**PROMISING WEIGHT MANAGEMENT STRATEGIES FOR PROGRAM
DEVELOPMENT IN INTER-PROFESSIONAL PRIMARY CARE:
AN AUGMENTED SCOPING REVIEW**

A Thesis

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by

OLIVIA O'YOUNG

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ABSTRACT

PROMISING WEIGHT MANAGEMENT STRATEGIES FOR PROGRAM DEVELOPMENT IN INTER-PROFESSIONAL PRIMARY CARE: AN AUGMENTED SCOPING REVIEW

**Olivia Rachel O'Young
University of Guelph, 2011**

**Advisor:
Professor P.M. Brauer**

A scoping review was conducted to identify promising new approaches for weight management in inter-professional primary care (IP-PC). Primary studies with participants of any age, in an IP-PC setting, that included a lifestyle component or report of a change in body mass, published in English between 2003 and 2009 were included. The search yielded 26,075 citations; 360 citations to 225 studies were included in the review. Almost 80% of articles were intervention studies. Of these, 48% focused on type 2 diabetes; 11 of 72 studies were conducted in representative groups and had promising results with hemoglobin A1c reductions of $\geq 1.0\%$. Similarly 6 of 73 studies were promising with $\geq 3\%$ weight loss. Most prominent strategies were: 1. Helping patients develop personal skills; 2. redesigning the delivery system; and 3. offering providers training and/or decision support tools. This review provides direction for research to improve effectiveness of IP-PC weight management programs.

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TABLE OF CONTENTS

1	OVERVIEW OF RESEARCH PURPOSE AND RATIONALE.....	1-2
2	LITERATURE REVIEW.....	3
2.1	Introduction to Literature Review.....	3
2.2	Overweight and Obesity	3
2.2.1	Prevalence	3
2.2.2	Obesity-related Co-morbid Conditions	5
2.3	Weight Management in Primary Care.....	6
2.3.1	Complexities of Treating Overweight and Obesity.....	6
2.3.2	Opportunity in Primary Care.....	7
2.3.3	Interdisciplinary Services.....	8
2.4	Context for the Present Review.....	9
2.4.1	Existing Literature.....	9
2.4.2	Obesity Management Planning Framework in Primary Care	11
2.4.2.1	World Health Organization Stepwise Chronic Disease Prevention Framework.....	11
2.4.2.2	Chronic Care Model	12
2.4.2.3	Developing an Obesity Management Planning Framework-Methods	14
2.5	Selection of an Augmented Scoping Review	15
2.5.1	Systematic Literature Review- Cochrane Collaboration Methodology	15
2.5.2	Scoping Review.....	16
2.5.3	Systematic Literature Review vs. Scoping Review	17
2.5.4	The Present Review	18
3	RESEARCH OBJECTIVES	19
3.1	Primary Research Objective	19
3.2	Secondary Research Objectives	19
4	METHODOLOGY.....	20
4.1	Defining the Review Question and Developing Criteria for Including Studies.....	20
4.1.1	Review Question	20
4.1.2	Criteria for Considering Studies for this Review	20
4.1.2.1	Inclusion Criteria.....	20
4.1.2.1.1	Types of Participants.....	20
4.1.2.1.2	Types of Settings.....	21
4.1.2.1.3	Types of Interventions and Outcome Measures.....	21
4.1.2.1.4	Types of Study Designs.....	22
4.1.2.2	Exclusion Criteria.....	22

4.2 Searching for Studies	23
4.2.1 Designing the Search Strategy- Search Terms and Phrases	23
4.2.2 Conducting the Pilot Search.....	24
4.2.3 Sources to Search- Electronic Database Selection.....	25
4.2.3.1 Included Electronic Databases	25
4.2.3.2 Excluded Electronic Databases	25
4.2.4 Conducting the Final Search	26
4.3 Selecting Studies and Collecting Data	27
4.3.1 Development of Screening Tool	27
4.3.2 Pilot Screening Process	27
4.3.2.1 Pilot Title and Abstract Screening Tool	27
4.3.2.2 Pilot Full-text Screening Tool	28
4.3.3 Final Screening Process- Selecting Studies and Collecting Data	28
4.3.3.1 Title and Abstract Screening	28
4.3.3.2 Full-text Screening	29
4.3.3.2.1 Hand-searching Protocol	30
4.3.3.2.2 Collecting Screening Data- Excel Spreadsheets	30
4.4 Assessing Risk of Bias in Included Studies	31
4.4.1 Rationale for Appraising Quality of Evidence	31
4.4.2 Quality Assessment Tool for Quantitative Studies	31
4.4.3 Pilot Quality Assessment Process	33
4.4.4 Final Quality Assessment Process.....	33
4.4.4.1 Collecting QA Data- Excel Spreadsheets.....	34
4.5 Presenting Results	34
4.5.1 Charting Data	34
4.5.1.1 Summary Tables.....	35
4.5.1.2 Outcome Measure Data.....	35
4.5.1.3 Excel Spreadsheets.....	35
4.5.1.4 Multiple Articles per Study	36
4.5.2 Collating, Summarizing and Reporting Results.....	36
4.5.2.1 Descriptive Data- All Included Intervention Studies	36
4.5.2.2 Heterogeneity of Studies	37
4.5.2.3 Evaluating and Analyzing Complex Interventions	37
5 RESULTS.....	39
5.1 Included Studies	39
5.2 Reporting Descriptive Data- Included Intervention Studies.....	42
5.3 Weight/BMI Studies.....	45
5.3.1 Defining Clinical Relevance	45
5.3.2 Characteristics of Clinically Relevant Studies	47
5.3.3 Interpreting by Appraising Quality of Evidence	60
5.3.4 Studies Likely to be Promising	68
5.3.4.1 Davies et al., (2008)	69
5.3.4.2 Janssen, Gorter, Stolk, & Rutten (2009)	70
5.3.4.3 Willaing, Ladelund, Jorgensen, Simonsen, & Nielsen (2004).....	72

5.3.5	Potentially Promising Studies	73
5.3.5.1	Mayer-Davis et al., (2004)	73
5.3.5.2	Kramer et al., (2009)	75
5.3.5.3	Bo et al., (2007).....	76
5.3.6	Characteristics of Potentially Promising and Promising Studies	78
5.3.6.1	Changes in Weight and BMI.....	78
5.3.6.2	Appraising the Quality of Evidence	78
5.3.6.3	Delivery Channels and Providers	79
5.3.7	Overview of Studies Not Likely to be Promising	81
5.4	Hemoglobin A1c Studies.....	82
5.4.1	Defining Clinical Relevance	82
5.4.2	Characteristics of Clinically Relevant Studies	84
5.4.3	Interpreting by Appraising the Quality of Evidence	98
5.4.4	Studies Likely to be Promising	103
5.4.4.1	Davies et al., (2008)	103
5.4.4.2	California Medi-Cal Type 2 Diabetes Group (2004)	104
5.4.4.3	Rothman et al., (2005).....	106
5.4.4.4	Scott, Boyd, Stephen, Augustine, & Reardon (2006)	107
5.4.4.5	Janssen et al., (2009)	109
5.4.4.6	Bray, Thompson, Wynn, Cummings, & Whetstone (2005).....	110
5.4.4.7	Rothe et al., (2008).....	111
5.4.5	Potentially Promising Studies	113
5.4.5.1	Mayer-Davis et al., (2004)	114
5.4.5.2	Gilmer, Philis-Tsimikas, & Walker (2005).....	115
5.4.5.3	Kirsh et al., (2007).....	116
5.4.5.4	Andrews & Holland (2003).....	118
5.4.6	Characteristics of Potentially Promising and Promising Studies	120
5.4.6.1	Changes in A1c Levels.....	120
5.4.6.2	Appraising the Quality of Evidence	120
5.4.6.3	Delivery Channels and Providers	121
5.4.7	Overview of Studies Not Likely to be Promising	123
5.5	Results of Methodological Studies	124
5.5.1	Quality Assessment Dictionary Addendum	124
5.5.2	Quality Assessment Tool Modifications	125
5.5.3	Issues with Conducting Quality Assessments	125
6	DISCUSSION	128
6.1	Discussion- Augmented Scoping Review.....	128
6.1.1	World Health Organization Stepwise Chronic Disease Prevention Framework.....	128
6.1.2	Ontario's Chronic Disease Prevention and Management Framework	129
6.1.2.1	Personal Skills and Self-Management Support.....	129
6.1.2.2	Delivery System Design.....	130
6.1.2.3	Provider Decision Support	131
6.1.2.4	Information Systems	132
6.1.2.5	Community Elements.....	132

6.1.3	The Quality of Studies Conducted in Primary Care.....	133
6.1.4	Contributions to the Existing Literature.....	134
6.1.5	Next Steps and Future Research.....	135
6.2	Discussion- Methodological Issues.....	137
6.2.1	Applicability of Quality Assessment Tool in Primary Care	137
6.2.2	Strengths and Limitations.....	138
7	CONCLUSION.....	141
8	REFERENCES	143
9	APPENDICES	151

LIST OF TABLES

Table 1: Steps of Cochrane SLR vs. Scoping Review	17
Table 2: Summary of Results- All Weight/BMI Studies	48
Table 3: Study Characteristics- Clinically Relevant Weight/BMI Studies.....	55
Table 3a: Intervention Details for Clinically Relevant Weight/BMI Studies.....	57
Table 4: Weight Results Table- Clinically Relevant Studies.....	61
Table 5: BMI Results Table- Clinically Relevant Studies.....	64
Table 6: QA Summary Table- Clinically Relevant Weight/BMI Studies	66
Table 7: Comparison of Delivery Channels- Weight/BMI Studies	80
Table 8: Comparison of Providers- Weight/BMI Studies	80
Table 9: Comparison of Provider Education- Weight/BMI Studies.....	81
Table 10: Summary of Results- All A1c Studies.....	84
Table 11: Study Characteristics- Clinically Relevant A1c Studies	90
Table 11a: Intervention Details for Clinically Relevant A1c Studies.....	93
Table 12: A1c Results Table- Clinically Relevant Studies.....	98
Table 13: QA Summary Table- Clinically Relevant A1c Studies	101
Table 14: Comparison of Delivery Channels- A1c Studies.....	122
Table 15: Comparison of Providers- A1c Studies	123
Table 16: Comparison of Provider Education- A1c Studies.....	123

LIST OF FIGURES

Figure 1: Flowchart for Screening Process	40
Figure 2: # of Studies by Country of Origin	42
Figure 3: % of Studies by Unique Target Group	43
Figure 4: % of Studies by Delivery Channel	44
Figure 5: % of Studies by Provider	45

LIST OF ABBREVIATIONS USED IN TEXT

Δ	CHANGE
$\bar{x}$	MEAN
A1c	HEMOGLOBIN A1c
AL	RESEARCHER- ALISSA LUNNEY
AP	RESEARCHER- AMANDA PAASHUIS
AVG	AVERAGE
BMI	BODY MASS INDEX
BP	BLOOD PRESSURE
CCHS	CANADIAN COMMUNITY HEALTH SURVEY
CCM	CHRONIC CARE MODEL
CCT	CLINICAL CONTROLLED TRIAL
CDPM	CHRONIC DISEASE PREVENTION AND MANAGEMENT
CENTRAL	COCHRANE CENTRAL REGISTER OF CONTROLLED TRIALS
CHD	CORONARY HEART DISEASE
CHS	CANADA HEALTH SURVEY
CINAHL	CUMULATIVE INDEX TO NURSING AND ALLIED HEALTH LITERATURE
CVD	CARDIOVASCULAR DISEASE
DR	RESEARCHER- DAWNA ROYALL
DSP	DIABETES SPECIALIST NURSE
EA	RESEARCH ASSISTANT- EDWOB AH ACKAH
EL	RESEARCHER- ELIZABETH LEE
EPHPP	EFFECTIVE PUBLIC HEALTH PRACTICE PROJECT
F/U	FOLLOW-UP
FHT	FAMILY HEALTH TEAM
GP	GENERAL PRACTITIONER
HTN	HYPERTENSION
INT	INTERVENTION
IPC	INTERDISCIPLINARY PRIMARY CARE
IP-PC	INTER-PROFESSIONAL PRIMARY CARE
ITT	INTENTION-TO-TREAT
MD	MEDICAL DOCTOR
MNGT	MANAGEMENT

