed for 4 weeks each. 1- SFA rich diet: % total energy from SFA, MUFA and PUFA was 24, 13 and 3% respectively 2- MSFA rich diet: % total energy from SFA, MUFA and PUFA was 11, 22 and 7% respectively	4 weeks each diet	Participants had lower weight (-2.6 ± 0.4 kg, $p = 0.0015$) and fat mass (2.6 ± 0.6 kg, $p = 0.0035$) at the end of the MUFA-rich diet as compared with values at the end of the SFA-rich diet	Supportive: Increased MUFA intake is inversely associated with body weight and fat mass.
Zambon <i>et al.</i> , 2000 (211)	RCT	Medium	55 adult men with polygenic hypercholesterol emia	This is a randomized crossover study. Participants provided two different diets followed for 6 weeks each. Diet 1: a cholesterol-lowering Mediterranean diet Diet 2: diet of similar energy and fat content to diet 1 in which walnuts replaced approximately 35% of the energy obtained from MUFA	6 weeks for each diet	Body weight at the baseline was 70.6 ± 12.1 kg and at the end of the control and walnut diet periods was 70.1 ± 12.3 kg and 69.9 ± 12.5 kg respectively. No significant changes were observed.	Not supportive: High intake of PUFA did not demonstrate any weight loss.
Walker KZ <i>et al.</i> , 1996 (209)	RCT	Medium	16 adult participants with Non-insulin-dependent diabetes	This is a randomized crossover study. Participants provided two different diets followed for 3 months each. 1-Fiber-rich, high-carbohydrate, low-fat (HCLF) diet 2-Modified-fat (MF) diet high in MUFA	3 months for each diet	Participants lost similar amounts of body fat consuming the HCLF and MF diets (-0.83 ± 0.37 and -0.87 ± 0.40 kg, respectively) despite a marked difference in total fat consumption.	Supportive: Modified fat, high MUFA diet caused body fat loss as the low fat, high fiber diet.

Evidence Summary: MUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Abbey M <i>et al.</i> , 1994 (207)	RCT	Medium	20 adult men	Week 1- 2: Background diet; 18% of energy from fat as nuts and 18% from other sources Week 3-5: reference diet; PUFA: MUFA:SFA = 0.5:1:1 to match the Australian diet Week 6-8: MUFA diet; background diet + 84 g raw almond (46 g fat) Week8-11 PUFA diet; background diet + 68 g walnuts (46 g fat)	11 weeks	There were no significant changes in body weight throughout the study. Mean body weights were 86.1±2.8 kg at the beginning of the study and 85.8± 2.9, 85.5±2.8 kg after the reference and MUFA diets periods, respectively.	Not supportive: Increased MUFA intake is not associated with body weight
Bes-Rastrollo M <i>et al.</i> , 2006 (212)	Cohort study	Medium	7,368 men and women Spanish university graduates	Participants were followed for a median period of 28.5 months to assess the association between olive oil (rich source of MUFA) consumption and the incidence of obesity. Dietary and non-dietary exposures were assessed through a self-administered questionnaire including 136-item food frequency questionnaire	28.5 months	Odds Ratios (95% CI) of incidence of overweight or obesity according to energy adjusted quintiles (Q1 – Q5) of baseline oil consumption were 1 (reference), 0.97 (0.67-1.40), 0.95 (0.65-1.40), 1.05 (0.72 – 1.53), 1.11 (0.76-1.61), <i>P</i> =0.45	Not supportive: No significant association was observed between olive oil intake and the risk of developing overweight or obesity during follow up

Evidence Summary: MUFA and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Trichopoulou A <i>et al.</i> , 2002 (213)	Cross-sectional study	High	27,862 health men and women aged 25-82 years	The study was carried out in the Greece cohort as part of a larger study carried out in several European countries. Information on usual food intake was collected through an interviewer-administered semi-quantitative food frequency questionnaire	-	The association between MUFA and BMI generally not significant but it appears to be positive and statistically significant among women	Not supportive: The association between MUFA intake and BMI is not significant and tends to be positive among women. Therefore, the increase intake of MUFA may not decrease BMI
Gonzalez CA <i>et al.</i> , 2000 (214)	Cross-sectional study	High	23,289 women and 1,437 men aged 29-69 years	The study was carried out in the Spanish cohort as part of a larger study carried out in several European countries. Information on usual food intake was collected by interviewers by means of a dietary history questionnaire	-	The association between MUFA and BMI was very weak, accounting for less than 1% of variance	Not supportive: No significant association between MUFA intake and BMI
Doucet E <i>et al.</i> , 1998 (215)	Cross-sectional study	High	128 adults men with BMI $28.1 \pm 0.4 \text{ kg/m}^2$	Participants were from Phase 2, Generation 2 of the Quebec Family Study. Food intake was assessed by a three-day dietary record. A comparison of body fatness was also performed between consumers of high (4th quartile) and low amounts (1st quartile) of total dietary fat intake (TFI), SFA, MUFA and PUFA	-	BMI was significantly higher in the upper quartile compared to the lower quartile in regards to MUFA (30.2 ± 1.0 vs 26.7 ± 0.8 , $p = 0.01$)	Not supportive: High MUFA intake is positively associated with BMI

Table 6.7 PUFA intake and weight loss: type, quality and number of supportive and non supportive studies

Study type	Study quality	Number of supportive studies	Number of non supportive studies
RCTs	High	3	2
	Medium	1	1
Cross-sectional studies	High	1	3
	Medium	-	-
Total		5	6

Table 6.8 MUFA intake and weight loss in adults

Study type	Study quality	Number of supportive studies	Number of non supportive studies
Review articles	Medium	-	-
RCTs	High	1	2
	Medium	2	2
Cohort studies	Medium	-	1
Cross-sectional studies	High	-	3
Total		3	8

6.3.2.3 Effect of low glycemic index diet on body weight in adults

Research question:

How effective is the increased intake of low glycemic index (GI) foods or reduced glycemic load (GL) diet on body weight, body fat or food intake in adults?

Date of literature review:

September 2008

Search words:

low glycemic index (GI) diet, glycemic load (GL) diet, body weight, body fat, food intake and weight loss

Possible Mechanisms:

- Low GI diets increase satiety and delay the return of hunger (217-223)
- Low GI diets have been shown to reduce REE (224, 225)
- Low GI diets promote nutrient oxidation rather than storage (226-230)

Evidence-based statement:

Low GI and low GL diets are associated with reduction of weight, body fat, BMI or food intake in adults

Level of evidence: Medium

Literature review:

- One high-quality Cochrane systematic review (including some meta-analysis) showed that weight, body fat and BMI decreased significantly in overweight or obese participants on low GI diets (231).
- Six RCTs (3 high-quality, 3 medium-quality) (232-237), 2 cohort studies (1 high-quality, 1 medium-quality) (238, 239) and 4 high-quality cross-sectional studies (240-243) have demonstrated that consumption of low GI or low GL diets is associated with lower weight, body fat, BMI and/or daily food intake.
- Eight RCTs (5 high-quality, 3 medium quality) (244-251) and 3 medium-quality cross-sectional studies showed significant reduction in weight, body fat, BMI and/or food intake (252-254).

Comments:

- The evidence for a positive effect of low GI on weight mainly comes from short-term trials. Long-term evidence is needed to assess usefulness in long-term weight loss.
- There are contradictions between conclusions from some health organizations regarding the use of low GI diets in weight management. The American Dietetic Association (ADA) reported strong evidence not recommending this approach (11). The conclusion was drawn from 9 studies considering the effect of low GI diets on weight and food intake only. Other studies that showed improvements in other parameters such as hunger and body fat were not considered as supportive studies for the use of low GI diets in weight management. On the other hand, the Dietitians Association of Australia (DAA) reported a weak evidence for the use of this approach (159) and the most recent Cochrane review is supportive (231).

Table 6.9 Evidence Summary: low glycemic index diet and weight loss in adults
(Studies grouped by study design and date order)

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Aston LM <i>et al.</i> , 2008 (244)	RCT	High	19 overweight and obese women with moderate hyperinsulinaemia	Randomized crossover intervention study including two consecutive 12-week periods. Lower or higher GI versions of key carbohydrate-rich foods were provided to subjects to be incorporated into habitual diets in <i>ad libitum</i> quantities. Foods intended as equivalents to each other were balanced in macronutrient composition, fiber content and energy density	12 weeks	There were no differences in energy intake, body weight or body composition between high GI and low GI diets	Not supportive: Low GI diet does not show any significant effect on body weight or composition.
Wolever TM <i>et al.</i> , 2008 (245)	RCT	High	162 adults with type II diabetes	Participants were randomly assigned to receive high-carbohydrate, high-GI diet, high-carbohydrate, low-GI diet, or low-carbohydrate, high-monounsaturated-fat (low-CHO) diet for 1 y.	1 year	The initial weight loss was mainly seen with the low-GI diet, and the late weight gain was mainly seen with the low-CHO diet, these differences were not significant (diet X time interaction, $P = 0.09$; main effect of diet, $P = 0.062$)	Not supportive: Low GI diet does not demonstrate any significant weight loss compared to high-carbohydrate, low-GI diet, or low-carbohydrate, high-monounsaturated-fat diet

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Maki KC et al., 2007 (232)	RCT	High	86 healthy adults	Participants were randomly assigned to a low GL ($n=43$) or a low-fat, portion controlled (control; $n=43$) diet groups. The low GL group was instructed to eat until satisfied, maintaining a low carbohydrate intake during weeks 0 - 2 and adding low-glycemic-index carbohydrate thereafter. Control subjects were instructed to reduce fat intake and decrease portion sizes, with a targeted energy deficit of 500 to 800 kcal/d. Weeks 0–12 were weight-loss treatment. At some point between weeks 12 and 24, each subject transitioned to a weight-maintenance phase. From week 24 on, all subjects were in the weight-maintenance phase	36 weeks	<ul style="list-style-type: none"> - The low GL group had lost significantly more weight than did the control group at week 12 (- 4.9 and - 2.5 kg, respectively; $P = 0.002$), but the 2 groups did not differ significantly at week 36 (- 4.5 and - 2.6 kg, respectively; $P = 0.085$). - Changes in fat mass differed between the groups at week 12 (- 1.9 and - 0.9 kg, respectively; $P = 0.016$) but not at week 36 (- 2.0 and - 1.3 kg, respectively; $P = 0.333$) 	Supportive: Low GL diet significantly reduces weight and fat mass compared with the restricted low fat diet during the weight-loss treatment
Sichieri R et al., 2007 (246)	RCT	High	203 healthy adults women	Participants were randomly assigned to an low GI or an high GI diet with a small energy restriction (100-300 kcal/day deficit)	1.5 year	The low GI group had a slightly greater weight loss in the first 2 months of follow-up (- 0.72 compared with - 0.31 kg), but after 12 months of follow-up both groups began to regain weight. After 18 months, the weight change was not significantly different ($P = 0.93$) between groups (low GI: - 0.41 kg; high GI: - 0.26 kg)	Not supportive: Long-term intervention with low GI does not significantly reduces weight compared to high GI diet

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
McMillan-Price J <i>et al.</i> , 2006 (233)	RCT	Medium	129 overweight or obese young adults	Participants were randomly assigned to 1 of 4 reduced-fat, high fiber diets: Diet 1: high carbohydrate and high GI Diet 2: high carbohydrate and low GI Diet 3: high protein and high GI Diet 4: high protein and low GI	12 weeks	- All groups lost a similar mean±SE percentage of weight (diet 1, -4.2%±0.6%; diet 2, -5.5%±0.5%; diet 3, -6.2%±0.4%; and diet 4, -4.8%±0.7%; P=0.09) - In women (n=98), the two reduced- GI diets were associated with 80% greater fat loss compared with the conventional low-fat diet (diet 1; P = 0.007), without compromising lean mass - In the carbohydrate diets, lowering GI doubled the fat loss from 2.8 kg to 4.5 kg, p = 0.02 while in the high protein diets lowering the GI did not increase fat loss	Supportive: Low GI diets in women are associated with significant fat loss. Also similar effect has been shown with the high carbohydrate and low GI diet.
Alfenas RC and Mattes RD, 2005 (247)	RCT	Medium	39 healthy adults	Participants were randomly assigned to consumed low or high glycemic index foods <i>ad libitum</i> for 8 days in either high (3 foods/meal) or low (1 food/meal) conditions. The study involved a washout period of at least 15 days. Appetite was assessed by rating of hunger, desire to eat, and fullness at stipulated times	8 days	There was no significant differences in appetite ratings or food intakes between meals	Not supportive: low GI food does not affect appetite or food intake

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Carels RA <i>et al.</i> , 2005 (248)	RCT	Medium	40 obese adults	Participants were randomly assigned to receive either a behavior weight loss program (BWLP) or a BWLP + GI education. Weight loss, body fat and food intake were assessed at baseline, after 20 weeks of treatment and after 1 year	20 weeks treatment and 1 year follow up	There were no significant pre- to post treatment differences between the BWLP and BWLP+GI groups in body weight, BMI, body fat or total daily calories intake	Not supportive: GI education does not show any significant affect on body weight, body fat or food intake
Ebbeling CB <i>et al.</i> , 2005 (234)	RCT	Medium	23 obese young adults	Participants were randomly assigned to the experimental (low-GL diet) or conventional (low-fat diet) treatment group. The experimental treatment emphasized <i>ad libitum</i> consumption of low GI foods, with 45–50% of energy from carbohydrates and 30–35% from fat. The conventional treatment was restricted in energy (250–500 kcal/d deficit) and fat (<30% of energy), with 55–60% of energy from carbohydrate. Study outcomes were measured at 0, 6, and 12 months	1 year	Body weight decreased significantly over a 6-months in both the experimental and conventional diet groups (-8.4% and -7.8%, respectively) and remained below baseline at 12 months (-7.8% and -6.1%, respectively).	Supportive: <i>ad libitum</i> consumption of low GI foods demonstrates a significant decrease in body weight

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Raatz SK <i>et al.</i> , 2005 (249)	RCT	Medium	29 healthy obese adults	<p>Participants were randomly assigned to 1 of 3 hypocaloric test diets:</p> <ul style="list-style-type: none"> - high GI (HGI) diet - low GI (LGI) diet - high fat (HF) diet <p>The study was conducted in 2 continuous phases:</p> <ul style="list-style-type: none"> - Feeding phase (first 12 weeks): all food was provided to subjects and instructed not to eat any other food - Free-living phase (for week13-36): diet assignment was maintained but participants prepared their own meals 	36 weeks	<p>- At 12 wk, weight changes from baseline were significant in all groups but not different among groups (- 9.3±1.3 kg for the HGI diet, - 9.9±1.4 kg for the LGI diet, and - 8.4±1.5 kg for the HF diet)</p> <p>- Weight changes between wk 12 and 36 did not differ among the groups and were - 1.8±1.9 kg, - 1.6± 1.9 kg, and 1.1±1.5 kg for the LGI, HGI, and HF groups, respectively</p>	Not Supportive: Low GI diet does not provide any added benefit to energy restriction.
Frost GS <i>et al.</i> , 2004 (250)	RCT	High	55 free-living patients with coronary heart Disease	Participants were randomly assigned to a control group, who received healthy eating dietary advice only, or an intervention group, who received healthy eating advice emphasizing low GI carbohydrates	12 weeks	All outcomes measures including body weight were similar after 12 weeks of the low GI diet or control diet	Not supportive: Healthy eating advice on low GI carbohydrates diet does not demonstrate any significant weight loss compared with general healthy eating dietary advice, suggesting no additional benefits of an low GI diet

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Pereira MA <i>et al.</i> , 2004 (235)	RCT	High	39 overweight or obese young adults	Participants were randomly assigned to an energy restricted diet, either low GL or low-fat. Participants were studied before and after 10% weight loss. REE, body compositions and hunger were assessed.	10% weight reduction achieved by 69.4±3.8 days for low fat group and 65.2±3.3 days for low glycemic load group	<ul style="list-style-type: none"> - Weight loss in low-fat diet and low GL diets groups were very similar (9.5±0.3 vs 9.6±0.3 kg, $p=.85$, respectively) - REE decreased less with the low GL diet than with the low-fat diet, expressed in absolute terms (96±24 vs 176±27 kcal/d; $P=.04$) or as a proportion (5.9±1.5% vs 10.6±1.7%; $P=.05$). - Participants receiving the low GL diet reported less hunger than those receiving the low-fat diet ($P=.04$) 	Supportive: <ul style="list-style-type: none"> - The low GL diet causes weight loss as much as the very low-fat diet - The low GL diet group demonstrates less hunger and less decrease in REE compared with the low fat diet group
Sloth B <i>et al.</i> , 2004 (251)	RCT	High	45 healthy overweight young women	Participants were randomly assigned to consume a low-fat, high-carbohydrate diet with either low GI or high GI on <i>ad libitum</i> . The low GI or high GI test foods, given as replacements for the subjects' usual carbohydrate-rich foods, were equal in total energy, energy density, dietary fiber, and macronutrient composition	10 weeks	There were no significant pre-to post-treatment differences between the low GI and high GI groups in body weight changes (- 1.9±0.5 vs 1.3±0.3 kg; $p= 0.31$, respectively), fat mass (- 1.0±0.4 vs -0.4±0.3 kg; $p = 0.20$, respectively)	Not supportive: Low GI diets are not more beneficial than the high GI diets

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Bouche <i>C et al.</i> , 2002 (236)	RCT	Medium	11 healthy adults men	Participants were randomly assigned to 5 weeks of an low GI or high GI diet separated by a 5-week washout interval in a crossover design	5 weeks each diet	The low GI diet resulted in lower total fat mass by ~ 700 g ($P < 0.05$) and a tendency to increase lean body mass ($P < 0.07$) without any change in body weight	Supportive: Low GI diet significantly decreases fat mass
Slabber M et al., 1994 (237)	RCT	High	30 hyperinsulinemic obese women	Two energy-restricted diets were followed for 12 weeks in crossover design with 12 weeks washout in between. The first diet was designed to evoke a low insulin response (ID) (low glycemic index), and the second was a conventionally balanced diet (ND). After the 12-week washout period, seven and nine subjects who had been on the ID and ND, respectively, changed to the alternative diet for 12 weeks	12 weeks	<ul style="list-style-type: none"> - Both diets resulted in statistically and clinically significant weight loss ($p < 0.001$) after the parallel study. The ND, subjects lost 7.41 ± 4.23 whereas treatment with the ID resulted in 9.34 ± 2.49 kg weight loss - The mean difference between the effects of the two diets in the parallel study was 1.93 kg ($p = 0.14$) - The difference in weight loss between the ND and ID in the crossover study was 2.94 kg ($p = 0.04$) 	Supportive: Low GI (ID) diet shows more weight loss than the normal diet.

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Hare-Bruun H <i>et al.</i> , 2006 (238)	Cohort study	High	376 healthy adults	This prospective cohort study was conducted in a sub-sample of men and women from the Danish arm of the Monitoring Trends and Determinants in Cardiovascular Disease study. A baseline health examination and a dietary history interview were carried out in 1987 and 1988; a follow-up health examination was performed in 1993 and 1994	6 years	<ul style="list-style-type: none"> - Positive associations between GI and changes in body weight ($p = 0.04$), percentage body fat ($p = 0.04$), and waist circumference ($p = 0.07$) were observed in women after adjustment for covariates - No significant associations with GI were observed in men, and no significant associations with GL were observed in either sex 	Supportive: GI is positively associated with changes in body weight and % body fat in women
LaHaye SA <i>et al.</i> , 2005 (239)	Cohort study	Medium	1554 cardiac adult patients	120 patients on a low GL diet were evaluated and compared with 1434 patients who were advised to follow the principles of Canada's Food Guide to Healthy Eating for People Four Years and Over as part of the Ontario Cardiac Rehabilitation Pilot Project	6 months	Participants on the low GL diet lost more weight at 6 months (2.8 kg loss vs 0.2 kg gain, $p < 0.0001$) and had a greater reduction in abdominal obesity (2.9 cm vs 0.4 cm, $p < 0.0001$)	Supportive: Low GL diet demonstrates a significant weight loss compared with the Canada's Food Guide

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Murakami K <i>et al.</i> , 2007 (240)	Cross-sectional study	High	3931 female Japanese dietetic students aged 18–20 years	This study was based on a self-administered questionnaire survey of a wide range of dietary and nondietary behaviors among dietetic students from 54 universities, colleges and technical schools in 33 of 47 prefectures in Japan. Dietary habits during the previous month were assessed using a previously validated, self-administered diet history questionnaire	-	Dietary GI and GL were independently positively correlated with BMI (20.8 and 21.2 kg/m ² ; <i>P</i> for trend = 0.03, and 20.5 and 21.5 kg/m ² ; <i>P</i> for trend = 0.0005, respectively)	Supportive: GI diet is positively correlated with BMI
Murakami K <i>et al.</i> , 2006 (241)	Cross-sectional study	High	1354 Japanese female adult farmers	This is a cross-sectional analysis of associations between dietary GI and GL and several metabolic risk factors in healthy Japanese women with traditional dietary habits. Dietary GI and GL were assessed with a self-administered diet-history questionnaire	-	After adjustment for potential dietary and non-dietary confounding factors, dietary GI was positively correlated with BMI (<i>P</i> for trend=0.017)	Supportive: GI diet is positively correlated with BMI

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Liese AD <i>et al.</i> , 2005 (252)	Cross-sectional study	Medium	979 adults with normal (67%) and impaired (33%) glucose tolerance	This study is cross sectional analysis of the Insulin Resistance Atherosclerosis Study. Food intake was assessed by a 114-item interviewer-administered food frequency questionnaire	-	After adjustment of energy total energy intake, there was no significant correlation between GI and BMI or WC.	Not supportive: GI is not associated with BMI or WC
Ma Y <i>et al.</i> , 2005 (242)	Observational cross-sectional study	High	572 healthy adults	This is an analysis of observational study in which 7-day dietary recalls were collected quarterly from each subject throughout a 1-year study period	-	Daily dietary GI was positively associated with BMI, with a five-unit increase in GI being significantly associated with an increase of 0.75 units in BMI ($p = 0.01$) from cross-sectional effects and an increase of 0.04 unit in BMI ($p = 0.02$) from longitudinal effects.	Supportive: GI is positively correlated with BMI
Sahyoun NR <i>et al.</i> , 2005 (253)	Cross-sectional analysis from a cohort study	Medium	2248 older adults aged 70-80 years	This is a cross-sectional analysis of relations of dietary GI and GL with measures of glucose metabolism and body fat distribution in participants of the Health, Aging and Body Composition Study, a prospective cohort study. Food intake was measured in the second year of the study with a 108-item food-frequency questionnaire	-	In men, dietary GI was inversely associated with thigh intramuscular fat (P for trend = 0.02), and not significantly associated with visceral abdominal fat. Dietary GL was inversely associated in men with visceral abdominal fat (P for trend = 0.02) and not significantly associated with thigh intramuscular fat. In women, although dietary GI and GL were not significantly related to body fat distribution.	Partially supportive: GL (but not GI) was inversely correlated with visceral body fat in men (but not women)

Evidence Summary: low glycemic index diet and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Amano Y et al., 2004 (254)	Cross-sectional study	Medium	32 healthy adult women	This is a cross-sectional study that was conducted to explore the associations between dietary GI, GL and dietary intakes, and CVD risk factors. Food intakes was assessed by a 3-day dietary records	-	Body weight and body fat percent were not significantly different among the different tertiles of dietary GI ($p = 0.403$ and 0.158 , respectively) and GL ($p = 0.068$ and 0.059 , respectively)	Not supportive: GI and GL are not significantly associated with weight or body fat
Toeller M <i>et al.</i> , 2001 (243)	Cross-sectional study	High	1458 males and 1410 females with type 1 diabetes	Cross-sectional, clinic-based study to determine nutrients that predict measures of body weight (BMI, WHR and WC). Food intake was assessed by a 3-day dietary record stepwise forward regression analysis was used to predict nutrients.	-	Low GI diet determined lower levels of WHR and WC	Supportive: Low GI diet is associated with lower WHR and WC

Evidence Summary: low glycemic index diet and weight loss in adults

Review Articles						
Author	Review design	Quality rating	Number and types of studies	Methods	Results	Conclusion
Thomas DE et al., 2008 (231)	Systematic review	High	6 RCTs (202 participants)	<p>Intervention: Low GI or low GL diets vs High GI or high GL or other diets</p> <p>Inclusion criteria:</p> <ul style="list-style-type: none"> - RCTs with dietary intervention lasting two weeks or longer - Males and females of any age (including children) who were classified as overweight or obese <p>Analysis: Data were summarized statistically when they were sufficiently uniform. For continuous outcomes, weighted mean differences (WMD) was calculated</p>	The decrease in body mass (WMD -1.1 kg, 95% CI -2.0 to -0.2, $P < 0.05$) (n = 163), total fat mass (WMD -1.1 kg, 95% CI -1.9 to -0.4, $P < 0.05$) (n = 147) and BMI (WMD -1.3, 95% CI -2.0 to -0.5, $P < 0.05$) (n = 48) was significantly greater in participants receiving low GI compared to the comparison diets	Supportive: Low GI diets shows significant decrease in body mass, total fat mass and BMI compare to other comparison diets

Table 6.10 low glycemic index diet and weight loss: type, quality and number of supportive and non supportive studies

Study type	Study quality	Number of supportive studies	Number of non supportive studies
Review articles	High	1	-
RCTs	High	3	5
	Medium	3	3
Cohort studies	High	1	-
	Medium	1	-
Cross-sectional studies	High	4	-
	Medium	-	3
Total		13	11

6.3.2.4 Effect of Fiber intake on body weight in adults

Research question:

How effective is increased intake of fiber on satiety and body weight in adults?

Date of literature review:

January 2009

Search words:

Fiber, satiety, body weight, weight loss

Possible Mechanisms:

- Food rich in fiber needs greater mastication in terms of effort and time which can promote satiation by reducing ingestion rate (255)
- Fiber chewing promotes the secretion of saliva and gastric acid (255, 256), resulting in gastric distension which trigger afferent vagal signals of fullness and hence contribute to satiety (257).
- Fiber delays gastric emptying, which may cause an extended feeling of fullness (256, 258)
- Fiber consumption increases secretion of some gut hormones that decrease appetite, hunger and food intake (259, 260)
- Soluble and fermentable fiber reduces the absorption of fat and protein. This may be because their presence in the gastrointestinal tract restricts the physiological contact between nutrients and intestinal villi necessary for absorption (261, 262).

Evidence-based statement:

Increased intakes of dietary fiber are associated with increased body weight loss, reduced energy intake, increased satiety and reduced hunger

Level of evidence: Low

Literature review:

- One high-quality RCTs demonstrated that high fiber intake did not show any significant effect on weight or satiety (263)
- One high quality RCT showed that high fiber diet reduces appetite and food intake (264)
- One medium-quality prospective cohort study showed that high fiber intake reduces body weight and fat in adult women (265)
- One medium-quality cross-sectional study indicated that high fiber intake is associated with lower BMI (240)
- Four non-systematic reviews (three medium-quality, one low-quality) (266-269) have concluded that high fiber consumption decreases body weight, body fat, BMI, food intake, hunger and/or increase satiety
- One medium-quality meta analysis showed that fiber supplements (guar gum) does not reduce body fat (270)

Comments:

- The role of fiber in weight management has been studied since 1959 when Yudkin conducted the first clinical trial to examine the effects of fiber on energy balance (271). Since that time extensive research and several reviews has been conducted on this topic. Therefore, this summary relied primarily on the existing reviews to assess the evidence, in addition to five more recent studies from 2007-2009.
- The American Dietetic Association position paper (272) published in 2008 concluded that dietary fiber intake may have some benefit in terms of weight loss and other health outcomes. The assigned grade for this conclusion was Grade III - Limited

Table 6.11 Evidence Summary: Fiber intake and weight loss in adults
(Studies grouped by study design and date order)

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Salas-Salvado J <i>et al.</i> , 2008 (263)	RCT	High	200 overweight or obese adults	This is a parallel, double-blind, placebo-controlled clinical trial. Participants were randomised to receive, in the context of an energy-restricted diet, a mixed fiber dose (3 g Plantago ovata husk and 1 g glucomannan) twice or three times daily or placebo (contain 3 g microcrystalline cellulose)	16 weeks	- Weight losses were higher after both doses of fibre (24.52 (SD 0.56) and 24.60 (SD 0.55) kg) than placebo (20.79 (SD 0.58) kg) but the differences in changes between groups were not statistically significant. -Similarly, postprandial satiety increased in both fibre groups compared to the placebo but the differences were not significant	Not supportive: A fibre supplement of up to 9 g Plantago ovata husk and 3 g glucomannan per day does not show any significant effect on body weight
Samara R <i>et al.</i> , 2007 (264)	RCT	High	31 healthy adult men with a BMI of 20-27	In a crossover study, high fiber (33 g insoluble fiber) cereal, low fiber cereal, white bread, and water control were administered to participants after an overnight fast.	Appetite was measured at 15 min intervals before and after an <i>ad libitum</i> meal at 75 minutes	<i>ad libitum</i> food intake was lower after the high fiber cereal and white bread than after the low fiber cereal and water (937±86, 970±65, 1109±90, 1224±89 kcal, respectively; $P < 0.001$). Appetite was lower ($P < 0.05$) after the high fiber cereal than after the white bread but not different from the low fiber cereal	Supportive: High fiber cereal at breakfast reduces appetite and food intake over a period of 75 minutes

Evidence Summary: Fiber intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Study duration	Results	Conclusion
Tucker L and Thomas K, 2009 (265)	Cohort study	Medium	252 adult women with a mean BMI of 31.3 ± 7.1	This prospective cohort study in which participants completed baseline and follow up assessments 20 months apart. Diet was measured using 7-d weighed food records.	20 months	Across the 20months, almost 50% of participants gained weight and fat. For each 1 g increase in total fiber consumed, weight decreased by 0.25 kg ($P = 0.0061$) and fat decreased by 0.25 percentage point ($P = 0.0052$)	Supportive: High fiber intake reduces body weight and fat in adult women
Murakami <i>et al.</i> , 2007 (240)	Cross-sectional study	Medium	3931 female Japanese dietetic students aged 18-20 years	Dietary fiber intake was assessed by a validated, self-administered, diet history questionnaire.	-	Dietary fiber intake was negatively correlated with BMI (adjusted mean = 21.1 kg/m^2 in the lowest and 20.7 kg/m^2 in the highest quintiles; P for trend = 0.0007)	Supportive: High fiber intake is associated with low BMI

Evidence Summary: Fiber intake and weight loss in adults

Review Articles						
Author	Review design	Quality rating	Number and types of studies	Interventions	Results	Conclusion
Pittler MH, 2001 (270)	Meta-analysis	Medium	11 RCTs	Fiber supplements (Guar Gum)	There was a non significant difference in participants receiving guar gum compared with participants receiving placebo (weighted mean difference – 0.04 kg; 95% CI: - 2.2 to 2.1)	Not supportive: Fiber supplementation with guar gum does not reduce body fat
Anderson JW <i>et al</i> , 2009 (269)	Non-systematic review	Medium	<ul style="list-style-type: none"> - 2 cross-sectional studies - 4 cohort studies - 5 RCT (dietary fiber) - 16 RCT (supplements) 	Dietary fiber and fiber supplements	<ul style="list-style-type: none"> - The cross-sectional studies indicated that men and women with the highest level of fiber consumption have a relative risk for obesity of 0.77 (95% CI, 0.68–0.87) compared to those with the lowest fiber intake - The cohort studies reported that women and men with the highest level of fiber consumption had lower rates of weight gain and less obesity than those with the lowest level of fiber intake, with relative risks of 0.70 (95% CI, 0.62–0.78). - The 5 RCTs reported that the mean weight losses over an 8-week period were approximately 1 kg greater with high-fiber diets than with control diets - The 16 RCTs reported that the percentages of weight loss, compared to initial body weight, for placebo and fiber supplemented diets, respectively, were as follows: 4 weeks, 2.0% and 3.2%; 8 weeks, 2.9% and 4.9%; and 12 weeks, 2.7% and 4.9% 	Supportive: <ul style="list-style-type: none"> - individuals with high intakes of dietary fiber appear to be at significantly lower risk for obesity - Fiber supplementation in obese individuals significantly enhances weight loss

Evidence Summary: Fiber intake and weight loss in adults

Review Articles						
Author	Review design	Quality rating	Number and types of studies	Interventions	Results	Conclusion
Slavin JL, 2005 (266)	Non-systematic review	Medium	9 Epidemiological studies and 5 intervention studies	Dietary fiber or fiber supplements	9 epidemiological studies and 4 intervention studies demonstrated that fiber intake is inversely associated body weight, body fat, BMI and/or skinfold thickness 1 intervention study showed that fiber supplements did not alter body weight	Supportive: fiber intake is associated with weight and body fat loss and lower BMI
Howarth NC <i>et al.</i> , 2001 (267)	Non-systematic review	Medium	<ul style="list-style-type: none"> - 11 studies assessed the effect of fixed fiber intake on weight loss - 11 studies assessed the effect of <i>ad libitum</i> fiber intake on weight loss - 18 studies assessed the effect of fiber intake on energy intake - 36 studies assessed the effect of fiber intake on satiety and hunger 	Dietary fiber or fiber supplements	<ul style="list-style-type: none"> - 8 studies out of 11 (> 4 weeks duration) showed a significant weight loss in studies comparing fixed higher fiber diets with a lower-fiber control diets - 6 studies out of 11 (> 4 weeks duration) showed a significant weight loss in studies comparing ad libitum higher fiber diets with a lower-fiber control diets - 11 studies out of 18 demonstrated significant decrease in energy intake during consumption of higher-fiber diets compared with a lower-fiber control diet - 26 studies out of 36 showed that dietary fiber increases satiety or reduces hunger compared to a low fiber control placebo treatment 	Supportive: The majority of studies have demonstrated increased body weight loss, reduced energy intake, increased satiety and reduced hunger during consumption of higher-fiber diets

Evidence Summary: Fiber intake and weight loss in adults

Review Articles						
Author	Review design	Quality rating	Number and types of studies	Interventions	Results	Conclusion
Stevens J, 1988 (268)	Non-systematic review	Low	25 clinical studies (studies type was not clearly described)	Dietary fiber and fiber supplements	16 studies out of 25 showed that fiber intake was associated with a decrease in body weight or food intake. The author reported many methodological limitations such as the absence of a placebo treatment, confounding with time, inadequate measurement of food intake, very low doses of fiber and inappropriate short treatment and observation periods	Supportive: Greater fiber intake decreases body weight and/or food intake

6.12 Fiber intake and weight loss in adults: type, quality and number of supportive and non supportive studies*

Study type	Study quality	Number of supportive studies	Number of non supportive studies
Review articles	Medium	3	1
	Low	0	1
RCTs	High	1	1
Cohort studies	Medium	1	0
Cross-sectional studies	Medium	1	0
Total		6	3

6.3.2.5 Effect of eating frequency and breakfast intake on body weight in adults

Research questions:

How effective is increased eating frequency (EF) in reducing food intake or body weight in adults?

How effective is breakfast intake in reducing food intake or body weight in adults?

Date of literature review:

February 2008

Search words:

Eating frequency, breakfast meal, body weight and body loss

Evidence-based statement:

Higher EF not exceeding 6 meals per day may help in weight reduction in adults.

Level of evidence: Low

Evidence-Based Statement:

Regular breakfast intake is associated with lower body weight

Level of evidence: Medium

Literature review reported by the ADA before July 2005:

- Four to five meals or snacks per day is associated with reduced or no obesity risk, while 3 or fewer and 6 or more meals per day may result in increased risk of obesity, depending on gender. Higher EF is related to lower total daily energy intake and body weights in men, but in women the data is less conclusive. These findings reported from one high-quality RCT and four cross-sectional studies (2 high-quality and 2 medium-quality) (273-277)
- One high-quality RCT, five cross-sectional studies (4 high-quality and 1 medium-quality) demonstrated that breakfast eaters had lower BMI and lower energy intake while breakfast skippers or less energy breakfast eaters had higher BMI (276, 278-281)

- One medium-quality RCT, one medium-quality cohort study and two high-quality cross-sectional studies showed that increased EF and breakfast intake did not support weight loss (282-285)

Literature review not covered by the ADA:

- Six RCTs (4 high-quality and 2 medium-quality) did not show any significant relationship between increased EF or snacks and body weight or energy intake(286-291)
- One high-quality cross-sectional study showed that increased eating frequency is associated with increased body fat (292)
- One high quality cross sectional study showed that there is no difference between BMI of regular breakfast eaters and breakfast skippers (293)
- Two high-quality cross sectional studies demonstrated that increased EF is significantly associated with lower BMI and WHR (294, 295)
- One medium quality review (296) summarized 5 studies that demonstrated strong inverse relationships between habitual meal frequency and body weight while other studies did not show any relationship. In dieting participants, only one study out of 11 studies demonstrated a much better weight loss in participants with higher EF. For the thermic effect of food (TEF), only one study out of five demonstrated increased TEF in participants with higher EF. This review also summarized the results of 5 studies that did not show any significant changes in total energy expenditure (TEE) according to meal patterns.

Comments

This review shows weak evidence indicating to an inverse relationship between high EF (4-6 meals/day) and obesity. This weak evidence may be related to the underreporting by obese people. However, the evidence also shows that the obesity is positively related to the very high EF (> 6 meals/day).

**Table 6.13 Evidence Summary: Meal frequency & breakfast intake and weight loss in adults
(Studies grouped by study design and date order)**

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Palmer M <i>et al.</i> , 2008 (286)	RCT	High	179 obese adults	<ul style="list-style-type: none"> - Participants were randomly assigned to either 3 meals, 3 meals and 3 snacks or 6 meals for 6 months on standardized energy reduction diets of 5-7.5 MJ (15%P±5%, 30%F±5%, 50%CHO±5%). - Body composition was measured at 1, 6, 9 and 12 months 	There were no differences between or within the groups over time for weight, waist and fat mass	Not supportive: There was no significant relationship between EF and body weight, waist or fat mass.
Chapelot D <i>et al.</i> , 2006 (287)	RCT	High	24 young normal-weight male subjects	<ul style="list-style-type: none"> - This study included 12 usual four meal and 12 usual three-meal eaters, differing only in the consumption of an afternoon meal - Participants omitted or added a fourth meal during a 28-day habituation period and were asked to report their intake on three 3-day occasions 	<ul style="list-style-type: none"> - Omitting a meal was followed by increases in fat mass (360±115 grams, $p = 0.05$) - Adding a meal had no effect 	Not supportive: There was no association between adding a meal and bodyweight

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Farshchi HB <i>et al.</i> , 2005 (288)	RCT	High	Ten healthy obese women aged 32–47 y	<ul style="list-style-type: none"> - This is a randomized crossover trial. - In phase 1 (14 d), the subjects consumed their normal diet on 6 occasions/d (regular meal pattern) or followed a variable meal frequency (3–9 meals/d, irregular meal pattern) - In phase 2 (14 d), the subjects followed the alternative pattern. - Subjects recorded their food intake on 3 d during each phase. - The thermogenic response to a test meal was ascertained by indirect calorimetry 	<ul style="list-style-type: none"> - Regular eating was associated with lower energy intake ($P = 0.01$), greater postprandial thermogenesis ($P = 0.01$) - There were no differences between the preintervention and postintervention body weights under either meal pattern - There were also no significant differences between preintervention and postintervention anthropometric measurements or body-fat composition under either meal pattern period 	Not supportive: There was no significant relationship between EF and body weight or other anthropometric measurements.
Westerterp-Plantenga MS <i>et al.</i> , 2002 (277)	RCT	High	20 healthy young men aged between 18 – 31 years	<ul style="list-style-type: none"> - Randomized, cross-over, within subjects' trial. - On 2 separate days after a 10 hour overnight fast, subjects were given a different preload (iso-energetic, iso-caloric high fat or high carbohydrate (CHO)) upon their first meal request, then had ad lib food intake measured for 8 hours. - The 2 conditions (high fat or high CHO) were tested on 2 different days, separated by at least 1 week 	<ul style="list-style-type: none"> - 1st intermeal interval was less for CHO preload compared to fat preload (62 vs 121 min, $p > 0.001$) - Habitual meal frequency from food records was positively related to manipulated meal frequency on test days ($r^2 = 0.86$, $p < 0.0001$) - High habitual meal frequency showed lower 24 hour intake 	Supportive: Increased EF is inversely associated with food intake that might cause weight loss.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Taylor MA & Garrow JS, 2001 (290)	RCT	High	26 obese female aged more than 18 years	<ul style="list-style-type: none"> - Subjects were confined to a chamber calorimeter from 19:00 h on day 1 to 09:30 h on day 6 - Each day they had a fixed diet providing 4.2 MJ with three pairs of meal patterns which were offered in random sequence. - Meal patterns: six meals vs two meals without access to additional foods (6vs2), or six meals vs two meals with access to additional food (6.vs2.), or six meals vs four meals (6.vsAMFAST). - In the AMFAST condition the first two meals of the day were omitted to reduce daily intake to 2.8 MJ and to create a morning fast, but additional food was accessible thereafter - From 09:00 h on day 2 subjects were allocated randomly to one of three studies which provided 2 days of one meal pattern followed by a second 2 days of a second meal Pattern 	<ul style="list-style-type: none"> - The difference between energy expenditure with six meals (10.00 MJ) and two meals (9.96 MJ) was not significant (P =0.88). - Total energy intake was higher (not significant, P=0.58) with two meals per day compared with six meals per day. - Neither meal frequency (6vs2, P=0.88; 6.vs2.; P=0.50) nor a morning fast (P=0.18) resulted in differences in energy balance that were statistically significant 	Not supportive: Higher EF was not associated with energy intake or energy expenditure.
Johnstone AM <i>et al.</i> , 2000 (289)	RCT	Medium	8 healthy, non-smoking men (mean age 27.3 ± 6.4 years)	<ul style="list-style-type: none"> - Subjects were each studied four times in a 9 d protocol per treatment - On days 1–2, subjects were given a medium-fat maintenance diet - On days 3–9, subjects consumed three mandatory isoenergetic, isoenergetically dense (380 kJ/100 g) snacks at fixed time intervals (11.30, 15.30 and 19.30 hours). subjects had <i>ad libitum</i> access during the rest of the day - The treatments were high protein (HP), high carbohydrate (HC), high fat (HF) and no snack (NS) 	<ul style="list-style-type: none"> - Total EI values were not significantly different at 14.6 (HP), 14.5 (HC), 15.0 (HF) and 14.2 (NS) MJ/d. - Body weight was unaffected by dietary treatment 	Not supportive: Higher EF was not associated with bodyweight or energy intake comparing diets with or without snacks.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Martin A <i>et al.</i> , 2000 (282)	RCT	Medium	Ten healthy men (mean age 28± 2 years)	<ul style="list-style-type: none"> - Subjects were assigned either a low energy, moderate fat breakfast (LE breakfast; 100 kcal; 34.4% fat) or a high energy, low fat breakfast (HE breakfast; 700 kcal; 24.6% fat) for two 2 week periods in a crossover design - During the 2 week periods the subjects ate their assigned breakfast at the metabolic unit between 7 and 9 am, after which they returned to their normal routine and recorded their intake for the remainder of the day 	<ul style="list-style-type: none"> - Subjects increased energy intake during other meals (p=.0051) when consuming LE breakfast - Total energy intake was significantly higher during the high-energy breakfast period than during the two other periods 	Not supportive: Eating substantial breakfast increases the total daily energy intake
Yates H <i>et al.</i> , 1998 (291)	RCT	Medium	10 male subjects aged 20-50 years	<ul style="list-style-type: none"> - This is a crossover intervention study over a six week period - One group consumed a given snack 30 minutes and the other 90 minutes before lunch and evening meals for a two-week period - After a washout period, the snacking regimes were reversed - Subjects completed a seven day semi-weighed dietary diary at baseline and a four-day diary during the second week of the two intervention periods 	<ul style="list-style-type: none"> - For all subjects, body weight remained virtually unchanged throughout the six weeks of the study - Most subjects compensated for the pre-meal snack (energy value 0.88MJ) by reducing energy intake at the next meal - Mean overall daily energy intake increased slightly on both snacking intervention regimes (Baseline = 3.08±0.90 MJ/d, 30 minutes snack = 2.88±0.67 MJ/d, 90 minutes snake= 2.75±0.82MJ/d) 	Not supportive: There was no association between snacking intervention regimes and body weight.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Schlundt DG <i>et al.</i> , 1992 (281)	RCT	High	52 moderately obese women aged between 18 and 55 years	<ul style="list-style-type: none"> - Subjects were stratified by their breakfast eating habits and then randomly assigned to 2 experimental conditions (breakfast or no breakfast). - Two 1200 kcal/d weight reduction programs were used - one divided into 2 meals/d (no breakfast group) and the other into 3 meals/d (breakfast group). - At 6 months after the beginning of the program, participants returned to be weighed and retested on several dependent measures 	<ul style="list-style-type: none"> - The breakfast treatment group showed a greater reduction in ($P < 0.001$): <ul style="list-style-type: none"> • energy and fat from impulsive snacking • meal size • energy and fat at social meals • frequency of very large meals • impulsive snacking - Interaction effect with breakfast skippers assigned to the breakfast treatment ($P < 0.001$) showing a greater reduction in: <ul style="list-style-type: none"> • impulsive snacking • meal size • uncontrolled eating • high energy and fat intake at work 	<p>Supportive:</p> <ul style="list-style-type: none"> - Eating breakfast is associated with a reduction in energy and fat intake - Breakfast eaters had a greater reduction in impulsive snacking
Kant AF <i>et al.</i> , 1995 (283)	Cohort study	Medium	7141 (large numbers were excluded for missing or unreliable data). Resulting n is 68% of eligible cohort of 10,424. (2580 men, 4567 women)	<ul style="list-style-type: none"> - Data was used from the NHANES I (1971-75) and NHANES I Epidemiologic Follow-up Study (1982-84) (NHEFS) - Frequency of eating occasions was estimated by summing the energy yielding consumption reported at one time using a single 24-hour recall at Time 1 (1971-75) - At follow-up (1982-84) respondents were asked one question each regarding the number of meals and number of snacks consumed daily and weight was measured 	<ul style="list-style-type: none"> - In women, mean baseline BMI decreased with increasing baseline frequency of eating occasions ($P < 0.006$) - In men, mean baseline BMI decreased with increasing baseline EF. - Mean dietary energy and alcohol intake increased with increasing baseline EF in both men and women - At follow-up, the highest eating frequency category ($\geq 6/d$) was associated with largest mean weight change and baseline BMI in women, but not men - For every unit increase in EF at baseline, men and women gained 0.22 kg (.48 lbs) ($P = 0.03$) and 0.34 kg (.75 lbs) ($P = 0.0002$) of body weight, respectively, over the period of follow-up. - After adjustment for age, and other confounders, this relationship was no longer significant 	<p>Not supportive:</p> <p>There was no independent association of frequency of food ingestion with prospective weight change over the preceding 8-10 years in the NHEFS cohort</p>