MO	MONTHS
MOHLTC	MINISTRY OF HEALTH AND LONG-TERM CARE
N	SAMPLE SIZE
NP	NURSE PRACTITIONER
NR	NOT REPORTED
OO	RESEARCHER- OLIVIA O'YOUNG
PA	PHYSICAL ACTIVITY
PB	RESEARCHER- PAULA BRAUER
PC	PRIMARY CARE
POST	POST-INTERVENTION
QA	QUALITY ASSESSMENT
QoL	QUALITY OF LIFE
RCT	RANDOMIZED CONTROLLED TRIAL
RD	REGISTERED DIETITIAN
RN	REGISTERED NURSE
SCI-EXPANDED	SCIENCE CITATION INDEX-EXPANDED
SD	STANDARD DEVIATION
SLR	SYSTEMATIC LITERATURE REVIEW
WHO	WORLD HEALTH ORGANIZATION
WT	WEIGHT

1 OVERVIEW OF RESEARCH PURPOSE AND RATIONALE

Over the last two decades, Canada has seen an alarming increase in the prevalence of overweight and obesity at all ages. Obesity is a growing public health concern, as it increases the risk for several clinical conditions and exacerbates the severity of others, resulting in higher rates of morbidity and mortality. As current treatments require sustained behaviour change, the most responsible strategy would be to improve the delivery of those that are most successful.

The majority of the population intersects with the health care system in primary care (PC). Inter-disciplinary services are emerging as the preferred model for PC in Canada, offering new opportunities to improve prevention services, including obesity management. The present review was undertaken as part of a larger project, to inform the development of an obesity-services planning framework.

Brauer and colleagues were funded to begin to address the hypothesis that interventions at the organization and delivery level can improve obesity prevention, management and treatment effectiveness (Royall, 2010; Glasglow et al., 2001). Before these interventions can be implemented and evaluated, they needed to be identified and prioritized. An augmented scoping review was conducted to identify promising new approaches to improve effectiveness in inter-professional primary care (IP-PC) settings.

Scoping reviews are increasingly being acknowledged as a subgroup or type of systematic literature review (SLR) method in their own right (Arksey & O'Malley, 2005). They provide a mechanism for summarizing and disseminating research to other researchers, policy makers, and practitioners where SLRs have been less helpful, such as complex interventions for chronic conditions with no efficacious curative treatment.

Weight management is a good example as interventions include multiple strategies applicable to the population that varies with respect to genes, lifestyle, age, health and motivation. This thesis will present data on the overall methodology for the review as a whole, the major descriptive results for the entire review, as well as detailed analysis and results for the two main quantitative outcomes found: weight change and change in hemoglobin A1c (A1c), a key intermediate clinical outcome in diabetes management.

2 LITERATURE REVIEW

2.1 Introduction to Literature Review

This section will give an overview of weight management issues, the role of primary care, and the context for the present review. More specifically, it will first review the prevalence of overweight and obesity, and its relationship to related co-morbid conditions. Following this, the current treatments of overweight and obesity, and possible opportunities in interdisciplinary primary care will be examined. Next, this section will discuss the context of the present review, including existing literature and the larger project in which this review is a part of. Lastly, the type of review being conducted will be discussed.

2.2 Overweight and Obesity

2.2.1 Prevalence

Obesity is defined as a body mass index (BMI) of $\geq 30 \text{ kg/m}^2$, while overweight is defined as a BMI of $\geq 25 \text{ kg/m}^2$ (CDC, 2009b). Eating is an essential function to live; yet food and eating also have complex roles in social and cultural life. In a permissive environment, the majority of people seem to be predisposed to weight gain. The entire weight distribution of the population has been shifting; the problem of excess weight is not confined to an unfortunate subset of the population. The majority of Canadian adults are now overweight or obese (Tjepkema, 2008).

Over the last two decades, the prevalence of obesity has risen at an alarming rate. The current Canadian lifestyle is fast paced and technologically driven. As such, individuals often engage in behaviours which contribute to the obesity epidemic.

Canadians are increasing their consumption of less nutritious foods and larger portion sizes, decreasing physical activity and increasing sedentary activities (Health Canada, 2006b; Starky, 2005). Consuming processed foods is promoted when there is a large supply of convenient, relatively inexpensive, palatable, energy-dense foods (Hill & Peters, 2003). With the constant time pressure, individuals often drive rather than walk, take the elevator instead of the stairs, and make other such choices which reduce their level of physical activity (Hill, Wyatt, Reed, & Peters, 2003). Similarly, there are fewer jobs requiring physical labour, a reduction in energy expenditure at school, and increase in sedentary behavior such as watching TV, surfing the internet and playing video games (Hill et al.). Together, these changes in behavior increase the risk of positive energy balance, therefore contributing to the increase in overweight and obesity.

The 2004 Canadian Community Health Survey (CCHS): Nutrition and the 1978-79 Canada Health Survey (CHS) demonstrated a drastic increase in the prevalence of adult (age 18 to 74) overweight and obesity. For each study, interviewers measured the height and weight of nationally representative samples of the adult population, making both surveys accurate and comparable (Shields, 2006). The 1978/79 CHS results revealed that 14% of adults were obese and another 35% were overweight (Universite Laval, n.d.). By 2004, the CCHS: Nutrition demonstrated that the percentage of overweight adults remained quite stable at 36%; however, the percentage of obese adults had risen significantly, to 23% (Tjepkema, 2008).

Unfortunately, this trend is not unique to the adult population. Increasingly, children and adolescents are overweight and obese. In 1978/79, 3% of 2- to 17- year olds were obese, while another 12% were found to be overweight (Shields, 2008). By 2004,

obesity rates among children and adolescents rose to 8%, while the percentage of those who were overweight increased to 18% (Shields, 2008). Obesity was once thought to be a disease that affected the aging adult population; however, these trends demonstrate that is no longer the case.

2.2.2 Obesity-related Co-morbid Conditions

It is evident that the prevalence of overweight and obesity has increased markedly for individuals of all ages; therefore making it a growing public health concern as it increases the risk for several clinical conditions and exacerbates the severity of others, resulting in higher rates of morbidity and mortality (Patrick, Bushnell, & Rothman, 2004; Dick, 2004). Ultimately, this negatively impacts quality of life as well as life expectancy (Thomson, Edelsberg, Colditz, Bird, & Oster, 1999). Several studies have shown associations between obesity and a variety of health problems including hypertension, dyslipidemia, coronary heart disease (CHD), type 2 diabetes mellitus, gallbladder disease, osteoarthritis, sleep apnea, and some forms of cancer (Duval, Marceau, Perusse, & Lacasse, 2006; Rippe, Crossley, & Ringer, 1998). In 2003, almost 80% of Ontarians over the age of 45 (3.7 million people) were living with at least one chronic condition; including 34% with arthritis, 9% with diabetes, and 30% with high blood pressure (MOHLTC, 2007). Statistics Canada (2003) reported that 70% of these chronically ill individuals had multiple conditions (as cited in MOHLTC, 2007). Such high levels of co-morbidity indicate that when a serious chronic condition is left untreated, it tends to lead to additional health problems (MOHLTC, 2007). Ontarians with diabetes for example, account for 32% of heart attacks, 43% of heart failures, 30% of strokes, 51% of new dialysis, and 70% of amputations in the province (Institute for Clinical Evaluative

Sciences, 2002, as cited in MOHLTC, 2007). In addition to these physical health issues, obesity has also been found to be associated with psychosocial disturbances such as depression, bipolar, and anxiety disorders (Kushner & Foster, 2000). Together, these issues add substantial costs to health and social services. Based on data from 1998, Statistics Canada (2002) estimated that major chronic diseases and injuries accounted for 33% of direct health care costs (as cited in MOHLTC, 2007). In Ontario, it has been estimated that chronic diseases account for 55% of direct and indirect health care costs (Statistics Canada, 2002 as cited in MOHLTC, 2007). With the rise of obesity and related co-morbid conditions, these percentages are likely to be much higher today.

2.3 Weight Management in Primary Care

2.3.1 Complexities of Treating Overweight and Obesity

As mentioned above, our environment fosters increased energy intake yet decreased energy expenditure, therefore causing a positive energy balance. Biology, however, also plays a role in an individual's risk of becoming overweight or obese. Both body weight and body composition are determined by interactions between the environment and genetics, which are not well understood (Hill & Peters, 1998). Energy balance is controlled by multiple body mechanisms; all with the goal of defending body weight. While our bodies have excellent physiological defenses against the depletion of energy stores, they have weaker defenses against the accumulation of excess energy stores when food is abundant (Hill & Peters, 1998).

Due to its complexities, overweight and obesity are not readily treated, once it develops. While prevention would be ideal, interventions by several sectors will be

needed to reverse current trends, and efforts to date have had limited impact. Although some treatments are efficacious, when implemented in practice, they tend not to be effective; no ‘magic bullet’ has been discovered. Approaches among multiple sectors need to be coordinated in order to improve both the prevention and treatment of obesity.

Moreover, different approaches may be most effective for different individuals. With an abundance of variation such as genes, lifestyle, age, health, levels of motivation, and learning styles, a given strategy may be more successful for some individuals than others. While a cure does not exist, the most responsible strategy would be to improve the delivery of the most successful current prevention and treatment methods. Using multiple strategies may help address this chronic condition affecting such a wide range of individuals.

2.3.2 Opportunity in Primary Care

Among possible delivery sectors, primary care health services have an important role to play. Primary care is a location where the highest proportion of the population is served as the majority of Canadians only interact with the health care system in this setting. It is the primary way that adults intersect with health and social services. Between 2007 and 2008, Statistics Canada found that almost 80% of the Canadian population (age 12 and over) reported visiting a family physician within the last 12 months (Statistics Canada CCHS, 2010). This interaction represents an opportunity in a way that acute or specialist health care does not. Primary care often provides patients’ their first point of contact with the health care system through a doctor or other health care professional (Health Canada, 2006a). In this way, it may act as a ‘gatekeeper’ to specialist services. It is also the least expensive health service available in Canada.

Moreover, it is also the major setting in which individuals are seen for chronic health conditions, including the management of cardiovascular disease, and type II diabetes. In the United States, one in three adults is obese, making obesity the most common presenting risk factor in the primary care setting (Dick, 2004). Canada presents with a comparable situation as almost one in four adults is obese (Tjepkema, 2008). Furthermore, primary care offers person-centered care and ongoing relationships with health care professionals. For these reasons, primary care represents a major setting in which weight management strategies should be targeted.

2.3.3 Inter-disciplinary Services

As inter-disciplinary primary care services are emerging as the better model for primary care in Canada, the number of inter-professional teams continues to increase (Brauer, 2008). Family Health Teams (FHTs) are an initiative of the Ontario government to provide disease management and prevention, disease cure, rehabilitation, palliative care and health promotion, using the inter-professional model, with a strong emphasis on quality improvement. In fact, the Quality Improvement and Innovation Partnership (QIIP) was created as part of the strategy to develop FHTs and it continues to assist FHTs as they move to a new model of primary health care (MOHLTC, 2008b). The FHT model is based on work by Wagner (1998) and others that have shown that multiple changes in the organization and delivery of care can improve outcomes in the management of chronic diseases.