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Yannakoulia M <i>et al.</i> , 2007 (292)	Cross sectional study	High	220 free-living women, 64 pre- and 50 postmenopausal (24 to 74 years)	<ul style="list-style-type: none"> - In this cross-sectional study non-low-energy-reporting women were analyzed - Anthropometric and body composition measurements (DXA) were performed in all study participants. - Eating frequency, energy, and macronutrient intake were assessed by 3-day food record. 	<ul style="list-style-type: none"> - No association between eating frequency and adiposity indices was detected in premenopausal women - Eating frequency was positively correlated with percentage body fat in postmenopausal women ($r = 0.30, p = 0.03$) - Multivariate analysis revealed that, in postmenopausal women, EF was a significant predictor of body fatness (standardized $\beta = 0.41, p = 0.01$). 	Not supportive: Higher frequent eating was associated with increased body fat in postmenopausal women
Forslund HB <i>et al.</i> , 2005 (275)	Cross sectional study	High	1891 obese men, 2368 obese women, 505 reference men, 587 reference women	The obese participants volunteered to participate in a study about diabetes in obese subjects. The reference groups were recruited from the Swedish Obese Subjects reference study. All participants completed questionnaires on meal patterns and dietary intake describing daily energy, macro- and micronutrient intake during the last 3 months	<ul style="list-style-type: none"> - Number of intake occasions was higher in women than in men ($P < 0.055$) - Obese group more frequently reported snacks ($P < 0.01$) - Obese group most frequently reported 6 intake occasions compared to 5 in the reference men and women ($P < 0.01$) - Obese group reported higher number of intake occasions (OR=1.21, CI=1.15-1.27, $P < 0.001$) and energy intake (OR=1.49, CI=1.37-1.62, $P < 0.001$) compared to the reference group 	Supportive: Very high EF (> 6meals/d) were observed more often in obese participants.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Song WO <i>et al.</i> , 2005 (279)	Cross sectional study	High	4,218 participants aged > 19 years	Cross-sectional comparison (NHANES 1999-2000) between breakfast consumers and non-consumers and the effect of breakfast habits on BMI	<ul style="list-style-type: none"> - Mean daily energy intake was higher for breakfast consumers than for breakfast nonconsumers among women (1871 vs 1657 kcal/d; $P=0.0009$), but not among men - Compared with female breakfast nonconsumers, women who consumed breakfast were less likely to have BMI ≥ 25 (OR=0.76, 95% CI=0.56 to 1.011, $P=0.57$) 	Supportive: Female breakfast consumers had lower BMI
Williams P <i>et al.</i> , 2005 (293)	Cross sectional study	High	10851 Australians aged 19 years and older	This an analysis of data collected in the 1995 Australian National Nutrition Survey. The survey included 24-h recalls, physical measurements and a food habits questionnaire.	Comparisons of the BMI of adult breakfast eaters and skippers found no significant difference between the two groups ($P = 0.159$)	Not supportive: There was no difference between BMI of regular breakfast eaters compared with breakfast skippers.
Cho S <i>et al.</i> , 2003 (278)	Cross sectional study	High	16,452 men and women with a mean age of 43.9 years.	<ul style="list-style-type: none"> - Cross-sectional analysis of NHANES III dietary data. - foods consumed at breakfast were categorized into 10 categories; skippers, dairy, meat and eggs, fruits and vegetables, ready-to-eat (RTE) cereals, cooked cereal, brads, quick brads, fats and sweets and beverages. 	<ul style="list-style-type: none"> - Subjects who ate RTE cereal, cooked cereal, or quick breads had a lower BMI compared to subjects who skipped breakfast or who ate meat and eggs ($p<0.01$). - Breakfast skippers had the lowest energy (kcal) intake throughout the day ($p<0.01$, with values ranging from 2027.9 for breakfast skippers and 2046.0 for fruit and vegetables group to 2324.8 for the cooked cereals group and 2433.7 for the meat and eggs group) 	Supportive: Subjects with different breakfast types had the lowest BMI compared to breakfast skippers despite the low energy intake of skippers.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Ma Y <i>et al.</i> , 2003 (276)	Cross sectional study	High	499 white men and women aged between 20-70 years	<ul style="list-style-type: none"> - Cross-sectional design using 3 24-hour recalls. - Body weight collected over 5 time periods equally spaced across 1 year 	<ul style="list-style-type: none"> - Number of eating episodes was inversely associated with the risk of obesity (95% CI: 0.33, 0.91)., with ≥ 4 episodes/day having a 45% lower risk of obesity, compared to ≤ 3 episodes/day - Skipping breakfast (75% of days measured by the 24-hour recall) was associated with a higher risk of obesity (OR=4.5; 95% CI: 1.57, 12.90). 	Supportive: Increased eating episodes were associated with a lower risk of obesity. Also skipping breakfast was associated with increased prevalence of obesity
Forslund HB <i>et al.</i> , 2002 (274)	Cross sectional parallel group study	Medium	83 Swedish obese women (47.7 \pm 5.9 years) and 94 reference group (49.6 \pm 7.2 years old) BMI: reference women = 23.8 \pm 3.1; obese women 41.0 \pm 3.4	Participants were selected from the registry of the Swedish Obese Subjects study and invited to participate. Questionnaire designed to assess meal frequency, type, and time for a typical 24-hour period were mailed to obese subjects and completed by reference subjects at a health exam.	<ul style="list-style-type: none"> - Obese participants consumed significantly more meals (6.1 vs 5.2, P = < 0.0001) and snacks (2.2 vs 1.6, P= 0.0001) per day than the reference group. - Obese group consumed significantly more daily energy (11970 KJ vs 9756 KJ), P<0.05) than reference group 	Supportive: Very high EF (>6 meals/d) and energy intake were observed in obese women

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Ruidavets JB <i>et al.</i> , 2002 (294)	Cross sectional study	High	330 free-living middle-aged men (45 – 64 y).	-A cross-sectional survey on cardiovascular risk factors and a nutritional survey were carried out in the region of Toulouse in France - Body mass index (BMI), waist-to-hip ratio (WHR) and 3-day food record were reported	- In the whole sample, BMI and WHR decreased significantly ($P < 0.05$) along with the increase of the number of eating occasions - For WHR, averages were 0.98, 0.95, 0.94 and 0.93 for 1 – 2, 3, 4 or 5 or more feedings a day, respectively - For BMI, mean values were 28.1, 26.2, 26.2 and 24.5 kg=m ² , respectively - After adjustment for confounders the linear trend for BMI and WHR throughout feeding categories was significant	Supportive: the increase of eating frequency is associated with lower BMI and WHR.
Wyatt HR <i>et al.</i> , 2002 (284)	Cross sectional study	High	2953 men and women aged more than 18 years	This is a descriptive study for a sample of subjects maintaining a weight loss in the National Weight Control Registry (NWCR).	- Almost 90% reported eating breakfast \geq 4 days/week, with 78.3% of the respondents (2313) reporting eating breakfast every day - There was no differences in weight lost between breakfast eaters (\geq 4 times/week, 34 kg) and non-eaters (\leq 3 times/week, 32 kg), $p = 0.14$ and also there was no difference in duration of weight loss maintenance (7.7 vs. 7.9 years, $p=0.29$)	Not supportive: Breakfast eaters do not tend to lose weight more than the non-eaters

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Titan SM <i>et al.</i> , 2001 (295)	Cross sectional study	High	14 666 men and women aged 45-75 years from the Norfolk cohort of the European prospective investigation into cancer (EPIC-Norfolk).	<ul style="list-style-type: none"> - This is an ongoing prospective cohort conducted in Norfolk. Participants were recruited from general practice registers between 1993 and 1997 -At the baseline survey participants completed a detailed health and lifestyle questionnaire and participated in a health examination 	<ul style="list-style-type: none"> - BMI was weakly significantly associated with increasing eating frequency in men and women (after adjustment for all variables except BMI) but in opposite directions: negatively in men and positively in women. - Waist to hip ratio was still significantly negatively associated with eating frequency only in women 	Supportive: BMI in men and WHR in women is significantly negatively associated with EF.
Drummond SE <i>et al.</i> , 1998 (273)	Cross sectional study	Medium	79 men and women aged between 20-55 years	<ul style="list-style-type: none"> - Participants recruited from 2 large manufacturing companies in Edinburgh and Glasgow. - Food intake was determined with a 7-day unweighed food diary - Anthropometric measures were made on one occasion 	<ul style="list-style-type: none"> - Body weight in men ($r=-0.3436$, $P=0.03$) was inversely related to EF. - Body weight in women was not related to EF ($P=0.41$) - There were no significant relationships between BMI and percent BF and EF for men or women, or for body weight and eating 	Supportive: Increased eating frequency is inversely associated with body weight in men.

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults

Author	Study design	Quality rating	Study Sample	Methods	Results	Conclusion
Summerbell CD <i>et al.</i> , 1996 (280)	Cross sectional study	Medium	220 free-living people in four age groups (13-91 years) including 44 middle-aged group	- Cross-sectional assessment of 7-day weighed energy intake - Intake was divided into 6 feeding periods, with the first feeding occasion classified as breakfast	In the middle-aged group-a high BMI was associated with lower energy intakes at breakfast ($P<0.05$), and higher energy intakes during the evening ($P<0.05$).	Supportive: Low energy breakfast is associated higher BMI.
Basdevant A <i>et al.</i> , 1993 (285)	Cross sectional study	High	273 obese French women aged between 18-65 years	Participants recruited from the outpatient clinic of the Department of Nutrition at Hotel-Dieu, Paris. Food intakes and eating patterns were assessed by diet histories.	- 86% of the snackers had 1 or 2 snacks per day, 13% had 3-4 snacks per day - Snackers consumed significantly more daily energy (2221.27 +/- 812.08 kcals vs 1576.38 +/- 549.35 kcals), $P<0.05$ - More non-snackers than snackers were losing weight (11% vs. 3%, $P<0.05$)	Not supportive: Snacking increases energy intake and body weight

Evidence Summary: Meal frequency & breakfast intake and weight loss in adults*

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Review Articles						
Author	Review design	Quality rating	Number and types of studies	Interventions	Results	Conclusion
Bellisle F <i>et al.</i> , 1997 (296)	Non-systematic review	Medium	This review included 31 studies. Types of studies were not clearly stated for all studies.	<ul style="list-style-type: none"> - 10 studies examined the relationship between meal frequency and measures of weight loss - 11 studies compared weight loss on energy restricted nibbling vs gorging regimes - 5 short-term studies compared thermic effect of feeding (TEF) on nibbling vs gorging - 5 studies compared total energy expenditure (TEE) on nibbling vs gorging regimes 	<ul style="list-style-type: none"> - 5 studies demonstrated strong inverse relationships between habitual meal frequency and body weight. The other 5 studies did not show any significant changes - Only one study out of 11 studies demonstrated a much better weight loss in dieting participants on a 7 meals daily regimen compared with 3 meals daily (142 vs 78 g/d, $p < 0.025$) - No strong evidence was found in support of difference in TEF according to meal patterns. Only one study is supportive. - No studies demonstrated significant changes in TEE according to meal patterns 	Supportive: A few studies demonstrated weak evidence.

Studies in this review are excluded from the evidence summary to avoid any duplication in terms of the number of supportive and non supportive studies

Table 6.14 Meal frequency and weight loss in adults: type, quality and number of supportive and non supportive studies

Study type	Study quality	Number of supportive studies	Number of non supportive studies
Review articles	Medium	1	0
RCTs	High	1	4
	Medium	-	2
Cohort studies	Medium	-	1
Cross-sectional studies	High	4	2
	Medium	2	0
Total		8	9

Table 6.15 Breakfast intake and weight loss in adults: type, quality and number of supportive and non supportive studies

Study type	Study quality	Number of supportive studies	Number of non supportive studies
RCTs	High	1	-
	Medium	-	1
Cross-sectional studies	High	3	2
	Medium	1	-
Total		5	3

6.3.2.6 Accuracy of equations for the calculation of REE in obese people

Research question:

How accurate are the most commonly used equations in Saudi clinical practice for prediction of REE for obese patients?

Date of literature review:

August 2008

Search words:

Harris-Benedict equation, Mifflin equation, Owen equation, Schofield equation, WHO/FAO/UNU equation, prediction equations, REE and obese

Evidence-based statements:

- The Harris-Benedict equation tends to overestimate REE in overweight and obese people. Its accuracy is low particularly with the use of adjusted or ideal body weight.
Level of evidence: High
- The Mifflin equation tends to slightly overestimate REE in overweight and obese people.
Level of evidence: Medium
- The Owen equation tends to underestimate REE in overweight and obese people.
Level of evidence: High
- The Owen equation is less accurate compared to other predictive equations.
Level of evidence: Low
- The Mifflin equation using actual weight is the most accurate equation for estimating REE for overweight and obese
Level of evidence: Medium

Literature review:

- Nine cross-sectional studies (5 high-quality and 4 medium-quality) showed that the Harris-Benedict equation tends to overestimate REE in obese participants when current weight was used in the calculation. Accuracy rate (defined as the prediction of REE within $\pm 10\%$ of measured REE) ranged from 38% to 64% across studies (68, 70, 74, 148, 297-301)
- Two cross-sectional studies (one high-quality and one medium-quality) showed that the Harris-Benedict equation tends to underestimate REE of obese participants when ideal or adjusted body weight was used in the calculation. Accuracy rate was poor and ranged from 13% to 26% of estimates (68, 301)
- Three cross-sectional studies (2 high-quality and one medium quality) indicated the Mifflin equation tends to slightly overestimate REE in obese participants (70, 74, 298). However, one high quality study indicated that Mifflin equation tends to underestimate REE (68)
- Only one high quality study calculated the accuracy of Mifflin equation which was high (70% of estimated values were accurate) compared to other predictive equations (68)
- Three high quality cross-sectional studies indicated that the Owen equation tends to underestimate REE in obese participants (68, 74, 298). However, one medium quality study indicated that the Owen equation tends to overestimate REE in obese participants (70)
- Only one high quality study calculated the accuracy of Owen equation which was low (51 % of estimated values were accurate) compared to other predictive equations (68)
- Only one high quality study evaluated the use of the Schofield equation in obese participants (298). Results showed that the Schofield equation overestimated the REE in obese participants.
- Only two high quality studies evaluated the use of the WHO/FAO/UNU equation in obese participants. Both studies showed that the equation overestimated REE (74, 298)

Comments:

- The Saudi national dietetic practice survey (Chapter 3) identified 5 equations as the most commonly used equations in clinical practice in Saudi Arabia (23). These equations included Harris-Benedict, Mifflin, Owen, Schofield, and WHO/FAO/UNU equations. Therefore, this review was limited to these equations.
- These predictive equations were developed for use with European population. Their accuracy for Arabs and Saudi people has not been validated yet. Therefore, they may not be accurate for these groups.
- Although most of dietitians (86%) in Saudi Arabia use the Harris Benedict equation in clinical practice (23), it has been shown to overestimate REE in several studies. Therefore, it may not be ideal in the obese population.
- The Mifflin equation appears to offer the most accurate estimate of REE and its use may be recommended at this time until more data are available about the validation of predictive equations in Saudi population or other similar populations. The ADA report (11) indicated that the Mifflin equation is the most accurate equation with a strong evidence. However, based on both the review in this chapter and the study in Chapter 5 the assigned evidence level was lowered to be a Medium level.
- Although there are many studies that have validated the use of the predictive equations in European populations, only limited studies examined their accuracy in obese people.
- This review assessed only 5 predictive equations and there are several other equations that may perform with high accuracy in clinical practice

Table 6.16 Evidence Summary: validation studies used to evaluate the Harris-Benedict equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Frankenfield DC <i>et al</i> , 2003 (68)	Cross sectional study	High	130 lean and obese adults (BMI: 18.8- 96.8)	REE was measured by indirect calorimetry (Deltatrac Metabolic Cart) and compared with the predictive equations.	In 64% of the obese participants, the prediction was within 10% of measured REE 6% underestimated 30% overestimated Adjusted Harris-Benedict equation: In 26% of the obese participants, the prediction was within 10% of measured REE 72% underestimated 2% overestimated
Siervo M <i>et al</i> , 2003 (74)	Cross sectional study	High	157 young women of Caucasian race (BMI: 21-39)	REE was measured by indirect calorimetry (V MAX 29n) and compared with 6 predictive equations	- In the overweight group, Harris-Benedict equation showed a mean numerical bias and a mean percentage bias of - 162.86 kcal/d and 10.78% (highest overestimation shown by the predictive equations). Predicted REE is significantly greater than the measured REE (1521.17±89.66 vs 1358.31±169.69 Kcal/d, $P < 0.001$). - In the obese group, Harris-Benedict equation showed a mean numerical bias and a mean percentage bias of - 130.04 kcal/d and 7.63% (overestimation). Predicted REE is significantly greater than the measured REE (1716.09±11.76 vs 1586.05±206.73 Kcal/d, $P < 0.001$). The range of mean percentage bias in other equations was (-9.42 % underestimation to 9.41% overestimation).
Forman JN <i>et al</i> , 1998 (297)	Cross sectional study	Medium	African-American (n=25) and Caucasian (n=22) premenopausal obese women (BMI=34-38)	REE was measured by indirect calorimetry (Sensormedics Vmax System) and compared with Harris-Benedict equation.	REE for obese Caucasian women were significantly under predicted (predicted vs measured: 1666±38 vs 1899±50 Kcal/d), while the predicted RMR for African-Americans did not differ from their measured RMR (predicted vs measured: 1732±43 vs 1697±48)

Evidence Summary: validation studies used to evaluate the Harris-Benedict equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Heshka S <i>et al</i> , 1993 (70)	Cross sectional study	Medium	126 obese adults	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 12 predictive equations.	In men and women, group mean errors of Harris-Benedict equation were negative (- 408 and – 81kcal/d, respectively) and statistically significant. This indicates that REE was overestimated by Harris-Benedict equation.
Scalfi L <i>et al</i> , 1993 (298)	Cross sectional study	High	- 104 young women aged 18-32 years. (74 lean and overweight women and 30 obese women)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 8 predictive equations	- The mean percent measured-predicted values for Harris-Benedict equation were 88.7% and 95.4% for lean and overweight women and obese women respectively. - With the exception of Owen equation all equations overestimated measured REE in both groups
Foster GD <i>et al</i> , 1988 (299)	Cross sectional study	Medium	80 obese female (BMI: 32-46)	REE was measured by indirect calorimetry (Deltatrac Metabolic Cart) and compared with the predictive equations	In 59% of the obese participants, the prediction was within 10% of measured REE 21% underestimated 20% overestimated
Owen OE <i>et al</i> , 1987 (148)	Cross sectional study	High	60 lean and obese adults male (BMI: 20.4-60.5)	REE was measured by indirect calorimetry (Deltatrac Metabolic Cart) and compared with the predictive equations.	In 38% of the obese participants, the prediction was within 10% of measured REE 6% underestimated 56% overestimated
Owen OE <i>et al</i> , 1986 (300)	Cross sectional study	High	44 lean and obese adults female (BMI: 18.2-50.0)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with the predictive equations.	In 38% of the obese participants, the prediction was within 10% of measured REE 0% underestimated 62% overestimated

Evidence Summary: validation studies used to evaluate the Harris-Benedict equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Feurer I <i>et al</i> , 1983 (301)	Cross sectional study	Medium	112 morbidly obese (176%-264% ideal body weight)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with Harris-Benedict equation.	<p>In 39% of the obese participants, the prediction was within 10% of measured REE 9% underestimated 52% overestimated</p> <p>Harris-Benedict equation using the Ideal Body Weight: In 13% of the obese participants, the prediction was within 10% of measured REE Most of obese participants were underestimated</p>
Overall conclusion	The Harris-Benedict equation tends to overestimate REE in obese people. Its accuracy is low particularly when the adjusted or ideal body weight is used in the calculation.				

Table 6.17 Evidence Summary: validation studies used to evaluate the Mifflin equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Frankenfield DC <i>et al</i> , 2003 (68)	Cross sectional study	High	130 lean and obese adults (BMI: 18.8-96.8)	REE was measured by indirect calorimetry (Deltatrac Metabolic Cart) and compared with the predictive equations.	In 70% of the obese participants, the prediction was within 10% of measured REE 21% underestimated 9% overestimated
Siervo M <i>et al</i> , 2003 (74)	Cross sectional study	High	157 young women of Caucasian race (BMI: 21-39)	REE was measured by indirect calorimetry (V MAX 29n) and compared with 6 predictive equations	- In the overweight group, Mifflin equation showed a mean numerical bias and a mean percentage bias of - 76.79 kcal/d and 5.28% (overestimation). Predicted REE is significantly greater than the measured REE (1435.8±120.09 vs 1358.31±169.69, $P < 0.001$). The range of mean percentage bias in other equations was (-3.74% underestimation to 10.78% overestimation). - In the obese group, Mifflin equation showed a mean numerical bias and a mean percentage bias of - 52.73 kcal/d and 3.13% (overestimation). Predicted REE is significantly greater than the measured REE (1638.78±135.97 vs 1586.05±206.73, $P < 0.05$). The range of mean percentage bias in other equations was (-9.42 % underestimation to 9.41% overestimation).
Heshka S <i>et al</i> , 1993 (70)	Cross sectional study	Medium	126 obese adults	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 12 predictive equations.	In men and women, group mean errors of Mifflin equation were negative (- 132 and - 23 kcal/d, respectively) and statistically significant. This indicates that REE was overestimated by Mifflin equation.

Evidence Summary: validation studies used to evaluate the Mifflin equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Scalfi L <i>et al</i> , 1993 (298)	Cross sectional study	High	- 104 young women aged 18-32 years. (74 lean and overweight women and 30 obese women)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 8 predictive equations	<ul style="list-style-type: none"> - The mean percent measured-predicted values for Mifflin equation were 94.9% and 99.6% for lean and overweight women and obese women respectively. - With the exception of one equation all equations over-estimated the measured REE in both groups - The lowest overestimation was obtained by Mifflin equation (276 KJ/day)
Overall conclusion	The Mifflin equation tends to slightly overestimate REE in obese people. Only one high quality study assessed its accuracy and supported its use in obese people.				

Table 6.18 Evidence Summary: validation studies used to evaluate the Owen equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Frankenfield DC <i>et al</i> , 2003 (68)	Cross sectional study	High	130 lean and obese adults (BMI: 18.8-96.8)	REE was measured by indirect calorimetry (Deltatrac Metabolic Cart) and compared with the predictive equations.	In 51% of the obese participants, the prediction was within 10% of measured REE 43% underestimated 6% overestimated
Siervo M <i>et al</i> , 2003 (74)	Cross sectional study	High	157 young women of Caucasian race (BMI: 21-39)	REE was measured by indirect calorimetry (V MAX 29n) and compared with 6 predictive equations	- In the overweight group, Owen equation showed a mean numerical bias and a mean percentage bias of 50.8 kcal/d and - 3.74% (underestimation). Predicted REE is significantly less than the measured REE (1307.5±55.84 vs 1358.31±169.69, $P < 0.05$). The range of mean percentage bias in other equations was (-3.74% underestimation to 10.78% overestimation). - In the obese group, Owen equation showed a mean numerical bias and a mean percentage bias of 138.52 kcal/d and - 9.42% (underestimation). Predicted REE is significantly less than the measured REE (1447.53±75.77 vs 1586.05±206.73, $P < 0.001$). The range of mean percentage bias in other equations was (-9.42 % underestimation to 9.41% overestimation). - Owen equation is the only equation that underestimated the REE.
Heshka S <i>et al</i> , 1993 (70)	Cross sectional study	Medium	126 obese adults	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 12 predictive equations.	In men and women, group mean errors of Owen equation were negative (- 132 and - 137 kcal/d, respectively) and statistically significant. This indicates that REE was overestimated by Owen equation.

Evidence Summary: validation studies used to evaluate the Owen equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Scalfi L <i>et al</i> , 1993 (298)	Cross sectional study	High	- 104 young women aged 18-32 years. (74 lean and overweight women and 30 obese women)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 8 predictive equations	- The mean percent measured-predicted values for Owen equation were 102.3% and 113.2% for lean and overweight women and obese women respectively. - Owen equation is the only equation that underestimated the measured REE in both groups.
Overall conclusion	The Owen equation tends to underestimate REE in obese people. However, there are not enough studies to evaluate its accuracy.				