QIIP has provided Resource Guides and Toolkits designed to help FHTs meet their goals of providing high-quality, patient-centered care. Resource Guides and/or Toolkits are available for needs assessments, logic model development, team building,

community partnership, human resources, privacy, inter-professional care, and chronic disease management (MOHLTC, 2008b). Logic models are generally a visual way to present the goals, activities and resources used to operate a program for a given target group (WK Kellogg Foundation, 2001).

Currently, there are 200 FHTs in Ontario which are all designed to give physicians support from complimentary health professionals (MOHLTC, 2008a). This interdisciplinary team may include nurse practitioners, registered nurses, registered dietitians, social workers, pharmacists, kinesiologists, psychologists and other such health care professionals. FHTs vary in size, composition, scope, and focus, depending on the needs of the local population, the local health care context, as well as the preferences of providers and communities (MOHLTC, 2008a). Together, the health care providers form a comprehensive and accessible team that may be able to more effectively manage diseases such as overweight and obesity. Presence of a team facilitates new interventions at the organization and delivery level which may offer important improvements in obesity prevention, management and treatment effectiveness, as discussed in more detail in the next section (Glasglow et al., 2001).

2.4 Context for the Present Review

2.4.1 Existing Literature

There exists considerable literature related to obesity, diabetes, CVD, hypertension, dyslipidemia and other chronic conditions. Ciliska and colleagues conducted a systematic literature review on “The Effectiveness of Nutrition Interventions for Prevention and Treatment of Chronic Disease in Primary Care” (Ciliska et al., 2006).

This review was commissioned by the Dietitians of Canada as part of a demonstration project to develop practice management guidance materials for interdisciplinary nutrition services in primary health care settings in Ontario (Ciliska et al.). However, the focus was not specifically on weight management, the large majority of studies reviewed were limited to systematic reviews or meta-analyses, studies with weak quality assessment were excluded, and they were published between 1999 and 2004. The study included 12 primary studies and 221 reviews. Findings included: 1. Diabetes self-management education can be effective in community settings; 2. Reducing overall and saturated fat and increasing omega-3 polyunsaturated fat intake has greater effect on reducing overall mortality than focusing on weight reduction or lipid lowering alone; 3. Focusing on weight loss under current primary care models is probably not intense enough to result in significant/maintained change; 4. Multiple risk factor interventions have demonstrated reductions in blood pressure and cholesterol levels; 5. Improving the dietary intake of pregnant women can significantly reduce the rates of low birth rate, very low birth weight, and small for gestational age infants.

Additionally, extensive research has been conducted on obesity treatment including the most recent publication of Canadian obesity treatment guidelines in April 2007 (Lau et al., 2006). These guidelines include recommendations which are given a rating for level of evidence and grade (e.g. Grade A, Level 2, for children, ongoing follow-up by a health professional for a minimum of 3 months); however the developers have recognized that additional implementation studies are needed as obesity is highly prevalent and chronic, with treatment only being modestly effective (Lau et al; Royall, 2010). Brauer and colleagues (i.e. the research group) were funded by the Canadian

Institutes of Health Research (CIHR) to begin to address the hypothesis that interventions at the organization and delivery level can improve obesity prevention, management and treatment effectiveness, including relapse prevention (Glasglow et al., 2001; Royall, 2010;). Before these interventions can be implemented and evaluated, they need to be identified and prioritized; therefore the research group attempted to merge the evidence from formal research studies with the perspectives of practitioners (Royall, 2010). Their findings were used to develop an “interdisciplinary obesity management planning framework in primary care”. The framework will be used to plan population-based programs by linking program activities with a hierarchy of desired outcomes for specific target groups in primary care (Brauer, 2008).

The present review was conducted to inform this framework by identifying promising new weight management (i.e. managing overweight and obesity) strategies within the context of inter-professional primary care. This is unlike the review conducted by Ciliska and colleagues (2006), as the strategies they identified were likely implemented in current practice. As previously mentioned, the “review of reviews” included studies published between 1999 and 2004; therefore, the present review included those published between 2003 and 2009.

2.4.2 Obesity Management Planning Framework in Primary Care

2.4.2.1 WHO Stepwise Chronic Disease Prevention Framework

The development of the obesity management framework has been grounded in the World Health Organization’s (WHO) chronic disease prevention framework for planning services (Brauer, 2008). The WHO promotes the idea of public health and primary care coordination, and a hierarchy of services depending on resources, ranging from basic to

desirable (WHO, 2005; WHO, 2008). The WHO's Stepwise Framework involves estimating population needs and advocating for action, formulating and adopting policy, and finally, identifying policy implementation steps (WHO, 2005). Policy implementation can be done at the National, Sub-national, or Individual level. This framework describes three steps to policy implementation. Step 1 CORE, refers to interventions that can be implemented with existing resources in the short term. They can be implemented in all countries including developing countries. They include providing basic information about risk factors, self-management, and community resources. Step 2 EXPANDED, refers to interventions that may be implemented with a realistically projected increase or reallocation of resources. Therefore these projects likely require more funding and may include educational and skill-building workshops/group appointments. Lastly, Step 3 DESIRABLE, refers to interventions which are evidence-based and beyond the reach of existing resources. They can be implemented in developed countries such as Canada. Interventions may include computerized patient self-assessment, individualized self-management plans, and supplementary self-management support by telephone or internet (WHO, 2005).

2.4.2.2 Chronic Care Model

The development of the obesity planning framework was also informed by the Chronic Care Management (CCM) model developed by Wagner et al (Glasgow et al., 2001). The current health care system has been criticized as it is designed to address acute illness rather than chronic disease (MOHLTC, 2007). As such, care tends to be reactive as opposed to proactive. The Ministry of Health and Long-Term Care (MOHLTC; 2007) believes that practitioners rely on patients to contact the system,

patients are usually passive while receiving treatment, visits are symptom focused (versus patient-centered), and promoting overall health, preventing disease, injury and disability are not priorities. In Canada, chronic diseases are among the most common and costly health problems; however, they are also among the most preventable (MOHLTC, 2007). Changes in modifiable behaviours and biological risk factors have the potential to significantly reduce chronic diseases. It has been found that healthy eating, regular exercise and not smoking can prevent up to 90% of type 2 diabetes, 80% of coronary heart disease, and one-third of cancers in Ontario (WHO, n.d., as cited in MOHLTC, 2007).

The MOHLTC (2007) developed a policy framework to guide the redesign of health care practices and systems with the aim of improving chronic disease prevention and management in Ontario. The Ontario Chronic Disease Prevention and Management (CDPM) Framework is evidence-based, population-based and client-centered. This framework is based on the CCM model developed in the United States (Wagner, 1998) and British Columbia's Expanded Chronic Care Model (ECCM; Barr, Robinson, Marin-Link, Underhill, Dotts, & Ravensdale, 2003). Key elements of Ontario's CDPM Framework include: 1. Providing personal skills and self-management support (e.g. shared decision-making and goal setting, educational programs and health information, behaviour modification programs, counseling and support services, community resources); 2. Delivery system design (e.g. interdisciplinary teams, health promotion and disease prevention, planned interactions and follow-ups, quality improvement, and population needs-based care); 3. Providing provider decision support (e.g. provider education on guidelines and working in interdisciplinary teams, tools, provider alerts and

reminders, access to specialist expertise, measurement/feedback); 4. Implementing advanced information technology systems (e.g. electronic health records, case management software, client registries, web support, information for clients, links); 5. Developing healthy public policies (e.g. legislations, regulations, fiscal and tax measures, guidelines); 6. Creating supportive environments (i.e. removing barriers to healthy living by promoting safe and enjoyable living and working conditions); 7. Promoting community action (e.g. collaboration between the health care sector and community organizations, and promoting public participation and intersectoral collaboration; MOHLTC, 2007). Research to date indicates that this approach to CDPM will improve the health of chronically ill individuals and reduce the incidence of chronic disease in the province (MOHLTC, 2007).

2.4.2.3 Developing the Obesity Management Planning Framework- Methods

The first draft of the planning framework was developed by the research group to show strategies and specific program activities in differing age groups. These age groups were based on an analysis of the population data in the Canadian Community Health Survey (CCHS) 3.1 (Royall, 2010). This draft was further developed in a workshop involving dietitians from FHTs across Ontario. Focus groups were conducted among health professionals and among patients at the Hamilton FHT in order to identify additional strategies to manage body weight issues in interdisciplinary primary care. Findings from the focus groups were incorporated into the development of the planning framework. Finally, a Delphi consensus process was conducted among interdisciplinary providers from the Guelph FHT. After being shown the latest draft planning framework, participants worked through a number of activities to help identify and decide on

preferred strategies and program activities for obesity management (Royall, 2010). In addition to population needs, theories, focus groups and workshops, the current review played a key role in informing the development of the draft obesity management planning framework.

2.5 Selection of an Augmented Scoping Review

This section briefly discusses the Cochrane Methodology for systematic literature reviews, scoping reviews, their differences, and the methods chosen for the present augmented scoping review; a hybrid of the two review methods.

2.5.1 Systematic Literature Review- Cochrane Collaboration Methodology

The current drive towards evidence-based practice has promoted a rapid growth in the number of reviews being conducted. Due to the rigorous nature of systematic literature reviews (SLRs), they have often been used within the medical community to support the development of clinical and public health practice guidelines, set research agendas and formulate scientific consensus statements (Lichtenstein, Yetley, & Lau, 2008).

The Cochrane Collaboration methodology for systematic literature reviews was developed for medical questions, is well known and has been extensively documented. It can be used or adapted for both qualitative and quantitative (meta-analysis) reviews. It includes all the main features of SLRs, with extensive software, user support and training tools.

2.5.2 Scoping Review

Although SLRs are well accepted in the field of dietetics, the more exploratory nature of the present study made a scoping review the appropriate choice. Scoping reviews “aim to map rapidly the key concepts underpinning a research area and the main sources and types of evidence available, and can be undertaken as stand-alone projects in their own right, especially where an area is complex or has not been reviewed comprehensively before” (Mays, Roberts, & Popay, 2001 as cited in Arksey & O’Malley, 2005).

Scoping reviews may be undertaken for four main reasons: 1. to examine the extent, range and nature of research activity; 2. to determine the value of undertaking a full systematic review; 3. to summarize and disseminate research findings; and 4. to identify gaps in the existing literature. The present review was undertaken to address the latter two reasons, but in the process also has addressed purpose number one. Scoping reviews are increasingly being acknowledged as a subgroup or type of SLR method in their own right (Arksey & O’Malley, 2005). The third and fourth scoping review approaches examine studies in more depth and describe findings in more detail, therefore providing a mechanism for summarizing and disseminating research to other researchers, policy makers, and practitioners where SLRs have been less helpful— such as complex interventions for mental health issues, complex conditions with no efficacious treatment, child development issues, etc. (Antman, Kupeinick, Mosteller, & Chalmers, 1992 as cited in Arksey & O’Malley, 2005, page 21).

2.5.3 Systematic Literature Review versus Scoping Review

Similar to systematic reviews, scoping reviews are both rigorous and transparent, enabling the synthesis of evidence with minimal selection bias (Arksey & O'Malley, 2005; Litchenstein et al., 2008). To maximize transparency, both types of reviews require the entire process to be documented in sufficient detail to enable replication by other researchers (Arksey & O'Malley, 2005). There are, however, two major differences between systematic and scoping reviews: 1. Systematic reviews normally include an appraisal of the quality of evidence of reviewed studies, while scoping reviews often do not; and 2. Systematic reviews aim to answer relatively narrow questions, while scoping reviews aim to provide answers to relatively broad questions. As such, the range of studies, data collection, analysis, and reporting of findings are quite different.