Table 6.19 Evidence Summary: validation studies used to evaluate the Schofield equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Scalfi L <i>et al</i> , 1993 (298)	Cross sectional study	High	- 104 young women aged 18-32 years. (74 lean and overweight women and 30 obese women)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 8 predictive equations	<ul style="list-style-type: none"> - The mean percent measured-predicted values for Schofield equation (based on weight equation) were 91.1% and 89.3% for lean and overweight women and obese women respectively. - The mean percent measured-predicted values for Schofield equation (based on weight and height equation) were 92.3% and 92.1% for lean and overweight women and obese women respectively - These findings indicate that both Schofield equations overestimated the measured REE in both groups
Overall conclusion	There are not enough studies to draw a clear conclusion regarding the use of the Schofield equation in obese people				

Table 6.20 Evidence Summary: validation studies used to evaluate the WHO/FAO/UNU equation in obese participants

Author	Study design	Quality rating	Study Sample	Methods	Results
Scalfi L <i>et al</i> , 1993 (298)	Cross sectional study	High	- 104 young women aged 18-32 years. (74 lean and overweight women and 30 obese women)	REE was measured by indirect calorimetry (Beckman Metabolic Cart) and compared with 8 predictive equations	<ul style="list-style-type: none"> - The mean percent measured-predicted values for WHO equation (based on weight equation) were 91.8% and 90.3% for lean and overweight women and obese women respectively. - The mean percent measured-predicted values for WHO equation (based on weight and height equation) were 91.9% and 93.9% for lean and overweight women and obese women respectively - These findings indicate that both WHO equations overestimated the measured REE in both groups
Siervo M <i>et al</i> , 2003 (74)	Cross sectional study	High	157 young women of Caucasian race (BMI: 21-39)	REE was measured by indirect calorimetry (V MAX 29n) and compared with 6 predictive equations	<ul style="list-style-type: none"> - In the overweight group, WHO equation showed a mean numerical bias and a mean percentage bias of - 143.38 kcal/d and 9.54% (overestimation). Predicted REE is significantly greater than the measured REE (1501.69±120.38 vs 1358.31±169.69, $P < 0.001$). The range of mean percentage bias in other equations was (-3.74% underestimation to 10.78% overestimation). - In the obese group, WHO equation showed a mean numerical bias and a mean percentage bias of - 164.86 kcal/d and 9.41% (overestimation). Predicted REE is significantly greater than the measured REE (1750.91±160.3 vs 1586.05±206.73, $P < 0.001$). The range of mean percentage bias in other equations was (-9.42 % underestimation to 9.41% overestimation)
Overall conclusion	There are not enough studies to draw a clear conclusion regarding the use of the WHO/FAO/UNU equation in obese people.				

6.3.3 Development of new consensus statements

As described previously, these statements were developed through several techniques including interviews with experts, consultation workshops and finalized by a Delphi technique. Details of initial statements and experts discussions are provided in Appendix R. The summary of these initial statements that were discussed in the 5 small workshops are presented below:

Topic ONE: Behaviour modification

- We recommend the use of one or more behaviour therapy techniques in combination with diet therapy and physical activity for Saudi people.
- The suitable techniques should be discussed with each individual patient. It appears that no one behavior therapy is superior to any other.
- Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed.
- A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy.
- Some Saudi people eat their lunch after they finish work. Therefore, patients should be instructed to eat at work or not to sleep directly after eating.
- Some Saudi people may find that on the days they skip breakfasts, they end up overeating later in the day and gaining weight. Patients may need to be instructed not to skip any meal.
- Self-monitoring may be suitable for educated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information may help both dietitians and patients in setting the appropriate goals to reduce weight.
- Patients should be asked about people who may be supportive of their behavior changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment.
- Patients should avoid certain social situations, particularly wedding parties, which elicit overeating of fatty food.

Topic TWO: Obesity and Ramadan

- Obese and overweight people should consider Ramadan as an ideal time to lose weight.
- Avoid over-eating especially at *sahur*
- Avoid fried and fatty foods.
- Avoid foods containing too much sugar
- Fried foods can be replaced by grilled foods or by using the oven instead of frying
- Eat three main meals in addition to some snacks if possible (*iftar*, dinner and *sahur*)
- Drinks lots of water between *iftar* and *sahur* to avoid dehydration
- Eat slow digesting foods (low glyceemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day
- Try to make the *iftar* immediately after sunset or as early as you can and make *sahur* just before dawn to minimize fasting hours.
- Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty.
- Avoid sedentary lifestyle in Ramadan by practising exercise especially at night.

Topic THREE: Goal setting for the management of overweight and obesity:

- Saudi people expectations of weight loss are often unrealistic and may remain higher than the reality.
- Dietitians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient.
- Dietitians may need to focus on weight stabilization for individuals with a history of weight-loss failure.
- Duration of weight loss program may vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss.
- The ideal weight loss period is at least 6 months that should be followed by a weight maintenance program that may continue for several years.

Topic FOUR: Physical activity

Evidence based statements adopted from existing obesity guidelines:

- Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits.

All the above statements were discussed in the small workshops. After several discussions, participants agreed on a list of statements to be included in the first Delphi consultation, shown in Appendix S. A summary of the statements included in Delphi 1 is presented below.

Section 1: Behaviour modifications techniques for obese Saudi clients

1. The use of one or more behaviour therapy techniques in combination with diet therapy and physical activity is recommended for the management of obese clients
2. The suitable techniques should be discussed with each individual patient. It appears that no one behaviour therapy is superior to any other
3. Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed and if the health organization system allow for this procedure
4. A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy
5. Obese people who sleep immediately after lunch meal should be counselled to have lunch at work to avoid this habit. Alternatively, they can eat a light snack before sleeping and eat lunch after waking.
6. Obese people who skip breakfast should be counselled to eat breakfast or a snack such as fruit or some juices when they wake up.
7. Self-monitoring may be suitable for motivated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information can help both dietitians and patients in setting the appropriate goals to reduce weight
8. Obese people should be asked about people who may be supportive of their behaviour changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment

Section 2: Specific dietary counselling strategies

9. Saudi social activity such weddings elicit overeating of fatty food. Therefore, obese people should be instructed how to choose their food in such events
10. Correct wrong beliefs about the effect of some foods on body weight such as honey, dates, olive oil, sunflower oil, herbs, and traditional foods
11. Advise obese people to eat variety of food especially fruit and vegetables
12. Teach obese clients what to eat when they go to restaurants for meals
13. Dietitians should explain to clients the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better
14. Dietitians should discuss patients' expectations
15. Obese people should be instructed to reduce portion sizes

Section 3: Obesity management in Ramadan

16. Obese people should consider Ramadan as an ideal time to maintain/lose weight
17. Avoid over-eating especially at *Sahur* and *Iftar*
18. Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled foods or by using the oven instead of frying
19. Eat two main meals in addition to 1-2 snacks if possible
20. Drink lots of water between *iftar* and *sahur* to avoid dehydration and reduce the consumption of high sugar drinks
21. Eat slow digesting foods (low glycaemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day
22. Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty
23. Avoid sedentary lifestyle in Ramadan by practising exercise especially at night
24. Encourage clients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan
25. Avoid sleeping most of the day and staying up at night

Section 4: Goal setting for the management of obesity

26. Saudi expectations of weight loss are often unrealistic. Dietitians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient
27. When dealing with compliant clients with a history of weight-loss failure, dietitians may need to focus on weight stabilization rather than weight loss
28. The duration of weight loss intervention will vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss
29. Weight loss goals are affected by several factors such as physical, social, and psychological factors
30. Patients should be instructed not to follow any commercial diet unless it is prescribed by a dietitian or physician

Section 5: Physical activity

31. Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits
32. Encourage night activities in summer
33. If outdoor exercise is not possible for females, encourage indoor activities at home or by joining female gyms
34. Correct the misconception that home duties for ladies are enough exercise for weight loss

6.3.3.1 Results of Delphi-1

The Delphi-1 Feedback and Second Round Questionnaire are presented in Appendix T. A brief summary is presented below.

- A total of 20 experts took part in the Round One consultation (Delphi-1) of this study. The results summarised below are from those 20 participants.
- Delphi-1 consisted of 34 statements developed from the previous consultation workshops.
- Analysis of Delphi-1 showed that 30 statements reached agreement scores > 75% and were accepted to be included in the clinical guidelines. Three statements reached agreement scores that ranged between 50 to 75% and were modified to be included in the next consultation round. Only one statement reached agreement score < 50 and was excluded from the clinical practice guidelines. Also there were 4 statements which reached agreement scores > 75% but were modified according to participants' comments and included again in the second round.

Section 1: Behaviour modifications techniques for obese Saudi clients

All statements in this section were accepted, except statements 5 and 6. Therefore, those statements were revised according to the received comments from the experts in Delphi-1

Statement 5 (original version): *Obese people who sleep immediately after lunch meal should be counselled to have lunch at work to avoid this habit. Alternatively, they can eat a light snack before sleeping and eat lunch after waking*

Participants indicated that this statement is restricted to workers despite that this habit is common even among non-employees.

Statements 6 (original version): *Obese people who skip breakfast should be counselled to eat breakfast or a snack such as fruit or some juices when they wake up*

Participants indicated that juices or fruit should not be introduced as a substitute for the breakfast meal. Also they thought that obese people should be instructed about the importance of breakfast.

Therefore, the above statements were modified and included in Delphi-2 for more discussion.

Statement 5 (revised version): *Obese people who sleep immediately after lunch meal should be counselled to eat a light snack before sleeping and eat lunch after waking.*

Statement 6 (revised version): *Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal*

Section 2: Specific dietary counselling strategies

Most participants agreed about statements in this section. However, some strategies for reduction of portion size were recommended (statement 15). Also one new statement that was suggested was added in this section.

Statement 15 (original version): *Obese people should be instructed to reduce portion sizes*

Participants indicated that this strategy was difficult to be achieved in the Saudi population and recommended the use of food models and other methods.

Suggestion of a new statement:

Participants indicated that many obese people eat because they are bored or due to social pressure. There is a need to develop appropriate behaviour counselling techniques to address this issue.

All statements in this section were accepted except statements 15. Therefore, this statement was revised according to the received comments from experts in Delphi-1

Statement 15 (revised version): *Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes.*

New statement: *Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress.*

Section 3: Obesity management in Ramadan

All statements in this section were accepted except statement 16. Also additional suggestions were recommended to be added to statement 18 and 22.

Statement 16 (original version): *Obese people should consider Ramadan as an ideal time to maintain/lose weight*

Some participants stated that Ramadan can be an extremely stressful period of time, both physically and emotionally, which may not lead to successful weight loss regimen. After *Iftar*, compensatory gorging and overeating of fatty and simple carbohydrates is not unusual, and often leads to weight gain.

Other participants indicated that Ramadan has time limit because it takes place once a year so focusing on the proper meal planning for this special month is more important. One participant stated that Ramadan is not the ideal time but a challenging time to avoid excessive eating, which is the cultural and social norm in Saudi Arabia

Statement 18 (original version): *Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled foods or by using the oven instead of frying*

Participants suggested adding other alternatives cooking methods such as boiling and baking.

Statement 22 (original version): *Start iftar with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty.*

Participants reported that *Iftar* traditions and eating habits differ amongst families: The first *Iftar* eating habit people consume only dates, highly sugary juices, soup and fried pastries. These families then consume the main meal later at night (around 11pm or 12am). The second type of *Iftar* eating habit consists of consuming everything from dates, soup and pastries to rice, meat and dessert all at once right after *Iftar* is allowed. They suggested the inclusion of a statement in the clinical practice guidelines regarding the advantage of the first *Iftar* eating habit.

All statements in this section were accepted except statements 16, 18 and 22. Therefore, these statements were revised according to the comments received from experts in Delphi-1

Statement 16 (revised version): *Obese people should aim not to gain weight in Ramadan if weight loss is unachievable*

Statement 18 (revised version): *Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying*

Statement 22 (revised version): *Start iftar with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night*

Section 4: Goal setting for the management of obesity

Statement 27 was excluded by participants in this section (< 50% agreement). Also some participants recommended some slight modification to statement 29.

Statement 27 (original version): *When dealing with compliant clients with a history of weight-loss failure, dietitians may need to focus on weight stabilization rather than weight loss*

Most participants did agree about this statement, but most of them indicated that the goal should be to reduce weight even if patients could not achieve this goal. Obese people may think the obesity is acceptable in this case and they may even gain weight.

Statement 29 (original version): *Weight loss goals are affected by several factors such as physical, social, and psychological factors*

Participants suggested adding that economic status as important factor that might affect weight loss. Also some participants have suggested replacing the word “social” by “socioeconomic status”.

Revised statement 29: *Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors*

Section 5: Physical activity

Participants agreed to include all statements in this section in the clinical practice guidelines without changes

6.3.3.2 Results of Delphi-2

The Delphi-2 Feedback and Delphi final report are presented in Appendix U. A brief summary of the results is presented below

- A total of 19 of the original 20 experts took part in Round two (Delphi-2) of this study. The results depicted below are from those 19 participants
- Delphi-2 consisted of 8 statements that were modified based on comments received from the Delphi-I feedback
- In the analysis of the Delphi-2 results, 7 statements reached a mean score percentage > 75% and were accepted to be included in the clinical guidelines. Only one statement did not reach this acceptable level of agreement score and was excluded from the clinical practice guidelines.

Table 6.21 Accepted statements with their scores in percentage:

<i>Statement number</i>	<i>Statement</i>	Mean score (% agreement)	
		Round I	Round II
6	Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal	73.6	91.7
15	Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes.	91.7	94.4
New	Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress.	-	93.1
16	Obese people should aim not to gain weight in Ramadan if weight loss is unachievable	63.9	91.7
18	Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying	87.5	95.8
22	Start <i>iftar</i> with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night.	88.9	91.7
29	Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors	91.7	95.8
Overall mean score		82.9	93.5

Excluded statement (Statement 5)

Obese people who sleep immediately after lunch meal should be counselled to eat a light snack before sleeping and eat lunch after waking (mean score: Delphi I = 66.7%, Delphi II = 69.4)

Reasons for disagreement about this statement:

Some participants indicated that adding a snack to their normal lunch would contribute to extra calories. Others participants mentioned that clients should not be instructed to eat even a small snack before sleeping. Also some participants indicated that sleeping patterns should be corrected instead of adjusting meal planning according to irregular sleeping times

6.3.3.3 Final consensus statements to be included in the clinical practice guidelines and their scores in percentage agreement

Section 1: Behaviour modifications techniques for obese Saudi clients

- The use of one or more behaviour therapy techniques in combination with diet therapy and physical activity is recommended for the management of obese clients (94%)
- The suitable techniques should be discussed with each individual patient. It appears that no one behaviour therapy is superior to any other (82%)
- Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed and if the health organization system allow for this procedure (75%)
- A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy (86%)
- Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal (92%)
- Self-monitoring may be suitable for motivated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information can help both dietitians and patients in setting the appropriate goals to reduce weight (82 %)
- Obese people should be asked about people who may be supportive of their behaviour changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment (79%)

Section 2: Specific dietary counselling strategies

- Saudi social activity such weddings elicit overeating of fatty food. Therefore, obese people should be instructed how to choose their food in such events (93%)
- Correct wrong beliefs about the effect of some foods on body weight such as honey, dates, olive oil, sunflower oil, herbs, and traditional foods (94%)
- Advise obese people to eat variety of food especially fruit and vegetables (94%)
- Teach obese clients what to eat when they go to restaurants for meals (92%)
- Dietitians should explain to clients the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better (92%)
- Dietitians should discuss patients' expectations (90%)
- Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes (94%)
- Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress (93%)

Section 3: Obesity management in Ramadan

- Obese people should aim not to gain weight in Ramadan if weight loss is unachievable(92%)
- Avoid over-eating especially at *Sahur* and *Iftar* (90%)
- Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying (96%)
- Eat two main meals in addition to 1-2 snacks if possible (75%)
- Drink lots of water between *iftar* and *sahur* to avoid dehydration and reduce the consumption of high sugar drinks (93%)
- Eat slow digesting foods (low glyceemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day (92%)
- Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night (92%)
- Avoid sedentary lifestyle in Ramadan by practising exercise especially at night (94%)
- Encourage clients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan (94%)
- Avoid sleeping most of the day and staying up at night (79%)

Section 4: Goal setting for the management of obesity

- Saudi expectations of weight loss are often unrealistic. Dietitians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient (92%)
- The duration of weight loss intervention will vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss (93%)
- Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors (96%)
- Patients should be instructed not to follow any commercial diet unless it described by dietitian or physician (86%)

Section 5: Physical activity

- Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits (96%)
- Encourage night activities in summer (86%)
- If outdoor exercise is not possible for females, encourage indoor activities at home or by joining female gyms (94%)
- Correct the misconception that home duties for ladies are enough exercise for weight loss (88%)

CHAPTER 7

SUMMARY AND CONCLUSIONS

7.1 SUMMARY OF THE RESEARCH

This research aimed to assess the current dietetic practices of obesity management in Saudi Arabia and to develop evidence-based clinical practices guidelines to be used by dietitians and other health practitioners in Saudi Arabia. The present thesis included three main research studies. Based on the outcomes of these studies, draft evidence-based practice guidelines for the nutritional management of obesity in Saudi Arabia have been prepared. These studies included the following:

- 1- Description of the dietetic practices in the assessment and treatment of obesity in Saudi Arabia. This study collected information about the practical and sustainable methods for the treatment of obesity for Saudi people and barriers that limit provision of effective treatment. The study was conducted through a survey of Saudi dietitians and the results compared with a similar survey conducted previously in Australia
- 2- Two studies focused on the validity of the most important practical tools used for the classification of obesity and the assessment of energy requirements for overweight and obese Saudi subjects. These two studies were:
 - An examination of the use of different BMI cut-off points for obesity classification in the Saudi population (through secondary analysis of data collected in a recent large national epidemiological survey of diabetes risk factors), and
 - Laboratory studies of the accuracy and validity of the use of prediction equations and a popular hand-held calorimeter (BodyGem) for assessment of energy requirements.
- 3- Development of evidence-based statements for the assessment and treatment of obesity by dietitians in Saudi Arabia. Findings from the previous two main studies were incorporated at this stage. Draft guidelines were developed, based

on a review of existing international guidelines, supplemented with systematic literature reviews, and refined through the use of Delphi technique consultations with Saudi experts and practitioners. This process also included two main consultation workshops conducted in Saudi Arabia. At the first workshop, the findings of the survey and the guidelines development process were discussed. The second workshop focused on the development of consensus statements in relation to areas where scientific evidence is lacking or insufficient.

Findings from the first study did not support Hypothesis One of this thesis (that current dietetic practices in Saudi Arabia are substantially different to practice in Australia and other countries). The results indicated that Saudi Arabian dietetic practice for the management of obesity does incorporate most best practice recommendations, but some specific elements are rarely used. None of the participants reported the use of local clinical practice guidelines for the management of overweight and obesity. However, sixty-one percent of participants who manage obesity reported that they use some international guidelines such as the American practice guidelines (11). These findings indicated an urgent need for developing clinical practice guidelines that could be used by dietitians and other health practitioners.

Hypothesis Two (that tools to classify obesity and measure REE in Western subjects can be applied to Saudi subjects) was also not supported. The validation studies indicated that the diagnostic usefulness of BMI alone in defining obesity is limited in the Saudi adult population, for both men and women. It seems likely that limiting management of obesity only to those individuals with a $BMI \geq 30$ may mean that many Saudis at risk of serious co-morbidities could be missing necessary interventions. Due to the inadequate performance of BMI as a predictive tool for health risk, dietitians in Saudi Arabia may need to consider additional direct assessment of some risk factors as part of their initial nutritional assessment, particularly blood pressure and blood glucose.

Based on the findings of the validation studies it was concluded that the Harris-Benedict, Schofield and WHO equations tend to predict REE more accurately than the BodyGem device. However, their accuracy was not clinically acceptable on an

individual level. The mini review (chapter 6) showed that the Mifflin equation is the most accurate equation for use with overweight subjects and therefore it could be used at present until more data are available about the validation of predictive equations in Saudi population or other similar populations.

Findings from the systematic mini reviews showed some low or medium level evidence for the use of some novel dietary interventions such as the high intake of calcium, PUFA or fiber to assist with weight loss or maintenance. There was also similar evidence for the use of a low glycemic index diet. Higher eating frequency, not exceeding 6 meals per day, may also help in weight reduction. Regular breakfast intake also appears to be associated with lower body weight.

Hypothesis Three (that evidence based practice guidelines for dietetic management from other countries can be adapted for use in Saudi Arabia) was supported. Consultation workshops and Delphi consultations indicated that there are cultural differences between Saudi Arabian population and other Western populations. Therefore, specific consensus statements were developed to cover practice areas such as behavioral modifications, dietary counselling strategies, physical activity and obesity management in Ramadan. However, many of the evidence statements in the final draft guidelines that were accepted by the Saudi experts were adopted or only slightly modified versions of existing international guidelines.

All the above findings were incorporated into a set of draft clinical practice guidelines for nutritional management of obesity in Saudi Arabia (Appendix V). Overall this thesis will help the dietitians in Saudi Arabia to improve their practices and understand the level of scientific evidence for several strategies they might use in their daily practices. The thesis also directed dietitians to be cautious when they use some predicted equations developed for other populations for the assessment of energy requirements. The same applies to the use of BMI in the classification of overweight and obesity.

7.2 SIGNIFICANCE OF THE RESEARCH

This thesis assessed and examined several issues and provided new findings related to the management of obesity in Saudi Arabia through several studies. Firstly, it provided a description of the current dietetic practice for the management of obesity and compared it with Australian practices and best practice. These findings will help dietitians to improve their practices and provide health organization leaders with important information about levels of service and barriers to obesity management. Therefore, appropriate efforts could be spent to improve the value of weight management services and new policies could be implemented to support the dietitian's role in Saudi Arabia.

Secondly, this thesis has identified some areas in obesity management where there are differences between Saudi population and Western population due to cultural, genetic, geographical or other factors. In such cases, the strategies, approaches or tools used by Western countries may not be suitable for Saudi people. This thesis examined the accuracy of the use of BMI for obesity classification in Saudi population. Also practical tools used for REE assessment were validated. The results provide clinicians with important information in these areas since these studies were conducted for the first time in the Saudi population.

Thirdly, findings from the systematic mini reviews showed low to medium level of evidence for the use of some novel dietary interventions such as the high intake of calcium, PUFA or fiber to assist with weight loss or maintenance. Delphi consultations also covered new areas such as behavioral modifications, Ramadan and physical activities.

Finally, the overall project has drafted the first clinical practice guidelines that will be used by dietitians and other health professionals to improve the consistency of care and provide recommendations that reassure practitioners about the appropriateness of their treatment strategies and approaches.

7.3 LIMITATIONS AND FUTURE RESEARCH

This research was a planned set of studies within a PhD, so it could not cover all areas of obesity management in Saudi Arabia. Moreover, the full development of effective clinical practice guidelines still requires further consultation and refinement which could take some time to complete. The long process of draft guidelines development needs to be followed by further consultation workshops to get agreement about the format of the final guidelines, and this was not feasible within the PhD time limit. The final guidelines then need to be sent to local practitioners, other stakeholders, and organizational policy makers for review and comment. Furthermore, the development of guidelines does not ensure their use in practice unless followed by a good dissemination and implementation processes (18). Also the guidelines should be updated as soon as each piece of relevant new evidence is published.

Guideline Endorsement and Implementation

The present draft clinical practice guidelines need to be finalized and submitted for approval by a local organization such as the Saudi Dietetic Association or the National & Gulf Centre for Evidence Based Medicine (302). Approval and endorsement of the project have been informally discussed and both organizations are interested to be involved in this process.