Table 1: Steps of Cochrane SLR vs. Scoping Review

Cochrane Collaboration Methodology	Scoping Review Methodology (Arksey & O'Malley, 2005)
Defining the Review Question and Developing Criteria for Including Studies	Identifying the Research Question
Searching for Studies	Identifying Relevant Studies
Selecting Studies and Collecting Data	Study Selection
Assessing Risk of Bias in Included Studies	Charting Data
Analyzing Data and Undertaking Meta- analyses	Collating, Summarizing, and Reporting Results
Presenting Results and Summary of Findings Tables	
Interpreting Results and Drawing	
Conclusions	

2.5.4 The Present Review

The present review was undertaken as an “augmented scoping review” according to the original purpose, and core strengths of SLR from the Cochrane Collaboration methodology were retained as much as possible, most importantly, conducting quality assessments. Therefore, documentation of screening and selection criteria, use of dual reviewers and the assessment of the quality of evidence of all quantitative intervention studies were planned. Additionally, coding schemes were to be attached to the summary tables in order to define how each section should be filled out. This makes data extraction much more efficient and systematic. Furthermore, data were to be collected and managed using spreadsheet software (Microsoft Excel), and references were to be managed using a reference management software (Reference Manager). Lastly, a reference list of all excluded citations would be provided.

The topic of weight management in primary care is very broad; therefore this review will include a wide range of articles including both quantitative and qualitative studies. Inclusion of qualitative data was seen as important, but methods for reviewing both types of data are descriptive and rudimentary. The purpose was to identify and prioritize new and promising approaches for weight management. For these reasons, using the scoping review framework while including some characteristics of SLRs appeared to be most appropriate choice for the present review. As the scope of the review is larger than a typical Masters thesis, a subset of key outcomes will be analysed in detail.

3 RESEARCH OBJECTIVES

3.1 Primary Research Objective

To determine which strategies are most relevant and promising for lifestyle weight management (overweight and obesity) for individuals of varying age groups (children/adolescents, adults, elderly) and chronic conditions (diabetes, CVD/HTN, overweight/obesity only) in the Canadian context of inter-professional primary care.

3.2 Secondary Research Objectives

- a) To describe the characteristics of primary lifestyle weight management (prevention or treatment) studies conducted in inter-professional primary care settings or relevant to Canadian inter-professional primary care settings 2003-2009.
- b) To identify promising strategies for weight change and to describe key characteristics of the interventions.
- c) Based on review results, to identify promising strategies for change in the second most commonly assessed outcome (hemoglobin A1c) and to describe key characteristics of the interventions.

4 METHODOLOGY

The methodology used for each stage of the augmented scoping review will be described in this section. Methods generally followed Cochrane Collaboration methodology unless otherwise stated. Steps taken in the present review included defining the review question, developing the inclusion/exclusion criteria, development and conduct of the search strategy, selecting studies for inclusion (including developing the screening tool), methods for quality assessment, and methods for presenting results.

4.1 Defining the Review Question and Developing Criteria for Including Studies

4.1.1 Review Question

The primary question includes the important components of a research question including: population and setting (individuals of all ages seen in primary care), condition of interest (overweight, obesity or related co-morbid condition), exposure (diet and/or physical activity component), and specific outcomes (change in body mass or other secondary outcomes). Each aspect of the clinical question was further refined in order to conduct the search.

4.1.2 Criteria for Considering Studies for this Review

Studies published between January 2003 and June 2009 were selected for inclusion if they met the following criteria.

4.1.2.1 Inclusion Criteria

4.1.2.1.1 Types of Participants

Participants could have been of any age (children/adolescents, adults, elderly) as the range of patients seen in primary care includes individuals of all ages. The conditions

of interest selected were overweight, obesity or any obesity-related co-morbid conditions (e.g. type 2 diabetes, hypertension, dyslipidemia, CHD, in which obesity prevention or treatment was needed to manage the condition). Overweight was defined as a BMI $\geq$ 85th percentile for children/adolescents of a given age and gender and defined as a BMI of $\geq$ 25kg/m² for adults (CDC, 2009a ; CDC, 2009b). Obesity was defined as a BMI $\geq$ 95th percentile for children/adolescents of a given age and gender and defined as a BMI of $\geq$ 25kg/m² for adults (CDC, 2009a; CDC, 2009b).

4.1.2.1.2 Types of Settings

The setting had to be in Canadian inter-professional primary care or in other settings (e.g. private practice, community centre, pharmacy) if the intervention could be replicated in Canadian IPC (i.e. relevant to Canadian IPC).

4.1.2.1.3 Types of Interventions and Outcome Measures

The studies had to include a lifestyle component (i.e. discusses diet and/or physical activity OR report a change in body mass), as well as address weight management by focusing on one of three main categories: 1. Diet and/or physical activity (PA) intervention (quantitative intervention studies); 2. Change in the organization of care (quantitative descriptive studies); or 3. Patient and/or provider perceptions of improved care (qualitative studies). Since the present review aimed to identify strategies relevant to IPC, it was important that the study focus reflected what is typically seen in this setting; therefore, only studies with a diet and/or PA component were considered. As mentioned above, a lifestyle component referred to the discussion of diet and/or physical activity OR reporting of a change in body mass (i.e. weight or BMI). Although most studies reported a change in body mass, it is important to clarify that based on this

criterion, studies could still be selected (considered to have a lifestyle component) if they discussed diet and/or PA, yet did NOT report weight or BMI. Similarly, studies could have been selected if they reported weight or BMI, however, did not discuss diet and/or PA. The purpose of the latter criterion was to ensure the inclusion of health behaviour intervention studies (e.g. self-management) which did not explicitly mention a diet and/or PA. Since these were not surgical or pharmacological interventions, the reported change in body mass was most likely a result of lifestyle interventions.

4.1.2.1.4 Types of Study Designs

Studies could be of any research design; however, they had to be primary studies in similar health systems as Canada and written in English. However, primary studies referenced from reviews (systematic or narrative), guidelines or grey literature could also be included if they met the above criteria.

4.1.2.2 Exclusion criteria

- a) Since studies had to include a lifestyle component, medical management studies, as well as drug and surgery interventions were excluded.
- b) Studies in cardiac rehabilitation centres (cardiac rehab), home care, or pediatric specialty clinics were excluded as they are not representative of the range of patients seen in IPC.
- c) Interventions which were not beyond usual care were excluded. As the aim of this review was to identify new and novel promising approaches, descriptions of standard/current practice were not useful. Similarly, studies on the prevalence of risk factors in IPC settings were also excluded.

- d) Studies that tailored interventions to homogeneous ethnic groups outside of Canada were excluded; however, if participants were incidentally of a homogenous ethnic group, they were included.
- e) Efficacy studies (i.e. phase II trials) were excluded, including metabolic studies, large cohort studies not from primary care, large multi-centre trials, diet counseling studies which focused on differing diets within homogeneous groups or diet counseling studies which focused on volunteers solicited mostly by advertising (e.g. mass media; U.S. NIH, 2008). These efficacy studies were excluded as they are not representative of the way in which weight is managed in IPC, nor are they representative of the range of patients seen in IPC.

4.2 Searching for Studies

The aim of this search strategy was to select any articles that could be used to identify promising strategies for weight management in IP-PC. These articles could have reported both clinical outcomes (e.g. weight, BMI, HbA1c, BP, lipids) as well as non-clinical outcomes, such as behaviour change, quality of life (QoL) and cost-effectiveness; however the focus was on the clinical outcomes. The search was relatively broad as weight management in primary care is a wide ranging issue which includes individuals of all ages who either have or are at risk of other chronic conditions.

4.2.1 Designing the Search Strategy- Search Terms and Phrases

A medical librarian with expertise in systematic searches from McMaster University was contracted to create a search strategy specific to each database. Each database was searched using terms from three distinct concepts: obesity and overweight,

non-drug treatments, and primary care setting. The search terms from the thesaurus of each database, as well as text words were used for each concept. All terms were combined with 'AND' or 'OR' in order to come up with the final search strategy for each database. A copy of the search strategy for each database is shown in Appendix A.

4.2.2 Conducting the Pilot Search

Prior to beginning the official search, the search strategy was piloted for articles published between January 2008 and May 2009. A pilot search was conducted for PubMed (includes MEDLINE), Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials (CENTRAL), Science Citation Index Expanded (SCI-Expanded), and PsycINFO to ensure the success of the entire search strategy. This helped researchers determine how to best enter search terms into each database, while troubleshooting for errors. It also enabled researchers to check that the number of citations retrieved from each database was appropriate; therefore suggesting the terms were correctly entered. By reviewing the citations retrieved, researchers could also examine the relevance of each database (to the research question). Lastly, the pilot searches also ensured that the citations retrieved from each database could be properly exported to Reference Manager commercial bibliographic software (version 12) and compiled into one database. Reference Manager, developed by Thomson Reuters, is used by researchers worldwide (Thomas Reuters, 2008). It is a searchable and sortable database, allowing each citation to be used in multiple contexts. Additionally, Reference Manager is known as the only citation management software with a true multi-user network version, which provides a tool for publishing Reference

Manager databases on the Web or to an intranet, and includes Cite While You Write integration with Microsoft Word (Thomas Reuters, 2008).

4.2.3 Sources to Search- Electronic Database Selection

4.2.3.1 Included Electronic Databases

For the official search, the electronic databases PubMed, CINAHL, CENTRAL, and SCI-Expanded were used. PubMed was chosen as it is a well recognized database that includes 20 million citations of biomedical literature from MEDLINE and many life sciences journals. Relevant citations and abstracts include the field of medicine, nursing and the health care system. CINAHL was chosen because it is the most comprehensive resource for nursing and allied health literature and is therefore highly relevant to the present review. CENTRAL was included to capture relevant clinical trials in the Cochrane Collaboration's register of controlled trials without including all the systematic literature reviews which were found through one or more of the other databases. Lastly, Science Citation Index Expanded offers 6,650 of the world's leading journals of science and technology across 150 disciplines.

4.2.3.2 Excluded Electronic Databases

Given that EMBASE specializes in the biomedical field, it was also considered for inclusion. Unfortunately, it was difficult to access through the University of Guelph library system during the development of the search strategy. EMBASE runs through OVID, and at the time, the University of Guelph did not support OVID. To evaluate the necessity of purchasing a subscription, EMBASE was further evaluated for relevance. It was found that all journals previously identified as containing relevant studies were already included in PUBMED and CINAHL. As a further check, a personal faculty

database of relevant hand-picked articles was searched for the most esoteric journals. The identified journals were the Australian Journal of Rural Health, Nutrition and Dietetics, Australian Health Review, Outcomes Management for Nursing Practice, Journal of Interprofessional Care, and Journal of Allied Health. It was found that all of the above journals are available through PUBMED, except Nutrition and Dietetics, which is available through SCI-Expanded. This process ensured that primary care journals relevant to topics on diet and exercise were available through the chosen databases. Therefore, an EMBASE subscription was not needed. Moreover, during the pilot search, the citations retrieved from PsychINFO nearly doubled the total number of citations to be retrieved, yet there was no greater yield of relevant studies. The subset of titles and abstracts which were screened were not relevant, and as mentioned above, all relevant journals which included studies on weight management in IPC were available through other already chosen databases; therefore, PsycINFO was excluded from the official search.

4.2.4 Conducting the Final Search

The final search involved entering selected search terms and phrases into their respective databases: PubMed, CINAHL, CENTRAL, and SCI-Expanded. Search parameters included selecting studies published in English between January 2003 and June 2009. The timeframe was chosen to identify studies completed since a previous search done by the Evidence-based Practice Centre at McMaster University. The search processes for each database were documented in detail. All retrieved citations were exported to, compiled and organized (including removal of duplicates) into one Reference Manager file.

4.3 Selecting Studies and Collecting Data

4.3.1 Development of Screening Tool

A title and abstract screening tool, as well as a full-text screening tool were developed based on the participants, setting, intervention and outcomes measures, and specific exclusion criteria. A copy of each tool is shown in Appendix B and Appendix C respectively. A coding manual was also developed to further define the different aspects of the full-text screening tool and improve consistency when using the tool. The coding manual is shown in Appendix D. This is further discussed in the ‘Screening Process’ section.

4.3.2 Pilot Screening Process

Prior to beginning the official screening process, a pilot screening was conducted by three researchers in order to improve the accuracy of citation selection.

4.3.2.1 Pilot Title and Abstract Screening Tool

The first step of the pilot screening process entailed screening the titles and abstracts of all citations retrieved from the pilot search strategy (studies published between January 2008 and May 2009). Three researchers (PB, OO, EL) screened titles and abstracts individually. Following this, they met and compared which citations passed the screening process and were selected to be read in full, and which citations were to be discarded. This process helped the researchers develop a shared understanding and interpretation of the title and abstract screening tool. The researchers were able to assess the range of study designs, settings, participants and chronic conditions found in the retrieved citations. At this time, they discussed reasons for inclusion or exclusion and made necessary revisions to the screening tool.

4.3.2.2 Pilot Full-text Screening Tool

The second part of the pilot screening process entailed randomly selecting and reading approximately thirty articles (identified in the first pilot screening process). Similar to the first process, each full-text article was read individually by four researchers (PB, DR, OO, EL). Following this, all four researchers met to compare which articles were chosen to be included in the review, which articles were excluded but held (e.g. reviews) and lastly, which articles were to be fully discarded. Comparing results allowed researchers to develop a shared understanding and interpretation of the full-text screening tool. As a result, articles were screened in a more consistent and efficient manner during the final screening process. The researchers also discussed and made adjustments to the screening tool and coding manual as they saw fit (e.g. the screening tool was found to be too inclusive therefore, the necessary changes were made).

4.3.3 Final Screening Process- Selecting Studies and Collecting Data

4.3.3.1 Title and Abstract Screening

Due to the diverse body of literature generated by this search, the first step of the screening process was to print and screen the titles and abstracts of all the retrieved citations. Screening was guided by the title and abstract screening tool (Appendix B) mentioned above. It was often difficult to determine whether an article met the eligibility criteria solely based on the title or abstract; therefore this first screening process was more inclusive than the second. Each of the retrieved articles was read by two of the four researchers (PB, DR, OO, EL). Each researcher was paired with the three other researchers so that all combinations of pairs screened a portion of the articles. This increased the reliability of article selection. After screening articles individually, each

pair came to a consensus regarding which articles were selected as potentially relevant and therefore read in full. Results from this process were documented. The articles selected from this title and abstract screening were compiled into a new Reference Manager database, which included citations from all four databases.

4.3.3.2 Full-text Screening

The second step of the screening process involved retrieving and reading the full articles of those selected as potentially relevant. Again, each article was read by two out of the four researchers (PB, DR, OO, EL). Screening of full-text articles was guided by the full-text screening tool (Appendix C) as well as the Coding Manual (Appendix D). The Coding Manual was used as a ‘dictionary’ that defined the criteria in the screening tool (e.g. what is considered a setting relevant to IPC). Once again, each researcher had the opportunity to be paired with three other researchers to increase reliability of article selection.

To determine whether the article was selected for inclusion, the researchers had to verify that the study met the criteria for each section of the screening tool. Firstly, the setting of all articles had to be relevant to Canadian IP-PC as well as include a lifestyle component. Having a lifestyle component referred to articles that discussed diet, physical activity, and/or reported a change in body mass. If these criteria were met, the researchers verified the focus of the article met one out of three criteria. The study had to focus on lifestyle therapy, a change in organization of care or provider and/or patient perceptions regarding improved care. If all of these criteria were met, the article was classified as ‘include’ (i.e. to be included in the review). If it did not meet the criteria, the article was either classified as ‘exclude-hold’ (i.e. primary study searched for, reviews checked for

references, or relevant background information) or ‘exclude-fully’ (i.e. to be discarded). After screening articles individually, each pair came to a consensus regarding how each article was categorized.

4.3.3.2.1 Hand-searching Protocol

During the full-text screening process, relevant reviews were put aside (i.e. exclude-hold). The references of these articles were screened by one researcher (EL) based on title and abstract. Subsequently, the selected citations were further screened by two researchers (EL, OO) based on the full text. The same steps for screening were taken, as outlined above.

4.3.3.2.2 Collecting Screening Data- Excel Spreadsheets

A research assistant (EA) was hired to program the full-text screening tool into Visual Basic (programming software) for ease of entry into an Excel database. Each researcher individually filled out the screening tool using the programmed form, allowing the information to be automatically entered into a Microsoft Excel spreadsheet. Each row was dedicated to one article, while the columns represented different sections of the screening tool. Therefore, decisions made for each criterion, including comments written by each researcher, were documented. Additionally, when researchers met for consensus, a new spreadsheet was saved with final decisions. Basic information was also collected for each article including name of the reviewer, Reference Manager ID number, author, year published, and title. The programmed screening tool allowed for proper data collection and entry, while making the screening process more efficient and organized.

4.4 Assessing Risk of Bias in Included Studies

4.4.1 Rationale for Appraising Quality of Evidence

All quantitative intervention studies included in the review underwent quality assessment. Quality assessment of the descriptive quantitative studies (i.e. articles on changes in organization of care) and the qualitative studies (i.e. articles on patient and/or provider perceptions) was deferred in this first analysis.

4.4.2 Quality Assessment Tool for Quantitative Studies

The Quality Assessment Tool for Quantitative Studies (developed by the Effective Public Health Practice Project) was used to appraise the quality of evidence of each included study (City of Hamilton- Effective Public Health Practice Project, 2007a). This is somewhat controversial as the Cochrane Collaboration now discourages the use of scales and checklists for assessing quality (Cochrane Collaboration, 2008); however, there are many reasons for which this tool was chosen as the most appropriate for the present review.

The quality assessment tool currently suggested by Cochrane is a “domain-based evaluation, in which critical assessments are made separately for different domains” including: adequate sequence generation, blinding (of participants, personnel, and outcome assessors), incomplete outcome data, selective outcome reporting, and other sources of bias (Cochrane Collaboration, 2008). This tool, however, was not suitable for the present review as it is strictly for randomized controlled trials. Since many of the studies included in the augmented scoping review were conducted in the community, various study designs were used (including controlled clinical trial and cohort studies).

The Quality Assessment Tool for Quantitative Studies is widely used in Canada, has been developed over several years and includes differing study designs, beyond randomized clinical trials (unlike the tool used by the Cochrane Collaboration and the Jadad scale), while acknowledging the strength of that design. It also addresses the large majority of the domains in the Cochrane quality assessment tool as well as other main study dimensions of interest relevant to the present review including selection bias, confounders, validity of methods, and intention to treat. Additionally, the Quality Assessment Tool for Quantitative Studies provides an overall global rating (strong, moderate, weak) for each assessed study. The Cochrane Collaboration (2008) believes “calculating a summary score inevitably involves assigning weights to different items in the scale...and [scales] are less likely to be transparent to users of the review.” In the present review however, studies were not discounted based on their global rating. Instead, individual aspects of the quality assessment were taken into consideration and details on important questions/domains are provided for readers (in the results section).

Furthermore, although there are over 120 different QA tools developed, the Quality Assessment Tool for Quantitative Studies is one of the recommended tools from the National Collaborating Centre for Methods and Tools of the Public Health Agency of Canada (National Collaborating Centre, 2009). Furthermore, this tool is now recognized for public health and health promotion studies in the Cochrane Handbook for Systematic Reviews of Interventions (The Cochrane Collaboration, 2008). The Cochrane Collaboration (2008) recognizes that these types of studies may be more difficult to appraise partly due to the wide variety of study designs. Lastly, no similar QA tool has been developed expressly for primary care and continued work is needed to develop a

tool for these complex interventions; therefore the Quality Assessment Tool for Quantitative Studies is currently the most appropriate existing tool for the range of studies included in the present review.

4.4.3 Pilot Quality Assessment Process

Quality assessment was piloted with five researchers, all of whom had MSc training (PB, DR, OO, AL, AP). Each researcher individually read and completed the QA tool for at least ten of the included studies. Following this, all five researchers compared results for each question and rating for each section of the tool. This process helped ensure that all five researchers understood how to complete the QA tool (including using the accompanying Dictionary) and shared a common interpretation of each question and section. During this process, changes were made to the QA Dictionary to better fit the range of studies in the present review. This is further discussed in the results section. As a result of this pilot process, articles were assessed in a more consistent and efficient manner.

4.4.4 Final Quality Assessment Process

Quality assessments were conducted on each of the quantitative intervention studies by two out of the four researchers (DR, OO, AL, AP) in order to obtain a more reliable assessment. Each researcher was paired with three other researchers so that all combinations of pairs reviewed a portion of the studies. This increased the reliability of the appraisal.

This QA tool included eight sections (A-H): selection bias; study design, confounders, blinding, data collection methods, and withdrawals and dropouts. Based on the Quality Assessment Tool for Quantitative Studies Dictionary, each article was rated

as ‘strong’, ‘moderate’, or ‘weak’. After completing the QA tool, each pair of researchers compared results (for each question in each section) and indicated the reason for any discrepancy. Each pair then made final decisions for each section and for the global rating.

4.4.4.1 Collecting QA Data- Excel Spreadsheets

Similar to the screening tool, a research assistant (EA) was hired to create a data entry template, using Visual Basic for ease of entry into the Excel database. Each researcher individually filled out the quality assessment tool on the programmed form, allowing the data to be automatically entered into Microsoft Excel. Each row was dedicated to one study, while each column represented a different question/section of the QA tool. Therefore decisions made for each question and comments written by each researcher were documented. Additionally, when researchers met for consensus, a new spreadsheet was saved with final decisions. Basic information was also collected for each article including name of the reviewer, Reference Manager ID number, author, year published, and title. The programmed QA tool allowed for proper data collection and entry, while making the screening process more efficient and organized.

4.5 Presenting Results- A ‘Descriptive Analytic’ Framework

4.5.1 Charting Data

Summary tables were created for each study selected to be included in the review (225 studies). Information identified as important were extracted and synthesized into tables (available upon request).

4.5.1.1 Summary Tables

The tables were used to present study characteristics to support the interpretation of the evidence addressing the stated research question (Glasgow et al., 2001). The original summary table template was developed for the intervention studies. The information compiled in these tables is comprehensive and includes data such as country of origin, purpose, study design, target group, setting, participant recruitment, theoretical basis, providers, delivery channels, outcome measures, QA rating, conclusion etc. The summary table template for intervention studies is shown in Appendix E. The format of this table was adapted to accommodate the varying studies included in this review (i.e. the quantitative descriptive studies and the qualitative studies). The summary table templates for the organization of care studies and patient and/or provider perceptions studies are shown in Appendix F and Appendix G respectively.