Strategies for the dissemination and implementation of the guidelines need to be discussed with a multidisciplinary panel to increase the awareness, understanding and the acceptance of the guidelines. Any barriers to their acceptance and implementation also need to be identified with possible strategies for overcoming these barriers. However, there are a range of possible dissemination and implementation strategies (18) that can be used for the present guidelines:

- Make the guideline as widely available as possible
- Use scientific journals and Media to distribute it to hospitals, health organizations and universities.
- Produce the guidelines for use in a range of formats, including on the internet and on computer disks

- Endorsement by medical and dietetics profession
- Training in use of guidelines is critical to successful implementation, including continuing evaluation of adoption and outcomes.
- Asking respected clinical leaders to promote the guidelines
- Incorporating the guidelines in routine procedures – such as quality assurance and review processes – of institutions and organizations that provide care
- Offering feedback on compliance with guidelines.

Further Research

Some of the studies undertaken in this thesis indicated the need for further future research. Findings from the BMI study indicated that the use of BMI as a tool for obesity classification in Saudi population is questionable. Future studies incorporating other measures such as WC, WHR, body fat composition, or a combination of tools need to be conducted to determine the best method to classify obesity accurately in the Saudi population.

Findings from the validation of the BodyGem device, and predictions equations on Saudi overweight and obese subjects indicated that more accurate tools for the assessment of REE in the Saudi population need to be clearly identified. This includes validation of other prediction equations and simple devices that could be used in daily practice for the assessment of REE. This could be achieved through the conduct of a validation studies with a larger sample size including males and females with different age and weight groups. Findings from this thesis also indicate an urgent need for the development of new prediction equation to be used for the assessment of REE in the Saudi population since there are no equations developed for this population at this time.

Evidence-based clinical practice guidelines for dietetic management from other countries were able to be adapted for use in Saudi Arabia. However, due to cultural differences further topics may need to be identified and included in the future. Several evidence statements included in these guidelines were based on evidence analysis done by the candidate. The topics included are the first step towards a comprehensive list of evidence based statements and recommendations to address the management of

overweight and obesity. However, clinical practice guidelines will not address all the uncertainties of current clinical practice and should be seen as only one strategy that can help improve the quality of care that patients receive.

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APPENDICES

Appendix A: Quality Criteria Checklist

Primary Research

Citation		
Study design		
Relevance Questions		Yes/NO Unclear/NA
1	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epidemiological studies)	
2	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	
3	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	
4	Is the intervention or procedure feasible? (NA for some epidemiological studies)	
<i>If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a "high" on the Evidence Quality Worksheet, depending on answers to the following validity questions.</i>		
Validity Questions		Yes/NO Unclear/NA
1	Was the research question clearly stated?	
	1.1 Was the specific intervention(s) or procedure (independent variable(s)) identified?	
	1.2 Was the outcome(s) (dependent variable(s)) clearly indicated?	
	1.3 Were the target population and setting specified?	
2	Was the selection of study subjects/patients free from bias?	
	2.1 Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	
	2.2 Were criteria applied equally to all study groups?	
	2.3 Were health, demographics, and other characteristics of subjects described?	
	2.4 Were the subjects/patients a representative sample of the relevant population?	
3	Were study groups comparable?	
	3.1 Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	
	3.2 Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
	3.3 Were concurrent controls used? (Concurrent preferred over historical controls.)	
	3.4 If cohort study or cross-sectional study were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	
	3.5 If case control study, were potential confounding factors comparable for cases and controls?	
	3.6 If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.	
4	Was method of handling withdrawals described?	
	4.1 Were follow up methods described and the same for all groups?	
	4.2 Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
	4.3 Were all enrolled subjects/patients (in the original sample) accounted for?	
	4.4 Were reasons for withdrawals similar across groups?	

	4.5 If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5	Was blinding used to prevent introduction of bias?	
	5.1 In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	
	5.2 Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3 In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4 In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5 In diagnostic study, were test results blinded to patient history and other test results?	
6	Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?	
	6.1 In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2 In observational study, were interventions, study settings, and clinicians/provider described?	
	6.3 Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4 Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5 Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6 Were extra or unplanned treatments described?	
	6.7 Was the information for 6d, 6e, and 6f assessed the same way for all groups?	
	6.8 In diagnostic study, were details of test administration and replication sufficient?	
7	Were outcomes clearly defined and the measurements valid and reliable?	
	7.1 Were primary and secondary endpoints described and relevant to the question?	
	7.2 Were nutrition measures appropriate to question and outcomes of concern?	
	7.3 Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4 Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5 Was the measurement of effect at an appropriate level of precision?	
	7.6 Were other factors accounted for (measured) that could affect outcomes?	
	7.7 Were the measurements conducted consistently across groups?	
8	Was the statistical analysis appropriate for the study design and type of outcome indicators?	
	8.1 Were statistical analyses adequately described the results reported appropriately?	
	8.2 Were correct statistical tests used and assumptions of test not violated?	
	8.3 Were statistics reported with levels of significance and/or confidence intervals?	
	8.4 Was “intent to treat” analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	

	8.5 Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6 Was clinical significance as well as statistical significance reported?	
	8.7 If negative findings, was a power calculation reported to address type 2 error?	
9	Are conclusions supported by results with biases and limitations taken into consideration?	
	9.1 Is there a discussion of findings?	
	9.2 Are biases and study limitations identified and discussed?	
10	Is bias due to study's funding or sponsorship unlikely?	
	10.1 Were sources of funding and investigators' affiliations described?	
	10.2 Was there no apparent conflict of interest?	
Low If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a "Low".		
Medium If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a "Medium".		
High If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a "High".		
Reviewer comments		
Quality Rating		

Quality Criteria Checklist: Review Articles

Citation		
Study design		
Relevance Questions		Yes/NO Unclear/NA
1	Will the answer if true, have a direct bearing on the health of patients?	
2	Is the outcome or topic something that patients/clients/population groups would care about?	
3	Is the problem addressed in the review one that is relevant to dietetics practice?	
4	Will the information, if true, require a change in practice?	
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a "High" on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
Validity Questions		Yes/NO Unclear/NA
1	Was the question for the review clearly focused and appropriate?	
2	Was the search strategy used to locate relevant studies comprehensive? Were the databases searched and the search terms used described?	
3	Were explicit methods used to select studies to include in the review? Were inclusion/exclusion criteria specified and appropriate? Were selection methods unbiased?	
4	Was there an appraisal of the quality and validity of studies included in the review? Were appraisal methods specified, appropriate, and reproducible?	
5	Were specific treatments/interventions/exposures described? Were treatments similar enough to be combined?	
6	Was the outcome of interest clearly indicated? Were other potential harms and benefits considered?	
7	Were processes for data abstraction, synthesis, and analysis described? Were they applied consistently across studies and groups? Was there appropriate use of qualitative and/or quantitative synthesis? Was variation in findings among studies analyzed? Were heterogeneity issues considered? If data from studies were aggregated for meta-analysis, was the procedure described?	
8	Are the results clearly presented in narrative and/or quantitative terms? If summary statistics are used, are levels of significance and/or confidence intervals included?	
9	Are conclusions supported by results with biases and limitations taken into consideration? Are limitations of the review identified and discussed?	
10	Was bias due to the review's funding or sponsorship unlikely?	
Low If most (six or more) of the answers to the above validity questions are "No," the review should be designated with a "Low".		
Medium If the answer to any of the first four validity questions (1-4) is "No," but other criteria indicate strengths, the review should be designated with a "Medium".		
High If most of the answers to the above validity questions are "Yes" (must include criteria 1, 2, 3, and 4), the report should be designated with a "High"		
Reviewer Comments		
Quality Rating		

Appendix B: Dietetic practices survey – English version

Current dietetic practices of obesity management in Saudi Arabia

National Survey 2007

A) Demographic Data:

1. How old are you?

- ☐ Less than 21 years
- ☐ 21 - 35 years
- ☐ 36 - 45 years
- ☐ 46 - 55 years
- ☐ 56 - 65 years
- ☐ more than 65 years

2. What is your gender?

- ☐ Male
- ☐ Female

3. What is your nationality?

- ☐ Saudi
- ☐ Non-Saudi

4. In which area do you work?

- ☐ Central area
- ☐ Eastern area
- ☐ Northern area
- ☐ Southern area
- ☐ Western area

5. Please identify which best describes the location in which you work?

- ☐ Urban
- ☐ Rural

6. Please indicate in which setting do you work?

(You can choose more than one option)

- ☐ Hospitals of Ministry of Health
- ☐ Private Hospitals or other hospitals such as Security, Armed, National Guard, King Faisal Specialist Hospitals etc.
- ☐ Private clinic or centre for weight reduction
- ☐ Academia
- ☐ If other, please specify _____

7. What are your qualifications?

- ☐ Diploma - Nutrition
- ☐ Bachelor - Clinical nutrition
- ☐ Bachelor - Food and nutrition
- ☐ Master - Clinical nutrition
- ☐ Master - Food and nutrition/ Human Nutrition
- ☐ PhD nutrition
- ☐ Other, please specify_____

8. How many years have you practiced as a dietitian?

- ☐ less than 2 years
- ☐ 2 - 5 years
- ☐ 6 -10 years
- ☐ 11-15 years
- ☐ more than 15 years

9. What is your main area of work?

- ☐ Clinical nutrition
- ☐ Food services
- ☐ Community nutrition
- ☐ If other, please specify_____

B) Barriers to obesity management:

10. Do you run a nutrition clinic at your service?

- ☐ Yes
- ☐ No

11. If you do not run a clinic, please list barriers in your service that may prevent you running a nutrition clinic? (You can choose more than one answer)

- ☐ No barriers
- ☐ Time
- ☐ Resources (e.g. space, facilities and tools)
- ☐ Referral related issues
- ☐ Lack of knowledge with best practice
- ☐ Lack of dietitians
- ☐ Service administration has not established a clinic yet

If other, please specify _____

12. Does the dietitian in your service give consultations for admitted patients?

- ☐ Yes
- ☐ No

13. If the answer of the previous question is “No”, Please list barriers in your service that may prevent you to be involved in obesity management? (You can choose more than one answer)

- ☐ It is not required from the dietitian to manage obesity in your service
- ☐ Time
- ☐ Resources (e.g. Space, facilities and tools)
- ☐ Referral related issues
- ☐ Lack of knowledge with best practice
- ☐ Lack of dietitians

If other, please specify _____

14. Do you see (manage) overweight or obese patients in your work (even if you are not working in the obesity management area)?

- ☐ Yes
- ☐ No

If No, please go to question 33 to end the study

15. On average how many overweight or obese patients do you see every week?

- ☐ Less than 5
- ☐ 5-10
- ☐ 11-20
- ☐ 21-30
- ☐ 31-40
- ☐ more than 40

C) Level of service and demand:

16. Does your service have clinical practice guidelines for obesity management?

- ☐ Yes
- ☐ No

If published, please provide us with the reference _____

17. Where do the majority of referrals for obese patients come from? (Please choose one only)

- ☐ Self-referrals
- ☐ Dietitians
- ☐ Physicians
- ☐ if other allied health staff, please specify _____

18. Do you have specific criteria for the referral of patients from other health practitioners to dietitians?

- ☐ Yes
- ☐ No

19. What resources do you have in your work?

(You can choose more than one answer)

- ☐ We do not have nutrition clinic
- ☐ Basic scales that measure weight only
- ☐ Scales that measure weight and body fat percentage
- ☐ Food models
- ☐ Access to data for patient management (e.g. Pathology)

Other, please specify _____

D) Models of obesity assessment:

20. Which predictive equations do you usually use to assess energy requirements?

- ☐ Harris Benedict Equations
- ☐ Owen equations
- ☐ World Health Organization (WHO) equations
- ☐ Schofield equations
- ☐ Mifflin equations
- ☐ Ireton-Jones equations
- ☐ Bernstein equations
- ☐ You do not estimate energy requirements
- ☐ If other, please specify _____

21. How many calories/day do you reduce from the daily energy requirements to achieve your goal?

- ☐ No plan
- ☐ 300 – 500 Kcal/day
- ☐ 500 – 1000 Kcal/day
- ☐ 1000-1500 Kcal/day
- ☐ More than 1500 Kcal/day

22. What is usually your time line to achieve your goal?

- ☐ No plan
- ☐ 1-3 months
- ☐ 3-6 months
- ☐ More than 6 months
- ☐ If other, please specify _____

23. Which "weight" do you usually use to calculate energy requirements for overweight patient (BMI 25-30)?

- ☐ Actual weight
 - ☐ Ideal body weight
 - ☐ Adjusted body weight
 - ☐ Other, please specify _____
- Comment:

24. Which "weight" do you usually use to calculate energy requirements for obese patient (BMI > 30)?

- ☐ Actual weight
- ☐ Ideal body weight
- ☐ Adjusted body weight
- ☐ Other, please specify _____

25. Which outcome measures do you usually use to measure success for obese patients: (you can choose more than one option)

- ☐ Weight
- ☐ BMI
- ☐ Waist
- ☐ Waist-to-hip ratio
- ☐ Other, please specify_____

26. Indicate the frequency of each of the following activities that you would provide to obese patients?

Strategy	Never/Seldom	Sometimes	often/usually
Calculation of BMI			
Assessment of exercise habits			
Assessment of weight history			
See client on one to one basis			
Assessment of readiness for change			
Assessment of client's expectations of weight loss/management			
Assessment of client's values and beliefs regarding the ability to lose weight			
Assessment of home environment for supportive structure of weight management/loss			
Assessment of the client's definition of successful outcomes in weight management			
Assessment of the weight history of the client's family			
Assessment of the clients preferred style of consultation/ method of intervention			
Assessment of client's progress for more than 6 month			
Offering more than one weight management strategy			
Accompanied by significant other			
Assessment of expected number of consultations clients need with you			
Assessment of client's anticipation of regaining weight loss			
Providing preventive advice to individuals and families			
Referral to another member of health care team			
See client in group format			
See client in combined one to one counseling/group format			
Review client's progress more than two years.			

E) Models of obesity interventions:

27. What is the philosophical approach to obesity in your service/practice? (Select one only)

- ☐ Diet, exercise and behavior modification
- ☐ Diet and exercise
- ☐ Behavior modification
- ☐ Diet only
- ☐ If other, please specify_____

28. The dietary approach of your service?

- ☐ General healthy eating advice
- ☐ General advice on low fat eating
- ☐ Non-diet approach but identifying specific ways to reduce energy intake
- ☐ Non-diet approach with eating behavior goals
- ☐ Specific low fat eating plan (fat < 30% energy)
- ☐ If other, please specify_____

29. How are specific dietary approaches or interventions selected for clients?

- ☐ Dietitian experience
- ☐ Patient preference
- ☐ Based on program prepared by the service with specific energy level (e.g. 1200 calories/day)
- ☐ As requested by medical referral
- ☐ If other, please specify_____

30. Do you include other members of a multidisciplinary team?

- ☐ Yes
- ☐ No

31. If yes, please choose the members

- ☐ Physicians
- ☐ Psychologist
- ☐ Social worker
- ☐ Physiotherapist

If other, please specify_____

32. When advising your clients on weight loss, indicate how often do you recommend the following strategies?

STRATEGIES	NEVER SELDOM	SOMETIMES	OFTEN USUALLY
General advice to do more exercise			
Pedometer or other exercise monitoring device			
Practical advice regarding shopping and cooking to achieve dietary goals			
Specific advice regarding opportunities for increasing incidental daily activity			
Specific advice to reduce total fat intake			
Specific advice re incorporating low intensity, long duration exercise such as walking into present lifestyle			
Planning for follow up in the short term			
Specific advice regarding ways of incorporating other forms of exercise into daily living			
Behavior modification techniques			
Specific advice to eat fewer kilojoules			
Keeping a food diary			
Planning for follow up in the long term			
Keeping a hunger awareness diary			
Keeping a weight diary			
Joining of a commercial or community-based “slimming group”			
Advice to use medications			
Surgical intervention			

Other, please specify_____

F) Evaluation of interventions:

33. Have you or your service assessed the effect of obesity interventions?

- ☐ Yes
- ☐ No

If yes, please provide us with the references or the results for non-published studies.

34. Would you like to make any other comments regarding dietary management of obesity in Saudi Arabia?

Please specify:

35. Would you like to receive a copy of the summary of results for this project?

- ☐ Yes
- ☐ No

If yes, provide us with your email address: _____

36. Do you want to receive similar nutritional surveys in the future via email?

- ☐ Yes
- ☐ No

Appendix C : Dietetic practices survey – Arabic version

Current dietetic practices of obesity management in Saudi Arabia

National Survey 2007

أ) البيانات الشخصية والسكنية:

1- كم عمرك؟

- ☐ أقل من 21 عاما
- ☐ 21- 35 عاما
- ☐ 36- 45 عاما
- ☐ 46- 55 عاما
- ☐ 56- 65 عاما
- ☐ أكثر من 65 عاما

2- ما هو جنسك؟

- ☐ ذكر
- ☐ أنثى

3- ما هي جنسيتك؟

- ☐ سعودي
- ☐ غير سعودي

4- ما هو مكان عملك؟

- ☐ المنطقة الوسطى
- ☐ المنطقة الغربية
- ☐ المنطقة الشرقية
- ☐ المنطقة الشمالية
- ☐ المنطقة الجنوبية

5- كيف تصف البلدة الذي تعمل فيها ؟

- ☐ حاضرة
- ☐ ريفية

6- أين تعمل؟ (يمكن اختيار أكثر من إجابة واحدة).

- ☐ مستشفيات وزارة الصحة
- ☐ مستشفيات خاصة أو مستشفيات القطاعات العسكرية أو المدنية الحكومية
- ☐ عيادات خاصة أو مراكز تخفيف الوزن
- ☐ جهات أكاديمية
- ☐ إذا أخرى, حدد _____

7- ما هي مؤهلاتك الدراسية؟

- ☐ دبلوم تغذية
- ☐ بكالوريوس تغذية إكلينيكية
- ☐ بكالوريوس الغذاء والتغذية
- ☐ ماجستير تغذية إكلينيكية
- ☐ ماجستير الغذاء والتغذية/ تغذية الإنسان
- ☐ دكتوراة في التغذية
- ☐ أخرى، حدد _____

8- كم عدد سنوات الخبرة في مجال عملك؟

- ☐ أقل من سنتين
- ☐ 2 – 5 سنوات
- ☐ 6 – 10 سنوات
- ☐ 11 – 15 سنة
- ☐ أكثر من 15 سنة

9- ما هو تخصصك في مجال العمل؟

- ☐ التغذية الإكلينيكية
- ☐ خدمات الطعام
- ☐ تغذية المجتمع
- ☐ أخرى، حدد _____

ب) معوقات التحكم في السمنة:

10- هل لديكم عيادة تغذية في المستشفى الذي تعمل به؟

- ☐ نعم
- ☐ لا

11. إذا كانت الإجابة بـ "لا"، فضلاً اختر العوائق التي تواجهونها في تأسيس عيادة للتغذية؟

- ☐ لا توجد عوائق
- ☐ الوقت
- ☐ الإمكانيات (مكان العيادة، أدوات العيادة.....الخ)
- ☐ مشاكل في تحويل المرضى للعيادة
- ☐ عدم وجود الخبرة العملية
- ☐ عدم وجود عدد كافٍ من أخصائيي التغذية
- ☐ الإدارة لم تؤسس العيادة حتى الآن
- ☐ أخرى، فضلاً حدد _____

12 – هل أخصائي التغذية لديكم يقوم بتقييم حالات المرضى المنومين في المستشفى؟

- ☐ نعم
- ☐ لا

13. إذا كانت الإجابة بـ "لا"، فضلاً اختر العوائق التي تمنعكم من تقييم الحالات؟ (يمكن اختيار أكثر من إجابة)

- ☐ لا يطلب من أخصائيي التغذية المشاركة في تقييم حالات المرضى
- ☐ الوقت
- ☐ الإمكانيات (مكان العيادة، أدوات العيادة.....الخ)
- ☐ مشاكل في تحويل المرضى للعيادة
- ☐ عدم وجود الخبرة العملية
- ☐ عدم وجود عدد كافٍ من أخصائيي التغذية
- ☐ أخرى، فضلاً حدد _____

14- هل تقوم بإعطاء توجيهات غذائية لمرضى السمنة وزيادة الوزن أثناء عملك (حتى لو لم تكن تعمل في عيادة التغذية أو السمنة)؟

- ☐ نعم
- ☐ لا

إذا كانت الإجابة بـ "لا" فضلاً انتقل إلى السؤال رقم 33 لإنهاء مشاركتك في هذه الدراسة.