4.5.1.2 Outcome Measure Data

Where available, outcome data were extracted from all quantitative intervention studies and entered into separate tables. There was a table for all relevant outcome measures (i.e. weight, BMI, blood pressure, lipids, hemoglobin A1c). Each study may have had data entered on more than one outcome data table. For a given study and outcome measure (e.g. weight), the sample size, mean, and standard deviation were collected and entered at baseline, post-intervention follow-up and additional follow-up periods, when available.

4.5.1.3 Excel Spreadsheets

Similar to the screening tool and QA tool, a research assistant (EA) was hired to create the intervention summary table (including outcome data tables) in Microsoft Excel.

This allowed for data to be entered with more flexibility and efficiency. For the main summary table, each column was dedicated to one study while each row represented different aspects of the summary. A coding scheme was provided in the spreadsheet (instructions for each row) in order to improve efficiency and consistency of data entry. For the outcome data tables, each row was dedicated to one study, while the columns represented the outcome data. Moreover, Visual Basic (programming software) was used to enable the: 1. Summary tables to be converted into individual tables in a Microsoft Word document; 2. Summary tables to be transposed so that the columns became rows and rows become columns (may choose to select certain columns only); and 3. Transposed tables to be converted into a Microsoft Word document so that characteristics or results could be compared across studies.

4.5.1.4 Multiple Articles per Study

Through the screening process, all relevant citations were selected; however, there were often multiple articles which were written on the same study (e.g. articles reporting the study protocol, process measures, clinical outcomes, qualitative data etc). In these cases, all related articles were amalgamated and discussed as one study. Therefore, quality assessments and summaries were completed for each study (as opposed to each article).

4.5.2 Collating, Summarizing and Reporting Results

4.5.2.1 Descriptive Data- All Included Intervention Studies

Basic descriptive data for all included intervention studies were calculated by country of origin, target group, intervention delivery channels, intervention providers, and intervention provider education.

4.5.2.2 Heterogeneity of Studies

Weight management is a broad and complex issue, and studies could be categorized in various ways, depending on the perspective taken. While a population-based approach is generally promoted for planning services, most studies were focused on interventions for particular diseases. Since the disease approach was dominant; it was used to create initial mutually exclusive categories of studies for descriptive purposes (as mentioned above). It was expected, however, that strategies developed in diabetes for example, might also apply to patients with dyslipidemia or hypertension.

4.5.2.3 Evaluating and Analyzing Complex Interventions

The intervention studies reviewed all fall into the category of complex interventions, which are becoming an increasing focus for review. The UK Medical Research Council defines complex interventions as those comprising “a number of separate elements which seem essential to the proper functioning of the interventions although the ‘active ingredient’ of the intervention that is effective is difficult to specify” (Medical Research Council, 2000, page 1). These interventions for example, may involve a wide range of health professionals delivering various treatments. They include several components which may be independent or inter-dependent.

When conducting a review, complex interventions are inherently difficult to evaluate and synthesize. As such, there have been a number of suggestions on how to analyze such interventions (Shepperd et al., 2009). Among the various approaches, realist reviews take the stance that it is important to understand the context for an intervention as much as whether it works or not. In this approach, the focus is on the lessons learned that will inform changes in the health care delivery system. Focusing on promising results is

a typical and well-established approach in emerging research areas, in contrast to typical approaches in SLRs which focus on finding an average effect for a specific intervention. In the case of the current analysis, the purpose was to identify promising strategies. Therefore, studies were first identified for the net effect of the intervention. A clinically relevant mean change for the outcome was chosen as a cut-point to facilitate review. Potentially more effective studies were then reviewed in detail to understand the context, and a judgment was made on the potential usefulness of the interventions in Canadian IP-PC. Three broad categories were used: likely to be promising, potentially promising, and unlikely to be promising. Quality assessment was principally used in the description of the key elements of the studies and informed judgment on promising elements of interventions.

5 RESULTS

5.1 Included Studies

The initial search yielded 26,075 titles and abstracts to be screened. Of these, 1039 met the initial eligibility criteria and were further reviewed (full-text screen). An additional 91 citations were handpicked (from reviews or citations which were part of a larger study) and screened. Once the full-texts were reviewed, only 32% (360 citations/225 unique studies) met the final eligibility criteria and were included in the review. Fifty-three percent of citations were excluded, 3% were set aside for background information, and 12% were reviews (reference lists screened for potentially relevant articles).

Of those studies chosen to be included, 78% (176 studies) were intervention studies, while the remaining addressed organization of care (16%, 35 studies) and patient and/or provider perceptions (6%, 14 studies).

Figure 1: Flowchart for Screening Process

For the purposes of this thesis, results and discussion will focus on the intervention studies. The aim of this review is to search for promising weight management studies in IPC, therefore, results will be focused specifically on those which reported BMI or weight. Almost 50% of studies were targeted at those with type 2 diabetes, making A1c the second most important clinical outcome to be assessed for promising approaches.

5.2 Reporting Descriptive Data- Included Intervention Studies

After conducting quality assessments on intervention studies, it was found that the majority were rated as weak (61%), sixty-seven studies were rated as moderate (38%) and only two were rated as strong (1%). The methodologically strong studies will be examined in detail below, and the quality of all interventions studies will be discussed in the “discussion” section.

The large majority of studies were published in the US (44%), followed by the UK (19%), Netherlands (8%), Australia (6%), Canada (5%), Sweden (3%), and a combination of European countries (3%). The remaining 11 countries published less than 5 studies each.

Figure 2: # of Studies by Country of Origin

Most prominent were the 48% of studies for type 2 diabetes, followed by 12% directed at those at high CVD risk, and the rest among diverse groups (all groups $\leq 7\%$ of studies).

Figure 3: % of Studies by Unique Target Group

The large majority of studies included one-on-one counselling (a variety of providers), with many including telephone counselling, group counselling and provider education. Mailed materials and computer/web-based tools were used much less often. Various combinations of these delivery methods were employed.

Figure 4: % of Studies by Delivery Channel¹

¹More than one delivery method may be indicated for each study

Most prominent was the involvement of allied health care providers (other than RDs), followed by MD/RN/NPs only, RDs, and then other educators. Lay persons were seldom involved.

Figure 5: % of Studies by Provider¹

¹More than one type of provider may be indicated for each study

5.3 Weight/BMI Studies

5.3.1 Defining Clinical Relevance

Out of the 176 intervention studies, 73 reported mean BMI or weight at baseline and follow-up. To explore which of these 73 studies used promising or potentially promising approaches for weight management, studies were first selected based on whether participants achieved clinically relevant weight loss. For the purposes of this review, clinically relevant was defined as a mean $\geq 3\%$ weight loss or a decrease of ≥ 1

BMI unit on a group basis. Modest weight loss has been found to contribute to important health benefits (Christian, Tsai, & Bessesen, 2010; Jackson, Coe, Cheater, & Wroe, 2007).

Losing $\geq 5\%$ of initial weight in an individual has been considered clinically relevant as many studies have shown that this percentage of weight loss is associated with clinical improvements including decreased incidence of type 2 diabetes for those at risk (Franz et al., 2007; Hamman et al., 2006; Klein et al., 2004; Scottish Intercollegiate Guidelines Network, 1996 as cited in Jackson et al., 2007; Tuomilehto et al., 2001), improved glucose control for those with type 2 diabetes (Klein et al., 2004), reductions in blood pressure (Franz et al., 2007; Klein et al., 2004; Scottish Intercollegiate Guidelines Network, 1996 as cited in Jackson et al., 2007), and improved lipid profiles (Franz et al., 2007, Klein et al., 2004).

A mean weight loss of $\geq 3\%$ on a group basis was chosen as a realistic cut-point given the typical attrition of up to 50% in weight loss intervention programs in PC practices (Counterweight Project Team, 2008). Additionally, effectiveness studies in primary care will not yield the same results as efficacy (phase II) studies in a highly controlled setting with highly motivated participants. Lastly, some studies have shown that even weight loss of $< 5\%$ may still be clinically relevant. Analysis of the Diabetes Prevention Program (DPP) lifestyle intervention data found that diabetes risk reduction began with losses as low as 2% weight loss (Christian et al., 2010). Results demonstrated that for every kilogram lost, patients with impaired glucose tolerance experienced a 16% reduction in risk of developing diabetes (Hamman et al., 2006). For these reasons, a weight loss of $\geq 3\%$ was chosen as the cut-point for studies to be considered clinically

relevant. As previously mentioned, for those studies that did not report weight, clinically relevant was also defined as a decrease of ≥ 1 BMI unit. It must be acknowledged, however, that this is not always equivalent to $\geq 3\%$ weight loss. As weight increases, a decrease of 1 BMI unit is equivalent to a lower percentage weight loss. The approximate height and weight which would make a decrease of 1 BMI unit equivalent to a 3% weight loss was relevant to the range of patients seen for weight management in primary care (e.g. At 170 cm, a BMI of 33 decreased to a BMI of 32 = 3% weight loss). The two methodological strong studies were also reviewed further.

5.3.2 Characteristics of Clinically Relevant Studies

Using the above criteria, 16% of studies (12 studies) which reported weight or BMI demonstrated clinically relevant results. Table 2 shows the main findings for all 73 studies (the 12 clinically relevant studies are bolded). This summary table indicates only key features as follows: Different interventions reported in the same study are shown as separate rows; Overall Quality refers to the results of the quality assessment; Intervention Length refers to the active intervention period as defined by authors, while F/U refers to additional follow-up assessment beyond the intervention period. If conducted, mean pre- and post data for the intervention group follow (based on latest follow-up period). If a control group was included, the NET change in BMI and weight are shown in the final 2 columns. Control group pre-post data are not shown.

Table 2: Summary of Results- All Weight/BMI Studies^{1,2,3,4}

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Absetz et al., (2007) Int #1- Females	Weak	8	12	270	32.5	86.0	0.2	0.6		
Absetz et al., (2007) Int #2- Males	Weak	8		91	32.0	100.0	0.5	1.5		
Adolfsson et al., (2007)	Moderate	7	12	42	30.4		0.4		0.2	
Amoroso et al., (2009)	Weak	1 session ± referral	3	118	26.1		0.0			
Andrews & Holland (2003)	Weak	3		119	33.5		0.8			
Benner et al., (2008)	Moderate	6		565		87.8		1.3		0.9
Bo et al., (2007)	Strong	12		169	29.7	81.7	0.3	0.9	0.9	3.2
Boegner et al., (2008)	Weak	1-2 sessions	6	427		80.2		0.0		
Botomino et al., (2008) Int #1- Intensive	Weak	1 session ± check-ups	3, 6, 12	568	28.8	81.7	0.4	1.6	0.0	0.2
Botomino et al., (2008) Int #2- High Risk	Weak	1 session ± check-ups	3, 6, 12	245	29.0	83.6	0.8	2.9	0.4	1.5
Boyd et al., (2006)	Weak	12		48	35.0	99.0	1.0	5.5		
The California Medi-Cal Type 2 Diabetes Study Group (2004)	Moderate	12+	36	182	34.0	89.4	0.0	0.1	-1.2	-0.3
Cheng et al., (2004)	Moderate	4		91	30.6		0.4		0.2	
Christ et al., (2004) Int #1- Diet	Weak	36		20	31.1	84.7		10.5		11.5

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Christ et al., (2004) Int #2- Diet/PA	Weak	36		18	30.5	85.7		15.2		16.2
Ciardullo et al., (2003	Weak	unknown	avg. 23 (6-50)	5260	28.8	78.3	0.3	0.9		
Clark et al., (2003) Int #1- Adherence Group #3	Weak	12		18	35.5	92.7	1.1	2.2	1.3	4.0
Clark et al., (2003) Int #2- Adherence Group #2	Weak	12		17	36.0	93.0	0.3	-0.6	0.5	1.2
Clark et al., (2004)	Weak	3	12		32.4		0.3		0.3	
Cotton et al., (2006)	Weak	3		21	35.0		-0.1			
Cusack et al., (2008)	Weak	avg. 32.5 (2-77)		46	29.1		0.3			
Daley et al., (2008)	Weak	6		50	33.0	91.1	0.9	2.6		
Davies et al., (2008)	Strong	1 session+	4, 8, 12	437		91.8		3.3		1.2
El Fakiri et al., (2008)	Weak	9	12	137	30.2		0.7		0.3	
Elley et al., (2003)	Moderate	12		451	30.0		0.1		0.1	
Eriksson et al., (2006)	Weak	9	12	75	30.1	87.0	0.5	1.7	0.3	0.9
Fluker (2005)	Moderate	2.5		31		87.0		2.9		2.7
Gabbay et al., (2006)	Moderate	12		150		93.6		-0.4		1.6
Gambino et al., (2009)	Weak	± 15		693	29.0		-0.2			
Georgiou et al., (2006)	Weak	24		2731	30.5		0.1			
Greaves et al., (2008)	Moderate	6		72		91.6		0.3		-1.6
Gusi et al., (2008)	Moderate	6		64	29.7		0.3		0.1	

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Hardcastle et al., (2008)	Weak	6		203	33.7	93.7	0.2	0.7	0.2	0.6
Haskell et al., (2006)	Moderate	6 or 12		99	30.4		0.0		0.3	
Hornsten et al., (2005)	Moderate	9	12	44	29.4		0.7		1.5	
Isaacs et al., (2007) Int #1- Leisure Centre	Weak	2.5	6	317	30.7	83.0	0.2	0.8	0.3	1.3
Isaacs et al., (2007) Int #2- Walking	Weak	2.5	6	311	30.6	82.4	0.1	0.1	0.2	0.6
Ismail et al., (2006)	Weak	12	72	442		80.5		-3.4		-2.2
Jackson et al., (2007)	Weak	12		89	37.1	102.1	4.0	10.3		
Janssen et al., (2009)	Moderate	12		255	31.2		1.4		1.6	
Kinmonth et al., (2008) Int #1- Telephone	Moderate	12		124	27.8	79.9	-0.6	-2.1	-0.6	-2.3
Kinmonth et al., (2008) Int #2- In Person	Moderate	12		120	27.7	78.6	0.0	-0.6	0.0	-0.4
Kirk et al., (2004)	Moderate	6 (mid int)		35	35.4		-0.2		-0.6	
Korhonen et al., (2003)	Weak	24		360		81.1		2.2		1.7
Kramer et al., (2009) Int #1- Phase I	Weak	3		51	36.6	98.2	0.9	2.1		
Kramer et al., (2009) Int #2- Phase II	Weak	3	12	42	34.6	94.7	1.5	4.8		
Laatikainen et al., (2007)	Weak	8	12	237	33.5	91.7	0.9	2.8		
Lawton et al., (2009)	Moderate	9	24	544		73.2		0.8		0.5
Lemon et al., (2004)	Weak	up to 6 (1-6 sessions)	6	244	34.6	101.8	0.9	2.8		

				INTERVENTION GROUP					NET (Intervention- Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Lin et al., (2007)	Weak	up to 36 (≥ 2 sessions)		33		87.7		-1.3		-1.2
Little et al., (2004) Int #1- Booklet	Moderate	1	6	152		82.0		-0.5		
Little et al., (2004) Int #2- Low Sodium	Moderate	1	6	138		82.0		-0.9		
Little et al., (2004) Int #3- Prompts	Moderate	1	6	145		82.0		1.5		
Ma et al., (2009) Int #1- Females	Moderate	15		137	35.2		0.2		0.2	
Ma et al., (2009) Int #2- Males	Moderate	15		75	33.1		0.3		0.4	
Mayer-Davis et al., (2004) Int #1- Intensive	Moderate	12		49	37.6	99.5	1.0	2.2	0.8	1.9
Mayer-Davis et al., (2004) Int #2- Reimbursable	Moderate	12		47	37.5	100.0	0.3		0.1	
Mensink et al., (2003)	Weak	24		55	29.8	86.0	0.8	2.8	0.8	2.7
Meulepas et al., (2008)	Moderate	12		427	28.7		-0.5		-0.6	
Moore et al., (2003)	Weak	up to 18	12, 18	415	37.0	100.8	-0.1	0.0	-0.1	-0.7
Munsch et al., (2003) Int #1- GP BASEL	Weak	16 sessions	12 after int. end	53	36.2	96.8	1.8	4.9	1.6	4.4
Munsch et al., (2003) Int #2- Clinic BASEL	Weak	16 sessions	12 after int. end	52	38.5	106.8	0.9	2.7	0.7	2.2
Murphy et al., (2009)	Weak	up to 18	18	437	28.7		0.3		0.2	
Oldroyd et al., (2006)	Moderate	24		37		85.3		2.1		3.9
Petrella et al., (2003)	Moderate	1 session	12	131	28.2		0.6		0.0	

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Read et al., (2004)	Weak	12		216	39.7	108.0	4.2	10.6		
Richardson et al., (2008)	Weak	1 session ± referral	12	290		79.0		-0.4		
Rothman et al., (2005)	Moderate	up to 12	12	112		101.0		-1.9		-1.8
Schillinger et al., (2009) Int #1- ATSM	Moderate	9	12	112	30.3		-0.4		-1.3	
Schillinger et al., (2009) Int #2- GMV	Moderate	9	12	113	31.9		-0.5		-1.4	
Scott et al., (2006)	Moderate	3	6, 9	76	36.4	102.4	0.4	1.8	0.2	0.6
Smith et al., (2004)	Moderate	up to 18	18	96	30.3		-1.3		-0.8	
Steuten et al., (2007)	Weak	up to 24	24	473	29.8		0.5			
Taylor et al., (2003)	Moderate	11	12	61	34.6		-0.5		-0.8	
Thoolen et al., (2007) Int #1- Intensive + Course	Moderate	3	12	39	29.8		0.4		0.6	
Thoolen et al., (2007) Int #2- Intensive + Control	Moderate	3	12	52	29.5		-0.5		-0.3	
Thoolen et al., (2007) Int #3- Usual + Course	Moderate	3	12	50	29.8		0.4		0.6	
Tonstad et al., (2007)	Weak	6		29	27.7	82.2	-0.2	-0.6	0.2	0.8
Tranche et al., (2005)	Weak	12		3466	28.9		0.9			
Tudor-Locke et al., (2004)	Weak	4		24		96.8		0.7		0.2
van Bruggen et al., (2008)	Moderate	up to 12	12	822	29.7		0.1		0.1	
VanWormer et al., (2004)	Weak	4		22	29.4		0.4			
Varroud-Vial et al., (2004)	Weak	up to 12	12	192	30.5		0.1		-0.3	

				INTERVENTION GROUP					NET (Intervention-Control)	
				Baseline			Baseline-Post or F/U			
Author/Date	Overall Quality	Intervention Length (mo.)	F/U (mo.)	N	Mean BMI (kg/m ²)	Mean Weight (kg)	Δ in BMI (kg/m ²)	% Weight Loss	NET Δ BMI	NET % WEIGHT LOSS
Verheijden et al., (2004)	Moderate	8		73	29.5		0.0		0.0	
Willaing et al., (2004)	Moderate	12		312	33.0		1.1		0.2	
Wolf et al., (2004)	Moderate	12		73		107.1		2.2		2.8
Woollard et al., (2003) Int #1- High	Weak	12	18	74	30.3	85.6	-0.4	-0.6	0.2	1.8
Woollard et al., (2003) Int #2- Low	Weak	12	18	57	28.0	78.0	-0.4	-0.6	0.2	1.8
Zwar et al., (2007)	Weak	12+		230		85.9		-0.1		

¹ All studies bolded author/date demonstrated clinically relevant weight loss ($\geq 3\%$ weight loss OR decrease of ≥ 1 BMI unit); OR were strong studies.

² All studies with author/date which are not bolded did not demonstrate clinically relevant weight loss

³ References for studies that did not demonstrate clinically relevant results are found in Appendix O

⁴ mo.= months, int= intervention, F/U= last follow-up measurement

Over half of the clinically relevant studies were conducted in the US and UK, and the remaining five studies were all conducted in different countries (The Netherlands, Switzerland, Denmark, Italy and Germany). The majority were targeted at patients with type 2 diabetes (42%) and mixed CVD risk factors (25%), while the rest were targeted at patients who were overweight or obese (17%), had established CHD (8%), and a combination of chronic conditions (8%). Compared to the 73 studies which reported weight or BMI, these 12 clinically relevant studies, included much more group counseling (9/12 vs. 40%), less face-to-face one-on-one counseling (7/12 vs. 77%), no telephone counseling (0/12 vs. 27%), no mailed materials (0/12 vs. 4%), no computer or web-based counseling (0/12 vs. 1%), and more provider education (6/12 vs. 40%).

Descriptions of provider education were divided into three levels, based on the amount of detail reported in the study (with higher levels indicating more detail). Level 1 generally indicated some provider education with minimal detail, Level 2 indicated the use of provider education with some detail, and Level 3 indicated substantive focus on provider education. There were fewer clinically relevant studies which included provider education at level 1 (2/6 vs. 45%), a similar percentage for level 2 (2/6 vs. 31%), and slightly more studies which included provider education at level 3 (2/6 vs. 28%).

Furthermore, more studies included RDs (7/12 vs. 41%), a similar percentage included other educators (3/12 vs. 23%), and fewer studies involved other allied health professionals (3/12 vs. 40%), and an MD/RN/NPs only (2/12 vs. 27%). Lastly, no studies included lay persons (0/12 vs. 3%). Table 3 and Table 3a describe further study characteristics and details on the intervention.