15- كم معدل مرضى السمنة وزيادة الوزن الذين تراهم كل أسبوع؟

- ☐ أقل من خمسة
- ☐ 5 - 10
- ☐ 11-20
- ☐ 21 - 30
- ☐ 31-40
- ☐ أكثر من 40

ج) مستوى الخدمة:

16 – هل لديكم قوانين وتوجيهات علمية وعملية معتمدة في عملكم للتحكم في السمنة

- ☐ نعم
- ☐ لا

إذا تم نشرها في مجلة علمية، فضلا اكتب المرجع _____

17 – من أين يأتي معظم تحويل مرضى السمنة لعيادتكم؟ (فضلا أختار إجابة واحدة فقط)

- ☐ من المريض نفسه
- ☐ أخصائيي التغذية
- ☐ الأطباء
- ☐ جهات أخرى، فضلا حدد _____

18 – هل لديكم معايير خاصة لتحويل المريض من المختصين الآخرين إلى أخصائيي التغذية؟

- ☐ نعم
- ☐ لا

19 – ما هي الإمكانيات لديكم في العيادة ؟ (يمكن اختيار أكثر من إجابة واحدة)

- ☐ ليس لدينا عيادة
- ☐ ميزان لقياس الوزن
- ☐ ميزان لقياس الوزن وكذلك نسبة الدهون في الجسم
- ☐ نماذج أطعمة
- ☐ دخول لبيانات المرضى (مثل التحاليل المخبرية)
- ☐ أخرى، فضلا حدد _____

د) طرق تقييم السمنة:

20- ما هي معادلة الطاقة التي تستخدمها غالباً لتقييم احتياج المريض للطاقة (السعرات الحرارية) ؟

- Harris Benedict Equations
- Owen equations
- World Health Organization (WHO) equations
- Schofield equations
- Mifflin equations
- Ireton-Jones equations
- Bernstein equations
- لا تقوم عادة بحساب الطاقة
- إذا طرق أخرى، فضلاً حدد _____

21 - كم سرعة حرارية في اليوم يتم إنقاصها من احتياج الطاقة حتى تصل إلى الوزن المطلوب تحقيقه ؟

- لا يوجد خطة محددة
- 300 – 500 سرعة حرارية في اليوم
- 500 – 1000 سرعة حرارية في اليوم
- 1000 – 1500 سرعة حرارية في اليوم
- أكثر من 1500 سرعة حرارية في اليوم

22 - ما هي المدة التي تحددها غالباً للوصول لتحقيق الوزن المطلوب لمريض السمنة؟

- لا يوجد مدة محددة
- 3 شهور
- 6 شهور
- أكثر من 6 شهور
- أخرى، فضلاً حدد _____

23- ما هو الوزن الذي تستخدمه عادة في المعادلات لحساب الطاقة لمرضى زيادة الوزن (كتلة الجسم: 25- 30)

- الوزن الحقيقي
- الوزن المثالي
- الوزن المعدل Adjusted Body Weight
- أخرى، فضلاً حدد _____

24 - ما هو الوزن الذي تستخدمه عادة لحساب الطاقة لمرضى السمنة (كتلة الجسم أكثر من 30)

- الوزن الحقيقي
- الوزن المثالي
- الوزن المعدل Adjusted Body Weight
- أخرى، فضلاً حدد _____

25- ما هي المقاييس التي تستخدمها عادة لمعرفة النجاح في انخفاض الوزن لمرضى السمنة؟ (يمكن اختيار أكثر من إجابة)

- الوزن
- مؤشر كتلة الجسم
- الخصر
- نسبة الخصر إلى الورك
- أخرى، فضلا حدد

26 – وضح تكرار عمل الأنشطة التالية التي تتبعها عادة مع مرضى السمنة وذلك باختيار المناسب في الجدول التالي:

النشاط	إطلاقاً / نادراً	أحياناً	عادة / غالباً
حساب مؤشر كتلة الجسم (BMI)			
تقييم العادات الرياضية لدى المرضى			
تقييم تغيرات وزن المريض السابقة			
تقديم الاستشارة للمريض بطريقة فردية وليس لمجموعة من المرضى			
تقييم استعداد المريض لتغيير وزنه			
تقييم توقعات المريض حول تخفيف وزنه والتحكم به			
تقييم اعتقادات المريض حول القدرة على تخفيف الوزن			
تقديم دعم نمط وأسلوب الأسرة في المنزل لتخفيف الوزن والتحكم به			
تقييم مفهوم مريض السمنة للنتائج الإيجابية في التحكم في الوزن			
تقييم وزن أسرة المريض السابق والحالي			
تقديم رغبة مريض السمنة في نوعية الاستشارة والنظام الغذائي الذي يفضلها			
تقديم ومتابعة تطور حالة مريض السمنة لمدة تزيد عن ستة أشهر			
تقديم أكثر من استراتيجية وطريقة للتحكم في الوزن			
تقديم حالة المريض في وجود مرافق لمساعدته (خاصة كبار السن والأطفال)			
تقديم عدد الاستشارات التي تتوقع أن المريض يحتاجها			
تقديم توقع المريض العودة للوزن الزائد بعد فقدان بعض الوزن			
تقديم نصائح وقائية للأفراد والعائلات			
تحويل مريض السمنة إلى مختص آخر في الفريق الطبي			
تقديم الاستشارة للمريض بطريقة المجموعة مع مرضى آخرين وليس لوحده فقط			
تقديم حالة المريض بطريقة فردية إضافة إلى الطريقة الجماعية مع المرضى الآخرين			
مراجعة تطور حالة المريض لمدة تزيد عن سنتين			

هـ) طرق التحكم في السمنة:

27 - ما هي الطريقة والفلسفة التي تتبع عادة في عملكم للتحكم في السمنة؟ (اختر إجابة واحدة فقط)

- ☐ الغذاء، الرياضة وتعديل السلوك الغذائي
- ☐ الغذاء والرياضة
- ☐ تعديل السلوك الغذائي فقط
- ☐ الغذاء فقط
- ☐ طرق أخرى، فضلاً حدد _____

28- ما هي الطريقة الغذائية التي تتبع عادة في عملكم للتحكم في السمنة؟

- ☐ نصائح غذائية صحية عامة
- ☐ نصائح غذائية عامة لتقليل الدهون
- ☐ لا نتبع طريقة غذائية معينة ولكن نتبع طرق لتقليل استهلاك الطاقة (السرعات الحرارية)
- ☐ لا نتبع طريقة غذائية معينة ولكن نهدف إلى تغيير السلوك الغذائي
- ☐ نصيحة غذائية معينة ومعتمدة على تقليل الدهون (الدهون > 30%)
- ☐ طرق أخرى، فضلاً حدد _____

29 - كيف يتم اختيار الطريقة الغذائية لمرضى السمنة؟

- ☐ اعتماداً على خبرة أخصائي التغذية
- ☐ اعتماداً على اختيار المريض
- ☐ اعتماداً على برنامج غذائي يحدد فيه مستوى الطاقة (مثال: 1200 سعرة حرارية/ اليوم) تم إعداده بواسطة مختصين.
- ☐ اعتماداً على ما هو موضح في التحويل الطبي
- ☐ طرق أخرى، فضلاً حدد _____

30 - هل يتم عادة علاج مريض السمنة بمساعدة طاقم طبي في تخصصات أخرى؟

- ☐ نعم
- ☐ لا

31- إذا الإجابة بـ "نعم"، فضلاً حدد أعضاء الطاقم الطبي:

- ☐ الأطباء
- ☐ أخصائيو النفس
- ☐ أخصائيو الاجتماع
- ☐ أخصائيو العلاج الطبيعي
- ☐ آخرون، فضلاً حدد _____

32 - عندما تعطي مريض السمنة بعض النصائح لتخفيف الوزن، وضّح مدى تكرار النصائح التالية باختيار المناسب في الجدول التالي:

النشاط	اطلاقاً / نادراً	أحياناً	عادة / غالباً
نصائح عامة لزيادة الأنشطة الرياضية			
استخدام مقياس الخطو أو أجهزة مشابهة أخرى			
نصائح عملية حول التسوق والطبخ لتحقيق الأهداف الغذائية			
نصائح خاصة لزيادة فرص النشاط من خلال الحركة اليومية المعتادة			
نصائح خاصة لتقليل الدهون			
نصائح خاصة لممارسة الرياضة قليلة الجهد والطويلة في المدة مثل إدخال المشي في نمط الحياة الحالي			
التخطيط لمتابعة مريض السمنة في فترات متقاربة			
نصائح خاصة حول طرق دمج أنواع الأنشطة الرياضية الأخرى ضمن نمط الحياة اليومية			
إعطاء طرق لتغيير السلوك الغذائي			
نصائح خاصة لتقليل استهلاك السرعات الحرارية			
نصح مريض السمنة لتسجيل ما يتناوله يومياً			
التخطيط لمتابعة مريض السمنة لفترة طويلة			
المحافظة على أوقات للشعور بالجوع يومياً			
نصح مريض السمنة لتسجيل تغيرات وزنه			
الالتحاق بأحد أندية تخفيف الوزن التجارية أو الاجتماعية			
نصائح باستخدام حبوب تخفيف الوزن لعلاج السمنة			
نصائح باستخدام الجراحة لعلاج السمنة			

أنشطة أخرى، فضلاً حدد

ز) تقييم الطرق الغذائية للتحكم في السمنة:

33 – هل سبق وان قمتم بدراسات لتقييم الطرق الغذائية التي تستخدمونها لتخفيف الوزن؟

- ☐ نعم
☐ لا

إذا الإجابة بـ "نعم"، فضلاً اكتب المصادر العلمية التي نشرت فيها هذه الدراسات:

34 – هل تريد أن تضيف أي تعليقات حول علاج السمنة في السعودية؟

35 – هل تريد الحصول على نتائج تحليل هذا الاستبيان؟

- ☐ نعم
☐ لا

فضلاً, اكتب عنوان بريدك الإلكتروني:

36 – هل ترغب في استقبال استبيانات لبحوث في التغذية في المستقبل على بريدك الإلكتروني؟

- ☐ نعم
☐ لا

Appendix D: Dietetic practices survey – samples of the web-based form



Obesity Survey - Windows Internet Explorer

http://www.surveymonkey.com/s.aspx?sm=pETc2qVL13rkufnNxcuHR7FGdk%2bHwjOsW5apN%2fbFYDU%3d

File Edit View Favorites Tools Help

University of Wollongong

Obesity Survey

Exit this survey >>

3. Barriers to obesity management

* 10. Do you run a nutrition clinic at your service?

11. If you do not run a clinic, please list barriers in your service that may prevent you running a nutrition clinic? (You can choose more than one answer)

☐ No barriers

☐ Time

☐ Resources (e.g. space, facilities and tools)

☐ Referral related issues

☐ Lack of knowledge with best practice

☐ Lack of dietitians

☐ Service administration has not established a clinic yet

☐ Other (please specify)

Done

start

SurveyMonkey - Que...

Obesity Survey - Win...

Microsoft Word - Doc...

Internet

100%

06:06

Obesity Survey - Windows Internet Explorer

http://www.surveymonkey.com/s.aspx?sm=pETc2qVL13rkufnNxcuHR7FGdk%2bHwjOsW5apN%2fbFYDU%3d

File Edit View Favorites Tools Help

University of Wollongong

Obesity Survey

Exit this survey >>

4. Level of service and demand

* 16. Does your service have clinical practice guidelines for obesity management?

* 17. Where do the majority of referrals for obese patients come from?

* 18. Do you have specific criteria for the referral of patients from other health practitioners to dietitians?

* 19. What resources do you have in your work? (You can choose more than one answer)

Done

start

SurveyMonkey - Que...

Obesity Survey - Win...

Microsoft Word - Doc...

Internet

100%

06:07

Obesity Survey - Windows Internet Explorer

http://www.surveymonkey.com/s.aspx?sm=ETC2qVL13rkufnNXcuHR7FGdk%2bHwjOsW5apN%2fbFXDU%3d

File Edit View Favorites Tools Help

University of Wollongong

Exit this survey >>

Obesity Survey

5. Models of obesity assessment

* 20. Which predictive equations do you usually use to assess energy requirements?

Harris Benedict Equations

* 21. How many calories/day do you reduce from the daily energy requirements to achieve your goal?

300 - 500 Kcal/day

* 22. What is usually your time line to achieve your goal?

Done

Internet 100%

start SurveyMonkey - Que... Obesity Survey - Win... Microsoft Word - Doc... 06:08

Obesity Survey - Windows Internet Explorer

http://www.surveymonkey.com/s.aspx?sm=ETC2qVL13rkufnNXcuHR7FGdk%2bHwjOsW5apN%2fbFXDU%3d

File Edit View Favorites Tools Help

* 26. Indicate the frequency of each of the following activities that you would provide to obese patients?

	Never/Seldom	Sometimes	Often/Usually
Calculation of BMI	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Assessment of exercise habits	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Assessment of weight history	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
See client on one to one basis	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Assessment of readiness for change	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Assessment of client's expectations of weight loss/management	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Assessment of client's values and beliefs regarding the ability to lose weight	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assessment of home environment for supportive structure of weight management/loss	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assessment of the client's definition of successful outcomes in weight management	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
Assessment of the weight history of the client's family	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Assessment of the clients preferred style of consultation/ method of intervention	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Assessment of client's progress for more than 6 month	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Offering more than one weight management strategy	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Accompanied by significant other	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Assessment of expected number of consultations clients need with you	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
Assessment of client's anticipation of regaining weight loss	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
Providing preventive advice to individuals and families	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

Done

Internet 100%

start SurveyMonkey - Que... Obesity Survey - Win... Microsoft Word - Doc... 06:09

Appendix E: Dietetic practices survey – Ethics Approval

University of Wollongong



INITIAL APPLICATION APPROVAL

In reply please quote: HE07/063
Further Enquiries Phone: 4221 4457

21 March 2007

Mr Ali Almajwa
Smart Foods Centre
University of Wollongong

Dear Mr Almajwal,

Thank you for your response dated 12 March 2007 to the conditional approval letter dated 8 March 2007. I am pleased to advise that the conditions have been met.

Ethics Number:	HE07/063
Project Title	A web based survey about current diabetic practices of dieticians in Saudi Arabia in the management of overweight and obese patients.
Name of Researchers:	Mr Ali Almajwal, A/Prof Peter Williams, Ms Marijka Batterham, Prof Linda Tapsell
Approval Date:	8 March 2007
Expiry Date:	7 March 2008

The University of Wollongong/SESAHS Health and Medical HREC is constituted and functions in accordance with the NHMRC *National Statement on the Ethical Conduct in Research Involving Humans*. The HREC has reviewed the research proposal for compliance with the *National Statement* and approval of this project is conditional upon your continuing compliance with this document. As evidence of continuing compliance, the Human Research Ethics Committee requires that researchers immediately report:

- proposed changes to the protocol including changes to investigators involved
- serious or unexpected adverse effects on participants
- unforeseen events that might affect continued ethical acceptability of the project.

You are also required to complete monitoring reports annually and at the end of your project. These reports are sent out approximately 6 weeks prior to the date your ethics approval expires. The reports must be completed, signed by the appropriate Head of School, and returned to the Research Services Office prior to the expiry date.

Yours Sincerely,

A/Professor Arthur Jenkins

Chairperson

Human Research Ethics Committee

Research Services Office University of Wollongong NSW 2522 Australia
Telephone: +61 2 4221 3386 Facsimile: +61 2 4221 4338
research_services@uow.edu.au www.uow.edu.au/research
CRICOS Provider No. 00102E

Appendix F: Dietetic practices survey – Introductory letter and participant information sheet (English version)

Dear Dietitian:

You are invited to take part in the research project “development of evidence-based practice guidelines for the nutritional management of obesity in Saudi Arabia” which is being conducted by Ali Almajwal as part of his PhD project, under the supervision of A.Professor Peter Williams and Dr. Marijka Batterham from the faculty of Health Sciences at the University of Wollongong, Australia.

Why is the research being done?

The purpose of the project is to describe the current dietetic practices of dietitians in the management of obesity in Saudi Arabia. The results of this survey are important for the development of evidence-based practice guidelines and the overall process will have an impact on the clinical practice, research and dietetic policy.

Who can participate in the research?

We are seeking all dietitians of Saudi Arabia (Saudi and non-Saudi) who see overweight or obese patients. This will also include dietitians who work in other clinical areas (e.g. renal diseases, liver diseases etc) if they manage the overweight and obesity for their patients. Dietitians who are not involved in the management of obesity are required to participate in this survey. They are required to answer the first 14 questions and the last 4 questions in the survey.

What choice do you have?

Participation in this research is entirely your choice. Whether or not you decide to participate, your decision will not disadvantage you in any way.

What are the risk and benefits of participating?

There is no known risk and no direct benefit to you during this study. However, your participation in this study will provide us with important information regarding the current dietary management of obese patients by Dietitians in Saudi Arabia today which will assist in improving future practice. A summary of results for this project will be available to you following project completion.

How will your privacy be protected?

All responses are treated in strict confidence. No individually identifiable data will be analyzed or reported on and all data will be reported as a group. Participants are potentially identifiable if their answer for questions 33 or 35 is "Yes".

What do you need to participate?

Please read this information statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Ali Almajwal as detailed below.

If you want to participate, please complete and return the questionnaire either “on line” via the survey’s webpage or by email or mail. This will be taken as your informed consent to participate. The questionnaire will take approximately 15 minutes.

Survey's webpage:

<http://www.surveymonkey.com/s.asp?u=523083235180>

(Using the webpage is the preferred method for your participation)

Further information:

Please feel free to contact **Ali Almajwal** (PhD Candidate, University of Wollongong, Australia) with any queries or concerns via email: amja695@uow.edu.au.

The research Team:

- Ali Almajwal, PhD Candidate from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia.
Email: amja695@uow.edu.au (phone: + 61 4 0000 3293)
- A/Professor Peter Williams from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia.
Email: peterw@uow.edu.au (Phone: +61 2 4221 4085)
- Dr. Marijka Batterham from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia.
Email: marijka@uow.edu.au (Phone: 61 2 4221 5303)

This Research project has been approved by the University’s Research Ethics Committee. If you have any enquiries regarding the conduct of the research please contact the Secretary of the University of Wollongong Human Research Ethics Committee on (02) 42214457.

Thank you for considering taking part in this study

Appendix G: Dietetic practices survey – Introductory letter and participant information sheet (Arabic version)

معلومات حول الدراسة

الممارسات العملية لأخصائيي التغذية في التحكم في السمنة وزيادة الوزن في المملكة العربية السعودية

الكرام

أخصائي / أخصائية التغذية

يسرنا دعوتكم للمشاركة في هذا المشروع " إصدار التعليمات والتوجيهات الغذائية والمعتمدة على البحوث العلمية للتحكم في السمنة وزيادة الوزن في السعودية". هذا البحث هو جزء من مشروع الدكتوراة والذي يقوم به السيد علي المجول، تحت إشراف الدكتور بيتر وليامز و ماريكا بترهام من كلية العلوم الطبية في جامعة ولونجونج في استراليا

ما هو الهدف من هذا البحث؟

يهدف هذا البحث إلى وصف الممارسات العملية لدى أخصائيي التغذية في السعودية للتحكم في السمنة. ونتائج هذا البحث مهمة في عمل التوجيهات والنصائح الغذائية لمرضى السمنة، كما أن له دور في تطوير العمل الإكلينيكي والبحوث وكذلك سياسة التغذية في السعودية.

من يشارك في الإجابة على هذا الاستبيان؟

جميع أخصائيي التغذية في السعودية (سعوديون وغير سعوديون) سواء الذين يتابعون مريض زيادة الوزن أو السمنة أثناء عملهم أو الآخرين الذين لا يعملون في هذا المجال. أخصائيو التغذية الذين لا يشاركون في التحكم في السمنة نحتاج إلى مشاركتهم وذلك عن طريق إجابة الأسئلة الأربعة عشر الأولى من الاستبيان وكذلك الأربعة الأخيرة.

هل لك حرية الاختيار في المشاركة ؟

المشاركة في الإجابة على الاستبيان هي خيار لك وحدك وعدم مشاركتك لن يسبب لك أي مشاكل بأي طريقة أو أخرى.

ما هي الأضرار والفوائد من المشاركة في هذا الاستبيان؟

لا يوجد ضرر أو فائدة مباشرة من مشاركتك في هذه الدراسة. ولكن مشاركتك وإجابتك على الأسئلة سيعطينا معلومات مهمة حول عمل أخصائي التغذية وطريقة علاجهم لمرضى السمنة في السعودية وهذا سيساعدنا في تطوير عمل الأخصائيين في المستقبل. كما أن ملخص نتائج البحث ستكون متاحة لكم بعد الانتهاء منه.

كيف يتم المحافظة على سرية المعلومات؟

جميع الإجابات سنتعامل معها بسرية تامة. ولن يكون هناك تعريف لأي استبيان بمفرده حيث ستحلل جميع البيانات على شكل مجموعات. إذا كانت إجابتك للسؤال 33 أو 35 "نعم" قد يؤدي ذلك إلى التعرف عليك.

ماذا تحتاج للمشاركة في هذا البحث؟

فضلا اقرأ المعلومات السابقة حول هذه الدراسة وتأكد من فهم جميع محتوياتها وإذا كان لديك سؤال أو استفسار تستطيع الاتصال بـ علي المجول والموضحة بياناته في الأسفل.

إذا تريد المشاركة تستطيع تعبئة الاستبيان وإعادةه سواء عن طريق البريد أو الإيميل أو عن طريق تعبئته من خلال موقع الاستبيان على الإنترنت. وإرسال الاستبيان يعتبر إقرار منك بالموافقة على المشاركة. الإجابة على أسئلة الاستبيان تستغرق حوالي 15 دقيقة.

موقع الاستبيان على الإنترنت وهذه هي الطريقة التي نفضل أن تشاركوا من خلالها في هذا البحث:

<http://www.surveymonkey.com/s.asp?u=449903245718>

أعضاء فريق البحث:

1- علي المجول، طالب دكتوراة من كلية العلوم الطبية في جامعة ولونجونج في أستراليا

هاتف: + 61 4 0000 3293 amja695@uow.edu.au بريد الكتروني:

2- د. بيتر وليامز، أستاذ مشارك من كلية العلوم الطبية في جامعة ولونجونج في أستراليا

هاتف: + 61 2 4221 4085 peterw@uow.edu.au بريد الكتروني:

3- د. ماريكا بترهام، عضو هيئة التدريس من كلية العلوم الطبية في جامعة ولونجونج في أستراليا

هاتف: + 61 2 4221 5303 marijka@uow.edu.au بريد الكتروني:

كل الشكر والتقدير لكل من شارك في هذا البحث وأجاب على أسئلة الاستبيان

Appendix H : BodyGem and prediction equations study – recruitment advertisement



Advertisement

Would like to participate in a study that measures your daily energy requirement and we will assess the accuracy of a handheld calorimeter

The Smart Foods Center at the University of Wollongong is seeking volunteers for a study to assess the accuracy of a hand held calorimeter (Body Gem). This device is relatively new and measures your resting energy expenditure, the number of calories a person burns in a day at rest.

If you fit these criteria, we would like to contact you:

- Aged > 18 years
- BMI > 25 kg/m²
- Generally well
- Not having diabetes or thyroid diseases

This study involves a two hours stay in the new whole room calorimeter at the university, a new facility that measures how many calories you burn. You will also be required on this visit to use a hand-held calorimeter machine (breathing into a disposable plastic mouth-piece for about 10 minutes) in order to measure your resting energy expenditure. Another short visit after one week will involve a repeated measurement of the resting energy expenditure using the hand calorimeter only. If you would like to register your interest and find out more, please leave a message on the study hotline at the Smart Food Center on 4221 4600.

Appendix I: BodyGem and prediction equations study – Screening questionnaire

Project: Validity of the BodyGemTM calorimeter and prediction equations for the assessment of REE in overweight and obese Saudi males

Screening questionnaire

In this questionnaire general questions are asked about yourself and your health. The information that you provide is confidential.

CHECKLIST:

- Aged >18 years
- BMI > 25 kg/m²
- Generally well
- Not having diabetes or thyroid disease

1. Title: ☐ Dr ☐ Mrs ☐ Mr ☐ Miss ☐ Ms

2. Full Name: _____

3. Address: _____

4. Phone No.: Home: _____ Work: _____

Mobile: _____

Email: _____

5. Date of birth: _____ day _____ month _____ year

6. Height _____ Ft _____ Inches **OR** _____ cm _____ BMI:

7. Weight _____ St _____ lbs **OR** _____ kg

8. Has your weight changed more than 3 kgs (7lbs) in the last 3 months?
(Please tick (✓) one box)

☐ Don't know

☐ No

☐ Yes - it has gone up by _____ lb. or _____ kg

☐ Yes - it has gone down by _____ lb. or _____ kg

9. Do you smoke cigarettes? (Please tick (✓) one box)

- ☐ No ☐ Yes, 11-20 per day
☐ Yes, 1-10 per day ☐ Yes, more than 20 per day

10. List any medications that you are taking regularly?

- 1- 2-
3- 4-

11. Do you currently follow a special or modified diet?

- ☐ YES ☐ NO ☐ NOT SURE

12. If you are following a special diet, please specify what this is:

I understand that the information provided will be used only for the purpose of determining my suitability to participate in the study. Completion of this questionnaire does NOT ensure that I will meet all the requirements for the study.

I understand that the Smart Foods Centre regularly conducts studies such as this one which ask for volunteers. I would like the information in this questionnaire:

☐ to be kept in a confidential file at the Smart Foods Centre for consideration in future research projects.

OR

☐ to be destroyed immediately.

Signed _____ Date _____

Thank you for your participation!

Appendix J: BodyGem and prediction equations study –Participant Information Sheet

Project: Validity of the BodyGemTM calorimeter and prediction equations for the assessment of REE in overweight and obese Saudi males



Validity and reproducibility of the hand-held calorimeter

Who are we?

This study is being conducted by a group of researchers from the Smart Foods Centre at the University of Wollongong. Associate Professor Peter Williams and Lecturer Marijka Batterham are academics in the Smart Foods Centre and the Department of Biomedical Science. Ali Almajwal is a PhD student in the Department of Biomedical Science.

Associate Professor Peter Williams (ph 4221 4085)
Lecturer Marijka Batterham (ph 4221 5303)
PhD Student, Ali Almajwal (ph 4221 4636)

Why are we doing this?

The project aims to assess the validity and reproducibility of the hand held calorimeter. The results of this research will contribute to a better understanding of the accuracy of this device in the measurement of resting energy expenditure.

What will we ask you to do?

This study involves the use of a facility, known as a whole room calorimeter (WRC) to measure the resting energy expenditure (REE). This facility is basically a small room which measures oxygen consumed and carbon dioxide produced by the person staying inside. From these measurements we are able to calculate the REE. This method is known as the gold standard for the measurement of REE.

If you decide to participate in the study, we will require you to come to the University on two separate visits in the early morning (8-10 o'clock).

1st Visit:

This visit will take approximately 2 hours.

At this visit -

You will:

- Arrive fasted (for 10-12 hours).
- Be asked not to smoke or do any exercise on the morning of the assessment and not to consume alcohol for at least 24 hour prior to the assessment
- Stay in the WRC for two hours. In the second hour, you will be asked to lie quietly on the bed.
- Wear a nose clip and Breathe into the hand-held calorimetry machine via a disposable plastic mouth-piece for about 10 minutes to measure your resting energy expenditure.

We will measure:

- Your weight, height, and waist.
- Body composition, using bioelectrical impedance analysis by Tanita scales

You will be given:

- A light breakfast.
- A coffee voucher to use at the Poolside Cafe
- A parking voucher

2nd Visit:

This visit will take approximately 35 minutes.

At this visit -

You will:

- Arrive fasted (for 10-12 hours)
- Be asked to stay for 25 minutes before the measurements
- Be asked not to smoke or do any exercise on the morning of the assessment and not to consume alcohol for at least 24 hour prior to the assessment
- Wear a nose clip and breathe into the hand-held calorimetry machine via a disposable plastic mouth-piece for about 10 minutes.

We will measure:

- Your weight
- Body composition, using bioelectrical impedance analysis by Tanita scales

What kinds of facilities are available for you in the WRC?

The University of Wollongong facility consists of two separate air-tight, ventilated and air-conditioned chambers (3 x 2.1 x 2.4 m), each with a bed, desk, chair, hand basin TV/VCR, computer, phone and toilet.

Who can participate

We are looking for healthy male and female participants aged 18 - 70 years.

You should not participate in this study if you:

- wear a pacemaker
- are having diabetes or thyroid diseases

What are the side effects of taking part?

The calorimeters are small rooms (3.0 x 2.1 x 2.4 m) which may cause discomfort to some people. If you feel too uncomfortable you may stop the study at any time. You may if you wish also withdraw your consent for the use of your data in the study.

What are the possible disadvantages and risks of taking part?

We do not foresee any other risks or any disadvantages (except for the time commitment required of you) of taking part in this study.

What will we do with the information we obtain?

All information will be kept secure and identified by a code rather than by your actual name. Nothing which identifies individual participants will be published. Standards of medical confidentiality will apply. As a result of the study you will be able to gain some information about your body fat percentage and how many calories you burn a day.

If at any time you have any questions, please do not hesitate to ask. Your involvement in the research is entirely voluntary. You are free to withdraw from the research at anytime without penalty. If you have any enquiries regarding the conduct of the research please contact the Secretary of the University of Wollongong Human Research Ethics Committee on (02) 42214457.

Appendix K: BodyGem and prediction equations study – Consent Form

Project: Validity of the BodyGemTM calorimeter and prediction equations for the assessment of REE in overweight and obese Saudi males

CONSENT FORM

Validity and reproducibility of the hand-held calorimeter in overweight and obese people

Chief investigators:

Associate Professor, Peter Williams (ph 4221 4085)

Dr Marijka Batterham (ph 4221 5303)

PhD student, Ali Almajwal (ph 4221 4636)

This study is being conducted by the team listed above in the Department of Biomedical Science and the Smart Foods Centre, University of Wollongong.

I understand that the data collected will be used to assess the validity and reliability of the hand held calorimeter. I consent for the data to be used anonymously in that manner. I agree to the following involvement:

First visit:

1. Staying in the WRC for two hours to measure the REE
2. Having my resting energy expenditure also assessed by breathing into a hand-held calorimetry machine via a disposable plastic mouth-piece
3. Having my weight, height, and waist measured
4. Having my body composition assessed using bioelectric impedance
5. Providing basic demographic information such as age, sex and ethnicity.

Second visit:

6. Having my resting energy expenditure assessed by breathing into a hand-held calorimetry machine via a disposable plastic mouth-piece for 10 minutes.
7. Having my weight, height, and waist measured
8. Having my body composition assessed using bioelectric impedance

Your participation in this research is voluntary, you are free to refuse to participate and you are free to withdraw from the research at any time. Your refusal to participate or withdrawal of consent will not affect your treatment or your relationship with the University of Wollongong in any way. If you would like to discuss this research further please contact Peter Williams on (02) 4221 4085 or Marijka Batterham on (02) 4221 5303 or Ali Almajwal (02) 4221 4636. If you have any enquiries regarding the conduct of the research please contact the Secretary of the University of Wollongong Human Research Ethics Committee on (02) 4221 4457.

Validity and reproducibility and of the hand-held calorimeter in overweight and obese people

I have read the participant information sheet and understand what I will be doing. I have been given the opportunity to speak with the researchers.

I, (Participant's name) consent to participate in the research conducted by Peter Williams, Marijka Batterham, and Ali Almajwal as it has been described to me in the information sheet. I understand that the data collected will be used to assess the accuracy of the hand held calorimeter. I consent for the data to be used anonymously in that manner.

Signed
Date

..... /...../.....

Appendix L: BodyGem and prediction equations study – Ethics approval

Project: Validity of the BodyGemTM calorimeter and prediction equations for the assessment of REE in overweight and obese Saudi males

University of Wollongong



INITIAL APPLICATION APPROVAL

In reply please quote: HE06/202

Further Enquiries Phone: 4221 4457

24 July 2006

Mr Ali Almajwal
Department of Biomedical Science
University of Wollongong

Dear Mr Almajwal,

I am pleased to advise that the Human Research Ethics application referred to below has been **approved subject to the following condition/s**:

i) Please replace 'anonymously' with 'in de-identified form' in the second line of the second paragraph on the consent form..

Ethics Number: HE06/202
Project Title: Validity and reproducibility of the hand-held calorimeter in overweight and obese people.
Researchers: Mr Ali Almajwal, A/Prof Peter Williams, Ms Marijka Batterham
Approval Date: 20 July 2006
Expiry Date: 19 July 2007

This certificate relates to the research protocol submitted in your original application as modified/clarified in your letter of **16 July 2006**. As a condition of approval, the Human Research Ethics Committee requires that researchers immediately report:

- proposed changes to the protocol including changes to investigators involved
- serious or unexpected adverse effects on participants
- unforeseen events that might affect continued ethical acceptability of the project.

You are also required to complete monitoring reports annually and at the end of your project. These reports are sent out approximately 6 weeks prior to the date your ethics approval expires. The reports must be completed, signed by the appropriate Head of School, and returned to the Research Services Office prior to the expiry date.

Yours Sincerely,

pp. 

A/Prof Arthur Jenkins
Chair, Human Research Ethics Committee

cc: A/Prof Peter Williams, Faculty of Health & Behavioural Science

Appendix M: Delphi consultations study- Participants list

1. Dr. AbdulAziz Alothman, Associate Professor, Academic
2. Dr. Nahar Alenezi, Consultant, Physician
3. Dr. Yasmin Altwaijri, Nutritional epidemiologist, Researcher
4. Dr. AbdulAziz Alothaimeen, Nutritional epidemiologist, Researcher
5. Abdulrahman Almoziny, Dietitian
6. Farah Delaigan, Dietitian
7. Hmidan Alturki, Dietitian,
8. Majid Alkhalaf, Dietitian
9. Mirza Baig, Dietitian
10. Mohammad Zagly, Dietitian
11. Monira Almuhanha, Dietitian
12. Nahla Bawazir, Dietitian
13. Nawaf Alruaili, Teaching Assistant, Academic
14. Reema Abo alfaraj, Dietitian
15. Rukaiah Al-Draiwesh, Dietitian
16. Samar Eskandarani, Dietitian
17. Sawsan Albalawi, Dietitian
18. Suhad Almuaigl, Dietitian
19. Theeb Almutairi, Dietitian
20. Zayed Alsharari, Dietitian

Appendix N: Delphi consultations study-Ethics Approval

University of Wollongong



INITIAL APPLICATION APPROVAL

In reply please quote: HE08/316

Further Enquiries Phone: 4221 4457

2 December 2008

A/Professor Peter Williams
Department of Biomedical Science
University of Wollongong

Dear A/Professor Williams,

I am pleased to advise that the Human Research Ethics application referred to below has been reviewed and the ethical aspects **approved**.

Please note there are some typographic errors need to be corrected:

- i) The word "shorted" should read "shorter" in the second last paragraph of Appendix 1
- ii) The second last sentence of Appendix 1 should read "Please read the attached Participant Information Sheet before making your decision."

Ethics Number: HE08/316
Project Title: Delphi consultation on development of consensus statements for inclusion in Clinical practice guidelines for the nutritional management of obesity in Saudi Arabia.
Name of Researchers: A/Professor Peter Williams, Dr Marijka Batterham, Mr Ali Almajwal, Prof Linda Tapsell
Approval Date: 27 November 2008
Expiry Date: 26 November 2009

This certificate relates to the research protocol submitted in your original application.

The University of Wollongong/SESIAHS Health and Medical HREC is constituted and functions in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research*. The HREC has reviewed the research proposal for compliance with the *National Statement* and approval of this project is conditional upon your continuing compliance with this document. As evidence of continuing compliance, the Human Research Ethics Committee requires that researchers immediately report:

- proposed changes to the protocol including changes to investigators involved
- serious or unexpected adverse effects on participants
- unforeseen events that might affect continued ethical acceptability of the project.



You are also required to complete monitoring reports annually and at the end of your project. These reports are sent out approximately 6 weeks prior to the date your ethics approval expires. The reports must be completed, signed by the appropriate Head of Unit, and returned to the Research Services Office prior to the expiry date.

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'A. Jenkins'.

A/Professor Arthur Jenkins

Chairperson

UOW&SESIAHS Health and Medical HREC

Cc: Professor Linda Tapsell, Smart Foods Centre

Appendix O: Delphi consultations study- Invitation Email

From: Ali Almajwal (amja695@uow.edu.au)

Title: Invitation to participate in Delphi consultations

Dear (participant name),

I am contacting you to invite you to participate in Delphi consultations that focus on development of consensus statements that could be included in the proposed clinical practice guidelines for the nutritional management of obesity in Saudi Arabia. These consultations will include the following topics:

- Behaviour modifications techniques and obesity management for Saudi people
- Specific dietary counselling strategies
- Management of obesity in Ramadan
- Achievable weight loss goals by Saudi people
- Physical activity and obesity management especially for Saudi women

In the first round, you will be asked to write your level of agreement regarding a list of statements that have been suggested by previous consultation workshops. You will be asked whether you think there are some statements that need to be modified, deleted or added to the list.

The second round will be shorted and will be limited for the new added or modified statements. A third round will be conducted only if consensus is not reached.

We hope that you will be able to take part in these consultations. If you are happy to be involved in this consultation process, please let me know by replying to this email. Please read the attached Participant Information Sheet before making your decision.

Many thanks in advance for your time and consideration.

Kind regards,

Ali Almajwal, PhD Candidate

School of Health Sciences

University of Wollongong

Wollongong, NSW 2522, Australia

Mobile: ++ 61(4)0000 3293

Fax: ++ 61(2)4221 3486

Appendix P: Delphi consultations study-Participant Information Sheet

Background

You are invited to take part in the research project “Development of evidence-based practice guidelines for the nutritional management of obesity in Saudi Arabia” which is being conducted by Ali Almajwal as part of his PhD project, under the supervision of A/Professor Peter Williams and Dr. Marijka Batterham from the faculty of Health Sciences at the University of Wollongong, Australia.

The research team is conducting series of surveys, expert's interviews, consultation workshops, critical reviews and online Delphi consultations to develop practice guidelines. A summary of the issues identified by key stakeholders at the first consultation workshop has been published (Almajwal et al. *New Egypt J Med* 2008;38(1):34-39.) The focus of this current Delphi study is to develop some consensus statements to be included in the guidelines.

Why a Delphi study?

This consultation will cover specific topics where there is insufficient evidence for the development of evidence based statements and therefore experts' opinion is needed. The Delphi consensus study aims to develop expert agreement about:

- Behaviour modifications techniques and obesity management for Saudi people.
- Specific dietary counselling strategies
- Management of obesity in Ramadan
- Achievable weight loss goals by Saudi people
- Physical activity and obesity management especially for Saudi women

Who is involved in this study?

An expert panel of around 25 academics and dietitians from Saudi Arabia are being invited to participate in this study as expert panellists. You have been recognised by your peers, through your professional profiling, as an expert in nutritional management of obesity. We hope you can add your insights and experience to this project.

What is involved in participating in this study?

By agreeing to participate in this study you will be prompted by us via email to complete two to three online rounds of Delphi questionnaires. It is anticipated that each questionnaire will take no more than 20 minutes to complete. All panellists will receive summary data and reports on results in each round of the survey process and will be invited to be acknowledged in any publications resulting from this study.

What choice do you have?

Participation in this research is entirely your choice. Whether or not you decide to participate, your decision will not disadvantage you in any way.

What are the risks and benefits of participating?

There is no known risk and no direct benefit to you during this study. However, your participation in this study will help in improving obesity clinical practices in Saudi Arabia. A summary of results for this project will be available to you following project completion.

How will your privacy be protected?

All responses are treated in strict confidence. No individually identifiable data will be analyzed or reported on and all data will be reported as a group.

What do you need to participate?

Please read this information statement and be sure you understand its contents before you consent to participate. If there is anything you do not understand, or you have questions, please contact Ali Almajwal as detailed below. If you want to participate, please confirm your participation by replying to the invitation email. This will be taken as your informed consent to participate.

How will this study be of benefit to dietetics practice?

We believe that developing consensus about nutritional management of obesity in Saudi Arabia is important so that we can more effectively share our learnings and enhance our practice. It will assist in making the care more consistent and efficient. We hope that this study can assist this process with your help.

Further information:

Please feel free to contact Ali Almajwal (PhD Candidate, University of Wollongong, Australia) with any queries or concerns via email: amja695@uow.edu.au. Any questions regarding the way the research is conducted can be directed to the Secretary of the University of Wollongong, Human Research Ethics Committee on + 61 2 4221 4457.

- Ali Almajwal, PhD Candidate from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia. Email: amja695@uow.edu.au (phone: + 61 4 0000 3293)
- A/Professor Peter Williams from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia. Email: peterw@uow.edu.au (Phone: + 61 2 4221 4085)
- Dr. Marijka Batterham from the Faculty of Health Sciences at the University of Wollongong, NSW, Australia. Email: marijka@uow.edu.au (Phone: 61 2 4221 5303)

Thank you for considering taking part in this study.

Appendix Q: Delphi consultations study-Delphi Emails

From: Ali Almajwal (amja695@uow.edu.au)

Title: Delphi 1

Dear (participant name),

Thank you for agreeing to be included in this Delphi consensus study as an expert panellist. The first round questionnaire has been attached to this email. We ask that you save this file to your own computer and complete your responses directly onto the Microsoft Word document. Please return your completed questionnaire within two weeks if possible to this email address (amja695@uow.edu.au). Once we have collated the results of the first round of this Delphi study, you will be forwarded the second round questionnaire with feedback of the pooled results of the round one questionnaire.

We look forward to receiving your expert input into this consensus development, which we believe is particularly relevant to nutrition management of obesity in Saudi Arabia.

Kind regards,

Ali Almajwal, PhD Candidate

School of Health Sciences

University of Wollongong

Wollongong, NSW 2522, Australia

Mobile: ++ 61(4)0000 3293

Fax: ++ 61(2)4221 3486

From: Ali Almajwal (amja695@uow.edu.au)

Title: Final Delphi

Dear (participant name),

Thank you for agreeing to be included in this Delphi consensus study as an expert panellist. The final questionnaire has been attached to this email. We ask that you save this file to your own computer and complete your responses directly onto the Microsoft Word document. Please return your completed questionnaire within two weeks if possible to this email address (amja695@uow.edu.au). Once we have collated the results of this round of this Delphi study, you will be forwarded the results with the final report

We look forward to receiving your expert input into this consensus development, which we believe is particularly relevant to nutrition management of obesity in Saudi Arabia.

Kind regards,

Ali Almajwal, PhD Candidate

School of Health Sciences

University of Wollongong

Wollongong, NSW 2522, Australia

Mobile: ++ 61(4)0000 3293

Fax: ++ 61(2)4221 3486

Appendix R: Workshop on the development of consensus statements

Aim:

To discuss possible consensus statements and recommendations for obesity management in some areas where there is insufficient evidence for the development of evidence based statements.

Methods:

Six small consultation workshops were conducted in different hospitals in Saudi Arabia. The project team developed some possible statements to be discussed in the workshops. Participants were encouraged to discuss and modify these statements and add new statements. Suggested statements will be then included in a Delphi consultation to produce consensus statements.

Participants:

Expert dietitians and physicians in Saudi Arabia (Saudi and non-Saudi) who are expert and interested in this topic were invited to participate in these workshops. Clinicians with more than 5 years experience were preferred. The total number of participants in these workshops were 61.

Experts not available for the workshops were invited for a separate consultation interview.

Major Discussion Topics:

Participants discussed several topics that had not been covered by the critical review due to the lack of adequate scientific evidence. These topics include:

- Behavior modifications techniques and obesity management for Saudi people.
- Management of obesity in Ramadan
- Physical activity and obesity management especially for Saudi women
- Number and distribution of meals during the day for Saudi people.
- Achievable weight loss goals by Saudi people

All participants received more details about the discussed topics and the project in general before the day of the workshop.

Topic ONE: Behaviour modification

Discussed recommendations with some suggestions from participants:

- 1- We recommend the use of one or more behaviour therapy techniques in combination with diet therapy and physical activity for Saudi people.**

Almost all participants have agreed to include this statement in the Delphi consultation

- 2- The suitable techniques should be discussed with each individual patient. It appear that no one behavior therapy is superior to any other.**

Participants indicated that cultural and regional differences in Saudi Arabia also influence the type of suitable technique. Therefore, most of them have agreed about this statement.

- 3- Dietitians may need to refer patient to other health practitioners to assist in behavioural therapy if needed.**

Most participants have agreed about this statement with slight changes. They suggested to mention the referral should be for special cases and if the health organization system allow for this procedure.

- 4- A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy.**

Most of participants have agreed about this procedure.

- 5- Some Saudi people eat their lunch after they finish work. Therefore, patients should be instructed to eat at work or not to sleep directly after eating.**

Participants indicated that this behaviour is common among Saudi people and they suggested asking the patient to eat a snack or salad and have the lunch after sleeping

- 6- Some Saudi people may find that on the days they skip breakfasts, they end up overeating later in the day and gaining weight. Patients may need to be instructed not to skip any meal.**

Participants indicated that this behaviour is common among Saudi people and they suggested asking the patient to have a small meal or at least to eat some fruit or to drink some juices at work.

- 7- Self-monitoring may be suitable for educated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information may help both dietitians and patients in setting the appropriate goals to reduce weight.**

Most participants have agreed to use this technique with motivated people even if they are not educated.

8- Patients should be asked about people who may be supportive of their behavior changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment.

Some participants have agreed about this statement especially with friends but other participants they think this techniques is not suitable due some cultural issues.

9- Patients should avoid certain social situations, particularly wedding parties, which elicit overeating of fatty food.

Most participants did not agree with this statement. They indicated the word "avoid" is very strong. Patients should attend but they should know how to choose the right food. Other suggested asking patient to eat before parties or to leave before dinner is served if possible.

Do you suggest any new statements about behaviour modification to be included in the guideline?

Some suggested statements:

- Saudi people usually eat together in one large plate and some participants suggested to instruct patients to eat separately to be aware about the quantity of food that everybody eat.
- Correct wrong believe about food and weight such as the effect of honey, dates, olive oil, sunflower oil, herbs, traditional foods on body weight.
- Instruct patient to eat variety of food
- Teach patients what to eat when they go to restaurants
- Explain for patient the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better.
- Reduce portion size
- Discuss patients expectations

Topic TWO: Obesity and Ramadan

Discussed recommendations with some suggestions from participants:

- 1- Obese and overweight people should consider Ramadan as an ideal time to lose weight.**

Most participants suggested considering Ramadan as an ideal time to maintain weight but other suggested to write both aims (lose\maintain weight) and to discuss the target with the patient.

- 2- Avoid over-eating especially at *sahur***

Participants suggested asking participants to avoid overeating at both *sahur* and *iftar*

- 3- Avoid fried and fatty foods.**

- 4- Avoid foods containing too much sugar**

- 5- Fried foods can be replaced by grilled foods or by using the oven instead of frying**

Most participants have agreed about the above three statements and suggested to combined all the three statements in one statement

- 6- Eat three main meals in addition to some snacks if possible (*iftar*, dinner and *sahur*)**

Most participants suggested eating two main meals in addition to one or two snakes

- 7- Drinks lots of water between *iftar* and *sahur* to avoid dehydration**

They have agreed about this statement and suggested asking patients to decrease the intake of high sugar drinks

- 8- Eat slow digesting foods (low glyceemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day**

Most participants have agreed about this statement

- 9- Try to make the *iftar* immediately after sunset or as early as you can and make *sahur* just before dawn to minimize fasting hours.**

Participants indicated that this recommendation is well known and we may not include it in the guideline

- 10- Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty.**

Most participants have agreed about this statement

11- Avoid sedentary lifestyle in Ramadan by practising exercise especially at night.

Most participants have agreed about this statement

Do you suggest any new statements about Ramadan to be included in the guideline?

Some suggested statements:

- Encourage patients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan
- Avoid sleeping most of the day and staying up at night
- Do not buy food while hungry

Topic THREE: Goal setting for the management of overweight and obesity:

Discussed recommendations with some suggestions from participants:

- 1- Saudi people expectations of weight loss are often unrealistic and may remain higher than the reality.**

Most participants have agreed about this statement and mentioned that most of Saudi people want to loose weight in a very short period

- 2- Dietitians may needs to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient.**

They agreed about this statement and suggested also to educate people about the healthy weight as well

- 3- Dietitians may need to focus on weight stabilization for individuals with a history of weight-loss failure.**

Participants indicated not to use this recommendation if the patient is not following the diet.

- 4- Duration of weight loss program may vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss.**

Most participants agreed about this statement

- 5- The ideal weight loss period is at least 6 months that should be followed by a weight maintenance program that may continue for several years.**

There was no general agreement about this statement. Participants indicated that this depends on the severity of obesity and the patient. They agreed that each successful weight loss should be followed by a weight maintenance program

Do you suggest any new statements about goal setting to be included in the guideline?

- Weight loss goals are affected by several factors such as physical, social, and psychological factors
- Patients should be instructed not to follow any commercial diet unless it described by dietitian or physician

Topic FOUR: Physical activity

Discussed recommendations with some suggestions from participants:

- 1- Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits.

Questions to participants:

How to minimize the effect of hot weather on physical activity?

How can we encourage Saudi women practice physical activity?

Suggested recommendations:

- encourage night activities in summer
- encourage indoor activities for females
- Females should join Gyms that designed for ladies

Do you suggest any new statements about physical activity to be included in the guideline?

Correct the misconception that home duties for ladies is an enough exercise for weight loss

Appendix S: Delphi consultations study-First round questionnaire

Please rate your level of agreement with the following statements to be included in the clinical practice guideline (highlight your answer in the table)

Section 1: Behaviour modifications techniques for obese Saudi client

	Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1	The use of one or more behaviour therapy techniques in combination with diet therapy and physical activity is recommended for the management of obese clients	1	2	3	4	5
Please type additional comments below:						
2	The suitable techniques should be discussed with each individual patient. It appears that no one behaviour therapy is superior to any other	1	2	3	4	5
Please type additional comments below:						
3	Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed and if the health organization system allow for this procedure	1	2	3	4	5
Please type additional comments below:						
4	A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy	1	2	3	4	5
Please type additional comments below:						

Section 1 (Cont.): Behaviour modifications techniques for obese Saudi clients

	<i>Statement</i>	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
5	Obese people who sleep immediately after lunch meal should be counselled to have lunch at work to avoid this habit. Alternatively, they can eat a light snack before sleeping and eat lunch after waking.	1	2	3	4	5
Please type additional comments below:						
6	Obese people who skip breakfast should be counselled to eat breakfast or a snack such as fruit or some juices when they wake up.	1	2	3	4	5
Please type additional comments below:						
7	Self-monitoring may be suitable for motivated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information can help both dietitians and patients in setting the appropriate goals to reduce weight	1	2	3	4	5
Please type additional comments below:						
8	Obese people should be asked about people who may be supportive of their behaviour changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment	1	2	3	4	5
Please type additional comments below:						

Please add any suggested new strategies or statements or comments that may have been missed?

Section 2: Specific dietary counselling strategies

	<i>Statement</i>	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
	Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
9	Saudi social activity such wedding elicit overeating of fatty food. Therefore, obese people should be instructed how to choose their food in such events	1	2	3	4	5
Please type additional comments below:						
10	Correct wrong beliefs about the effect of some foods on body weight such as honey, dates, olive oil, sunflower oil, herbs, and traditional foods.	1	2	3	4	5
Please type additional comments below:						
11	Advise obese people to eat variety of food especially fruit and vegetables	1	2	3	4	5
Please type additional comments below:						
12	Teach obese clients what to eat when they go to restaurants for meals	1	2	3	4	5
Please type additional comments below:						

13	Dietitians should explain to clients the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better	Statement				
		1 Strongly agree	2 Agree	3 Neutral	4 Disagree	5 Strongly disagree
Please type additional comments below:						
14	Dietitians should discuss patients' expectations	1	2	3	4	5
Please type additional comments below:						
15	Obese people should be instructed to reduce portion sizes	1	2	3	4	5
Please type additional comments below:						

Section 2 (Cont.): Specific dietary counselling strategies

Please add any suggested new strategies or statements or comments that may have been missed?

Section 3: Obesity management in Ramadan

	16	Obese people should consider Ramadan as an ideal time to maintain/lose weight	1	2	3	4	5
		Strongly agree	Agree	Neutral	Disagree	Strongly disagree	
		Please type additional comments below:					
22		Start <i>iftar</i> with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested	1	2	3	4	5
		Please type additional comments below:					
	18	Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled foods or by using the oven instead of frying	1	2	3	4	5
		Please type additional comments below:					
	19	Eat two main meals in addition to 1-2 snacks if possible	1	2	3	4	5
		Please type additional comments below:					
	20	Drinks lots of water between <i>iftar</i> and <i>sahur</i> to avoid dehydration and reduce the consumption of high sugar drinks	1	2	3	4	5
		Please type additional comments below:					
	21	Eat slow digesting foods (low glycaemic index foods that contain grains and seeds) at <i>Sahur</i> including fiber-containing-foods that result in less hunger during the day	1	2	3	4	5
		Please type additional comments below:					

**Section 3
(Cont.):
Obesity management in Ramadan**

	foods such as soups since the stomach is completely empty							
Please type additional comments below:								
		Statement		Strongly agree	Agree	Neutral	Disagree	Strongly disagree
23	Avoid sedentary lifestyle in Ramadan by practicing exercise especially at night	Statements of weight loss are often unrealistic. Physicians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient	2		3		4	
Please type additional comments below:			1		2		3	
24	Encourage clients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan	Please type additional comments below:	2		3		4	
Please type additional comments below:								Please add any suggested new
25	Avoid sleeping most of the day and staying up at night		1		2		3	
Please type additional comments below:								

Section 4: Goal setting for the management of obesity		Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	
		27 When dealing with compliant clients with a history of weight-loss failure, providers may need to focus on weight stabilization rather than weight loss.						5
31	Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity.	The duration of weight loss interventions will vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss.	1	2	3	4	5	
	Please type additional comments below:							
32	Encourage night activities in summer		2	3	4	5		
	Please type additional comments below:							
29	Weight loss goals are affected by several factors such as physical, social, and psychological factors		1	2	3	4	5	
	Please type additional comments below:							
30	Patients should be instructed not to follow any commercial diet unless it is prescribed by a dietitian or physician		1	2	3	4	5	
	Please type additional comments below:							

any suggested new strategies or statements or comments that may have been missed?

Section 5: Physical activity

							Please add any suggested new strategies or statements or comments that
Please type additional comments below:							
33	If outdoor exercise is not possible for females, encourage indoor activities at home or by joining female gyms	1	2	3	4	5	
Please type additional comments below:							
34	Correct the misconception that home duties for ladies are enough exercise for weight loss	1	2	3	4	5	
Please type additional comments below:							

may have been missed?

About You

In order to describe basic attributes of the expert panel, we would greatly appreciate you providing us with the following information.

- **Please list all of your relevant expertise (eg dietitian, medical practitioner, academic researcher)**

- **How many years have you been working in the field of nutrition?**
- **What is your gender (Male, Female)**
- **What is your main place of employment (hospital, private clinic, university)?**
- **Are you willing to give consent to be acknowledged as part of the expert panel in any publications that may result from this research?**

Appendix T: Delphi consultations study-Round 1 Feedback and Final Round Questionnaire

Round 2 Delphi Questionnaire Procedures:

- This document includes feedback from the first round questionnaire you completed before. Please consider this feedback when responding to questions in the second round questionnaire.

- Throughout this document you are asked to rate your agreement with 7 modified statements and one new statement recommended by you and other experts in the first round.
- It would be appreciated if you could respond to this second/final round by 22nd April 2009.
- Please do not hesitate to contact me by email if you have any queries.

Results summary

- A total of 20 experts have taken part in Round one (Delphi-1) of this study. The results depicted below are from those 20 participants
- Delphi-1 consisted of 34 statements developed from previous consultation workshops
- The candidate analysed every statement and the comments on the statement
- When there was general agreement score of $> 75\%$, the statement was entered into the set of accepted draft clinical guidelines. In the case of 50 to 75% agreement score, statement were changed with the aid of the participants' comments in Delphi-1. Statements with agreement score $< 50\%$ were excluded.
- In our analysis for Delphi-1, 30 statements reached agreement $> 75\%$ and accepted to be included in the clinical guidelines. Three statement reached agreement ranged between 50 to 75% and have been modified to be included in this round. Only one statement reached agreement score $< 60\%$ and was excluded from the clinical practice guidelines. Also there were 4 statements which reached

agreement scores > 75% but have been modified according to participants comments and included again in this round.

Section 1: Behaviour modifications techniques for obese Saudi clients

All statements in this section were accepted except statements 5 and 6. Therefore, we modified these statements according to the received comments from you and other experts in Delphi-1

Statement 5 (original version): Obese people who sleep immediately after lunch meal should be counselled to have lunch at work to avoid this habit.

Alternatively, they can eat a light snack before sleeping and eat lunch after waking

Participants indicated that this statement is restricted to workers despite that this habit is common even among non-employers.

Statements 6 (original version): Obese people who skip breakfast should be counselled to eat breakfast or a snack such as fruit or some juices when they wake up

Participants indicated that we should not introduce juices or fruit as a substitute for breakfast meal. Also they think that obese people should be instructed about the importance of breakfast.

Please rate your level of agreement with the following modified statements to be included in the clinical practice guideline (highlight your answer in the table)

Section 2: Specific dietary counselling strategies

Most participants agreed about statements in this section. However, some strategies for reduction of portion size have been recommended (statement 15). Also one new statement has been suggested to be added in this section.

	Revised Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
5	Obese people who sleep immediately after lunch meal should be counselled to eat a light snack before sleeping and eat lunch after waking.	1	2	3	4	5
6	Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal	1	2	3	4	5

Statement 15 (original version): Obese people should be instructed to reduce portion sizes

Participants indicated that this strategy was difficult to be achieved in the Saudi population and recommended the use of food models and other methods.

Suggestion of a new statement:

Participants indicated that many obese people eat because they are bored or due to social pressure. There is a need to develop appropriate behaviour counselling techniques to address this issue.

Please rate your level of agreement with the following statements to be included in the clinical practice guideline (highlight your answer in the table)

Section 3: Obesity management in Ramadan

All statements in this section have been accepted except statement 16. Also additional suggestions have been recommended to be added to statement 18 and 22

	Revised Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
15	Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes.	1	2	3	4	5
New	Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress.	1	2	3	4	5

Statement 16 (original version): Obese people should consider Ramadan as an ideal time to maintain/lose weight

Some participants stated that Ramadan can be an extremely stressful period of time, both physically and emotionally, which may not lead to successful weight loss regimen. After *Iftar*, compensatory gorging and overeating of fatty and simple carbohydrates is not unusual, and often leads to weight gain.

Other participants indicated that Ramadan has time limit because it takes place once a year so focusing on the proper meal planning for this special month is more important

One participant stated that Ramadan is not the ideal time but a challenging time to avoid excessive eating, which is the cultural and social norm in Saudi Arabia

Statement 18 (original version): Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled foods or by using the oven instead of frying

Participants suggested to add other alternatives cooking ways such as boiling and baking

Statement 22 (original version): Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty.

Participants reported that *Iftar* traditions and eating habits differ amongst families: The first *Iftar* eating habit people consume only dates, highly sugary juices, soup and fried pastries. These families then consume the main meal later at night (around 11pm or 12am). The second type of *Iftar* eating habit consists of consuming everything from dates, soup and pastries to rice, meat and dessert all at once right after *Iftar* is allowed. They suggested the inclusion of a statement in the clinical practice guidelines regarding the advantage of the first *Iftar* eating habit.

Please rate your level of agreement with the following modified statements to be included in the clinical practice guideline (highlight your answer in the table)

	Revised Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
16	Obese people should aim not to gain weight in Ramadan if weight loss is unachievable	1	2	3	4	5
18	Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying	1	2	3	4	5
22	Start <i>iftar</i> with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night.	1	2	3	4	5

Section 4: Goal setting for the management of obesity

Statement 27 has been excluded by participants in this section (<60% agreement). Also some participants recommended to slightly modify statement 29.

Statement 27 (original version): When dealing with compliant clients with a history of weight-loss failure, dietitians may need to focus on weight stabilization rather than weight loss

Most participants did agree about this statement, but most of them indicated that our goal should be to reduce weight even if we could not achieve this goal. Obese people may think the obesity is acceptable in this case and they may even gain weight.

Statement 29 (original version): Weight loss goals are affected by several factors such as physical, social, and psychological factors

Participants have suggested to add the economic status as important factor that might affect weight loss. Also some participants have suggested to replace the word “social” by “socioeconomic status”.

Please rate your level of agreement with the following modified statement to be included in the clinical practice guideline (highlight your answer in the table)

Section 5: Physical activity

Participants have agreed to include all statements in this section in the clinical practice guidelines without changes

	Revised Statement	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
29	Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors	1	2	3	4	5

Appendix U: Delphi consultations study- Round 2 Feedback and Final report

Analysis procedures:

- The mean score for each statement was presented on the 5-point Likert scales

	<i>Statement</i>	Mean score (%)
--	-------------------------	-----------------------

[strongly agree (4 points), agree (3 points), neutral (2 points), disagree (1 point) and strongly disagree (0 points)] as a percentage of the maximum obtainable score

- A cut-off point of 75% has been chosen for including the statement in the clinical practice guidelines.

Results summary

- A total of 19 experts have taken part in Round two (Delphi-II) of this study. The results depicted below are from those 19 participants
- Delphi-II consisted of 8 statements modified based on comments received from Delphi-I feedback
- In our analysis for Delphi-II, 7 statements reached mean score percentage > 75 and accepted to be included in the clinical guidelines. Only one statement reached mean score $< 75\%$ and was excluded from the clinical practice guidelines.

		Round I	Round II	Accepted statements with their scores in percentage:
6	Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal	73.6	91.7	
15	Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes.	91.7	94.4	
New	Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress.	-	93.1	
16	Obese people should aim not to gain weight in Ramadan if weight loss is unachievable	63.9	91.7	
18	Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying	87.5	95.8	Excluded statement (Statement 5) Obese people who sleep immediately after lunch meal
22	Start <i>iftar</i> with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night.	88.9	91.7	
29	Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors	91.7	95.8	

should be counselled to eat a light snack before sleeping and eat lunch after waking (mean score: Delphi I = 66.7%, Delphi II = 69.4)

Reasons for disagreement about this statement:

Some participants indicated that adding snack to their normal lunch will contribute to extra calories. Others participants mentioned that clients should not be instructed to eat before sleeping even small snack. Also some participants indicated that sleeping patters

should be corrected instead of adjusting meal planning according to irregular sleeping times

**Final consensus statements to be included in the clinical practice
guidelines and their scores in percentage**

Section 1: Behaviour modifications techniques for obese Saudi clients

- The use of one or more behaviour therapy techniques in combination with diet therapy and physical activity is recommended for the management of obese clients (94.4%)
- The suitable techniques should be discussed with each individual patient. It appears that no one behaviour therapy is superior to any other (81.9%)

- Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed and if the health organization system allow for this procedure (75.0%)
- A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy (86.1%)
- Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal (91.7%)
- Self-monitoring may be suitable for motivated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information can help both dietitians and patients in setting the appropriate goals to reduce weight (81.9 %)
- Obese people should be asked about people who may be supportive of their behaviour changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment (79.2%)

Section 2: Specific dietary counselling strategies

- Saudi social activity such wedding elicit overeating of fatty food. Therefore, obese people should be instructed how to choose their food in such events (93.1%)
- Correct wrong beliefs about the effect of some foods on body weight such as honey, dates, olive oil, sunflower oil, herbs, and traditional foods (94.4%)
- Advise obese people to eat variety of food especially fruit and vegetables (94.4%)
- Teach obese clients what to eat when they go to restaurants for meals (91.7%)
- Dietitians should explain to clients the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better (91.7%)
- Dietitians should discuss patients' expectations (90.3%)
- Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes (94.4%)

- Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress (93.1%)

Section 3: Obesity management in Ramadan

- Obese people should aim not to gain weight in Ramadan if weight loss is unachievable(91.7%)
- Avoid over-eating especially at *Sahur* and *Iftar* (90.3%)
- Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying (95.8%)
- Eat two main meals in addition to 1-2 snacks if possible (75.0%)
- Drink lots of water between *iftar* and *sahur* to avoid dehydration and reduce the consumption of high sugar drinks (93.1%)
- Eat slow digesting foods (low glyceemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day (91.7%)
- Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night (91.7%)
- Avoid sedentary lifestyle in Ramadan by practising exercise especially at night (94.4%)
- Encourage clients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan (94.4%)
- Avoid sleeping most of the day and staying up at night (79.2%)

Section 4: Goal setting for the management of obesity

- Saudi expectations of weight loss are often unrealistic. Dietitians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient (91.7%)
- The duration of weight loss intervention will vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss (93.1%)
- Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors (95.8%)

- Patients should be instructed not to follow any commercial diet unless it described by dietitian or physician (86.1%)

Section 5: Physical activity

- Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits (95.8%)
- Encourage night activities in summer (86.1%)
- If outdoor exercise is not possible for females, encourage indoor activities at home or by joining female gyms (94.4%)
- Correct the misconception that home duties for ladies are enough exercise for weight loss (87.5%)

Appendix V: Draft clinical practice guidelines for nutritional management of obesity in Saudi Arabia

Contents

1. Obesity assessment
2. Goals for weight loss
3. Dietary approaches
4. Determination of resting energy expenditure
5. Behaviour modification and obesity management

6. Physical activity
7. Specific dietary counseling strategies
8. Obesity management in Ramadan

1. Obesity assessment

Adopted statement

1.1 Practitioners should use the BMI to assess overweight and obesity. Body weight alone can be used to follow weight loss, and to determine efficacy of therapy (Low, Adopted from NHLBI and ADA guidelines. The grading of the level of evidence for this recommendation was moved down one grade to a Low level, based on analysis conducted on Saudi population for this purpose, until more data are available for the Saudi population)

2. Goals for weight loss

2.1 Adopted evidence based statements

2.1.1 Diet therapy should last at least 6 months or until weight loss goals are achieved with implementation of a weight maintenance program after that time (High, ADA guidelines)

2.1.2 Initial goal should be to reduce weight by 10% from baseline (High, ADA and NHLBI guidelines)

2.1.3 Weight loss should be about 1 to 2 lb/week (0.454-0.907 kg) for a period of 6 months (High, ADA and NHLBI guidelines)

2.1.4 A loss between 5 and 10% of original weight can produce significant improvement in cardiovascular and metabolic health (High, DAA guideline)

2.1.5 A long term weight loss of greater than 10% provides further health benefit but is less commonly achieved (High, DAA guideline)

2.2 New consensus statements

2.2.1 Saudi expectations of weight loss are often unrealistic. Dietitians may need to educate patients about the realistic weight loss goals and set a suitable weight loss program for each individual patient

2.2.2 The duration of weight loss intervention will vary between individuals and can be affected by several factors such as patient readiness to change, severity of obesity, ethnicity, gender, age, and previous attempts at weight loss

2.2.3 Weight loss goals are affected by several factors such as physical, socioeconomic status, and psychological factors

2.2.4 Patients should be instructed not to follow any commercial diet unless it described by dietitian or physician

Level of evidence for the above statements : Expert opinion

3. Dietary approaches:

3.1 Adopted evidence based statements:

3.1.1 The main requirement of a dietary approach to weight loss is a reduction in total energy intake (High, ADA and NHLBI guidelines)

3.1.2 Reducing fat as part of a low-calorie diet is a practical way to reduce calories (High, NHLBI and DAA guidelines)

3.1.3 Reducing dietary fat and/or carbohydrates is a practical way to create a caloric deficit of 500-1000 kcals (2092-4184 kJ) below energy estimated needs and should result in a weight loss of 1-2 lbs (0.454-0.907 kg) per week (High, ADA guidelines)

3.1.4 Low fat *ad libitum* diets can result in long-term weight loss (High, DAA guidelines)

3.1.5 The combination therapy of diet, physical activity and behavioral therapy is more successful than using any one intervention alone (High, ADA and NHLBI guidelines)

3.2 New developed evidence based statements:

3.2.1 Calcium/dairy diet and body weight

Evidence-based statement:

Increased intakes of calcium or dairy products are associated with weight loss.

Level of evidence: Low

3.2.2 Polyunsaturated fatty acids and Monounsaturated fatty acids and body weight

Evidence-based statement:

Increased intakes of PUFA are associated with weight loss

Level of evidence: Medium

3.2.3. Low glycemic index diet on body weight

Evidence-based statement:

Low GI and low GL diets are associated with reduction of weight, body fat, BMI or food intake in adults

Level of evidence: Medium

3.2.4 Fiber intake and body weight

Evidence-based statement:

Increased intakes of dietary fiber are associated with increased body weight loss, reduced energy intake, increased satiety and reduced hunger

Level of evidence: Low

3.2.5. Eating frequency and body weight

Evidence-based statement:

Higher EF not exceeding 6 meals per day may help in weight reduction in adults.

Level of evidence: Low

3.2.6. Breakfast intake and body weight

Evidence-Based Statement:

Regular breakfast intake is associated with lower body weight

Level of evidence: Medium

4. Determination of REE:

New developed evidence based statements

4.1 The Harris-Benedict equation tends to overestimate REE in overweight and obese people. Its accuracy is low particularly with the use of adjusted or ideal body weight.

Level of evidence: High

4.2 The Mifflin equation tends to slightly overestimate REE in overweight and obese people.

Level of evidence: Medium

4.3 The Owen equation tends to underestimate REE in overweight and obese people.

Level of evidence: High

4.4 The Owen equation is less accurate compared to other predictive equations.

Level of evidence: Low

4.5 The Mifflin equation using actual weight is the most accurate equation for estimating REE for overweight and obese subjects

Level of evidence: Medium

5. Behaviour modifications and obesity management

New Consensus statements

5.1 The use of one or more behaviour therapy techniques in combination with diet therapy and physical activity is recommended for the management of obese clients

5.2 The suitable techniques should be discussed with each individual patient. It appears that no one behaviour therapy is superior to any other

5.3 Dietitians may need to refer patients to other health practitioners to assist in behavioural therapy if needed and if the health organization system allow for this procedure

5.4 A multidisciplinary team including physicians, dietitians and psychologists may be needed to assist in behavioural therapy

5.5 Obese people who skip breakfast should be counselled to eat breakfast with emphasis on the importance of the breakfast meal

5.6 Self-monitoring may be suitable for motivated people. Patients can be asked to record the types and amounts of food eaten. Also they may record information related to places, times and feeling associated with eating. This information can help both dietitians and patients in setting the appropriate goals to reduce weight

5.7 Obese people should be asked about people who may be supportive of their behaviour changes (e.g. family members, friends, colleagues) and discuss the possibility of including them in weight loss treatment.

Level of evidence for the above statements: Expert Opinion

6. Physical activity

6.1 Adopted statements

6.1.1 At least 30 minutes/day of moderate intensity physical activity. Physical activity contributes to weight loss, may decrease abdominal fat, and may help with maintenance of weight loss (High, ADA, DAA and NHLBI guidelines)

6.1.2 The combination of a reduced calorie diet and increased physical activity is recommended (High, ADA and NHLBI guidelines)

6.1.3 In the absence of dietary change, moderate to vigorous exercises (3-5 hours a week) produces modest weight loss of about 2 kilograms over one year. If combined with energy restriction, leads to further 3-6 kilograms of weight loss with a greater loss of abdominal fat than *ad libitum* low-fat diets or exercise alone over one year (High, DAA guidelines)

6.2 New consensus statements

6.2.1 Due to the sedentary nature of the Saudi population, health care providers should educate people about the importance of physical activity and encourage active living and discourage sedentary habits

6.2.2. Encourage night activities in summer

6.2.3 If outdoor exercise is not possible for females, encourage indoor activities at home or by joining female gyms

6.2.4 Correct the misconception that home duties for ladies are enough exercise for weight loss

Level of evidence for the above statements: Expert Opinion

7. Specific dietary counselling strategies

New consensus statements

7.1 Saudi social activity such weddings elicit overeating of fatty food. Therefore, obese people should be instructed how to choose their food in such events

7.2 Correct wrong beliefs about the effect of some foods on body weight such as honey, dates, olive oil, sunflower oil, herbs, and traditional foods

7.3 Advise obese people to eat variety of food especially fruit and vegetables

7.4 Teach obese clients what to eat when they go to restaurants for meals

7.5 Dietitians should explain to clients the overall benefit of healthy eating such as reducing the risk of chronic diseases, sleeping better, looking better, and feeling better

7.6 Dietitians should discuss patients' expectations

7.7 Obese people should be instructed to reduce portion sizes. This can be difficult when people are eating from a large common plate of food (which is the traditional style food served in Saudi). Food models, pictures, or food measuring tools can help teach appropriate portion sizes. Slower eating behavior can be useful to achieve reduction in portion sizes

7.8 Obese people should be instructed that social pressure and stress may cause weight gain. Patients should be counselled not to use food as a reward or distraction in times of stress

Level of evidence for the above statements : Expert opinion

8. Obesity management in Ramadan

New consensus statements

8.1 Obese people should aim not to gain weight in Ramadan if weight loss is unachievable

8.2 Avoid over-eating especially at *Sahur* and *Iftar*

8.3 Avoid fried and fatty foods. Alternatively, fried foods could be replaced by grilled, boiled or baked foods or by using the oven instead of frying

8.4 Eat two main meals in addition to 1-2 snacks if possible

8.5 Drink lots of water between *iftar* and *sahur* to avoid dehydration and reduce the consumption of high sugar drinks

8.6 Eat slow digesting foods (low glycemic index foods that contain grains and seeds) at *Sahur* including fiber-containing-foods that result in less hunger during the day

8.7 Start *iftar* with an easily available energy source in the form of glucose, from foods such as dates, to bring low blood glucose level to normal. This should be followed by easily digested foods such as soups since the stomach is completely empty but avoiding overeating. The main meal can be consumed later at night

8.8 Avoid sedentary lifestyle in Ramadan by practising exercise especially at night

8.9 Encourage clients to eat vegetables and fruit because most of Saudi people do not eat these foods in Ramadan

8.10 Avoid sleeping most of the day and staying up at night

Level of evidence for the above statements : Expert Opinion