Table 3: Study Characteristics- Clinically Relevant Weight/BMI Studies

Author/ Date	Study Design	Target Group	Patients	Social Cognitive Theory	Health Belief Model	Transtheoretical Model	Theory of Planned Behaviour	Other Theory	No Theory Used
Bo et al., (2007)	RCT	Dysmetabolic patients between the ages of 45 and 64.	Intervention group: n=169 Control group: n=166						Yes
Boyd et al., (2006)	Cohort (1 group)	"low-income patients with type 2 diabetes."	n=48 No control group						Yes
Christ et al., (2004)	CCT (2 int groups)	Patients with unmedicated, uncomplicated HTN and two additional symptoms of the metabolic syndrome.	Diet group: n =20 Diet/exercise group: n=18 Control group: n=14						Yes
Clark et al., (2003)	Cohort (1 group)	"older adult, female primary care patients in two neighborhood community health centers."	n=71 No control group						Yes
Davies et al., (2008)	RCT	Adults with newly-diagnosed diabetes.	Control group: n=387 Intervention group: n=437					Yes	
Jackson et al., (2007)	Cohort (1 group)	Individuals with a BMI over 30.	n=89 No control group						Yes

Author/ Date	Study Design	Target Group	Patients	Social Cognitive Theory	Health Belief Model	Transtheoretical Model	Theory of Planned Behaviour	Other Theory	No Theory Used
Janssen et al., (2009)	RCT	Patients with diabetes.	Intervention: n=255 Control group: n=243						Yes
Kramer et al, (2009)	Cohort (1 group x2)	Patients with type 2 diabetes.	Phase 1 intervention: n=51 Phase 2 intervention: n=42						Yes
Mayer-Davis et al., (2004)	RCT (2 int groups)	Patients 45 years or older with diabetes, BMI of ≥ 25 (kg/m ²) during the previous calendar year.	Intensive lifestyle group: n=49 Reimbursable lifestyle group: n=47 Control group: n=56						Yes
Munsch et al., (2003)	RCT (2 int groups)	Patients from a clinical centre that were obese (BMI ≥ 30 kg/m ²).	GP BASEL group: n=53 Clinic BASEL group: n=52 GP Control Group: n=17	Yes					
Read et al., (2004)	Cohort (1 group)	Adults with BMI ≥ 30 , and CHD risk factors such as HTN, CHD, type 2 diabetes, or a family history of CHD."	n=216 No control group						Yes
Willaing et al., (2004)	RCT	Patients with a high BMI, large waist circumference, dyslipidemia, or type 2 diabetes.	Dietitian group: n=312 GP group: n=191					Yes	

Table 3a: Intervention Details for Clinically Relevant Weight/BMI Studies

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Bo et al, (2007)	Family physician, "trained professionals (nutritionists, specialists in endocrinology, and internal medicine)."	One-on-one, face to face counseling with group sessions.	1 year intervention consisting of 5 sessions of at least 60 minutes.	12 months (immediate post-intervention)
Boyd et al., (2006)	Exercise coach (pharmacist, RN, licensed practical nurse, or medical assistant).	Group exercise class involving motivation, encouragement, and initiating goal setting.	"All patients received free exercise classes twice per week lasting up to 12 months." Each exercise class was approximately 1 hour.	12 months (immediate post-intervention)
Christ et al., (2004)	"A trained exercise physiologist supervised all exercise sessions." Article does not directly indicate who facilitated the dietary counselling - may have been "trained experts."	Dietary counselling - one on one sessions with additional group sessions for support. Exercise program - group training.	Dietary counselling - "Patients were weekly trained for all nutritional aspects for the first 4 weeks and subsequently every 2 weeks" (36 month program). Additional supportive group sessions were conducted in 2-4 week intervals. Exercise classes - "Regular training program...was performed two times per week...The exercise routine consisted of 15 min of warm up exercises, 40 min of endurance training ...and 15 min of cool down exercise."	Clinical parameters were measured at baseline, 3, 6, 12, 24, and 36 months (immediate post-intervention).
Clark et al., (2003)	Research assistant and other study personnel.	Group exercise classes.	1 year intervention. "Patients were encouraged to attend at least three exercise classes per week...Classes consisted of 20 minutes of chair-based or standing leg and arm movements and up to 30 minutes of indoor walking."	12 months (immediate post-intervention)

Davies et al., (2008)	"Registered healthcare professionals" (practice nurse or dietitian).	Structured group education programme. Likely had one on one counselling following this programme.	"The programme was six hours long, deliverable in either one day or two half day equivalents." Patients were offered access to diabetes education afterwards (not part of main intervention).	4, 8, and 12 months follow-up. No immediate-post-intervention measurement reported.
Jackson et al., (2007)	Specialist health visitor (public health nurse) and physician.	Face to face, individual counselling.	"Participants' first appointment with the specialist health visitor was within 3 weeks of the initial referral [approx. 1 hr]. Participants were seen subsequently at two weekly intervals for 12 months [approx. 20 minutes]. Contact after 12 months was negotiated, depending on need."	Data were collected at week 1 (baseline), 13, 27 and 52 (immediate post-intervention).
Janssen et al., (2009)	Physicians and diabetes nurses.	One-on-one, face to face counselling during office visits.	After diagnosis of type 2 diabetes, patients "were first seen by their GP" and then had subsequent visits with the diabetes nurse "2, 4, 6, 8, and 12 weeks after diagnosis until target levels were reached. Thereafter, patients were requested to visit the GP or nurse every 3 months. One year after screening, an extensive visit to the GP took place."	12 months (immediate post-intervention)
Kramer et al., (2009)	Phase 1- nurse health educator, exercise specialist. Phase 2- registered dietitian, registered nurse, exercise specialist.	Group education classes for patients.	"12 weekly 1-hour sessions delivered over 12-15 weeks."	3 months (immediate post-intervention), 12 months follow-up (for Phase 2 group only)
Mayer-Davis et al., 2004	Study nutritionists	Individual and group counselling; face to face.	1 year intervention; "Intensive-lifestyle participants met weekly with the study nutritionist for delivery of the first 4 months of the core curriculum (intensive), every other week for the next 2 months (transition), and once a month for the remaining 6 months (maintenance)."	12 months (immediate post-intervention)

Munsch et al., (2003)	GP BASEL Group- GP Clinical BASEL- "treated by an interdisciplinary team consisting of a trained physician, a psychologist and a dietician".	Group counseling for patients.	16 group sessions of 90 min each. No information on frequency or duration provided.	On completion of the 16 sessions (immediate-post; time frame not given), and 12 months after the intervention had ended.
Read et al., (2004)	Dietitian	Face to face group education sessions.	"Seven 2-hour education and support group sessions were run by the dietitian at intervals of 2 weeks. Further 2-hour sessions were delivered at 4 months, 6 months, 9 months, and 12 months."	3 months (end of intensive stage), and 12 months (end of maintenance stage; immediate-post intervention).
Willaing et al., (2004)	Dietitian and general practitioner.	One on one, face to face counselling.	12 month intervention with 5 counselling sessions by either GP or dietitian. GP group- "the initial counselling session was assumed to be approximately 30 min and the following sessions approximately 12 min. Dietitian group- "the initial session was assumed to be approximately 1h and later sessions approximately 30 min. The dietitian briefed the GP on the phone after 6 and 12 months." The intervention by the dietitian was by referral.	12 months (immediate post-intervention).

5.3.3 Interpreting by Appraising the Quality of Evidence

Detailed tabular results for the 12 studies with quality assessment results are shown in Tables 4-6. Weight results are shown in Table 4, BMI results in Table 5, and QA results in Table 6.

Table 4: Weight Results Table- Clinically Relevant Studies

			INTERVENTION GROUP										
			Baseline			Post-Intervention			F/U			Difference (Baseline-Post or F/U)	
Author/Date	Int Length (months)	F/U (months)	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	$\bar{x}$ Δ Wt (kg)	% Wt Loss
Bo et al., (2008)	12		169	81.7	14.9	169	81.0	15.7				0.7	0.9
Boyd et al., (2006)	12		48	99.0		35	93.6					5.4	5.5
Christ et al., (2004) Int #1- Diet	36		20	84.7	4.4	20	75.8	4.1				8.9	10.5
Christ et al., (2004) Int #2- Diet/PA	36		18	85.7	5.7	18	72.7	4.9				13.0	15.2
Clark et al., (2003) Int #1-Adherence Group#3	12		18	92.7	21.4	18	90.7					2.0	2.2
Clark et al., (2003) Int #2- Adherence Group#2	12		17	93.0	17.8	17	93.6					-0.6	-0.6
Davies et al., (2008)	1 session +	4, 8, 12	437	91.8	19.2				417	88.8		3.0	3.3
Jackson et al., (2007)	12		89	102.1	17.8	29	91.6	19.0				10.8	10.3
Janssen et al., (2009)	12		255			255							
Kramer et al., (2004) Int #1- Phase I	3		51	98.2	19.2	51	96.1	19.5				2.1	2.1
Kramer et al., (2004) Int #2- Phase II	3	12	42	94.7	16.9	42	90.2	17.7	42	90.5	18.6	4.2	4.4
Mayer-Davis et al., (2004) Int #1- Intensive	12		49	99.5	17.1	49	97.3					2.2	2.2
Mayer-Davis et al., (2004) Int #2- Reimbursable	12		47	100.0	19.8								

			INTERVENTION GROUP										
			Baseline			Post-Intervention			F/U			Difference (Baseline- Post or F/U)	
Munsch et al., (2003) Int #1- GP BASEL	16 sessions	12 after int. end	53	96.8	17.1	41	93.0	17.6	41	92.1	18.2	4.7	4.9
Munsch et al., (2003) Int #2- Clinic BASEL	16 sessions	12 after int. end	52	106.8	26.1	33	105.2	26.1	16	103.9	21.8	2.9	2.7
Read et al., (2004)	12		216	108.0	20.0	73	96.5	16.9				11.5	10.6
Willaing et al., (2004)	12		312			312							

	CONTROL GROUP											
	Baseline			Post-Intervention			F/U			Difference (Baseline- Post or F/U)		
Author/Date	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	$\bar{x}$ Δ Wt (kg)	% Wt Loss	NET % Wt Loss (Intervention- Control)
Bo et al., (2008)	166	81.3	13.5	166	82.9	14.0				-1.9	-2.3	3.2
Boyd et al., (2006)												
Christ et al., (2004) Int #1- Diet	14	83.0	5.8	14	83.8	5.4				-0.8	-1.0	11.5
Christ et al., (2004) Int #2- Diet/PA	14	83.0	5.8	14	83.8	5.4				-0.8	-1.0	16.2
Clark et al., (2003) Int #1-Adherence Group#3	36	91.4	24.8	36	93.0					-1.6	-1.8	4.0
Clark et al., (2003) Int #2- Adherence Group#2	36	91.4	24.8	36	93.0					-1.6	-1.8	1.2
Davies et al., (2008)	387	91.6	20.2				387	89.7		1.9	2.1	1.2
Jackson et al., (2007)												
Janssen et al., (2009)	243			243								
Kramer et al., (2004) Int #1- Phase I												
Kramer et al., (2004) Int #2- Phase II												
Mayer-Davis et al., (2004) Int #1- Intensive	56	93	20.3	56	92.7					0.3	0.3	1.9
Mayer-Davis et al., (2004) Int #2- Reimbursable	56	93	20.3	56	92.7							
Munsch et al., (2003) Int #1- GP BASEL	17	86.3	6.4	12	85.6	6.8	8	85.9	9.2	0.4	0.5	4.4
Munsch et al., (2003) Int #2- Clinic BASEL	17	86.3	6.4	12	85.6	6.8	8	85.9	9.2	0.4	0.5	2.2
Read et al., (2004)												
Willaing et al., (2004)	191			191						-2.5		

Table 5: BMI Results Table- Clinically Relevant Studies

			INTERVENTION GROUP										
			Baseline			Post-Intervention			F/U			Difference (Baseline-Post or F/U)	
Author/Date	Intervention Length (mo.)	F/U (mo.)	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	Δ BMI (kg/m ²)	% Δ in BMI
Bo et al., (2008)	12		169	29.7	4.1	169	29.4	4.4				0.3	1.0
Boyd et al., (2006)	12		48	35		35	34					1	2.9
Christ et al., (2004) Int #1- Diet	36		20	31.1	1.7	20							
Christ et al., (2004) Int #2- Diet/PA	36		18	30.5	1.7	18							
Clark et al., (2003) Int #1-Adherence Grp#3	12		18	35.5	7.9	18	34.4					1.1	3.1
Clark et al., (2003) Int #2- Adherence Grp#2	12		17	36.0	7.0	17	35.7					0.3	0.8
Davies et al., (2008)	1 session +	4, 8, 12	437						417				
Jackson et al., (2007)	12		89	37.1	5.5	29	33.1	5.7				4	10.5
Janssen et al., (2009)	12		255	31.2	5.1	255	29.8	4.8				1.4	4.5
Kramer et al., (2004) Int #1- Phase I	3		51	36.6	7.4	51	35.7	7.5				0.9	2.5
Kramer et al., (2004) Int #2- Phase II	3	12	42	34.6	5.4	42	33.0	5.8	42	33.1	5.9	1.5	4.4
Mayer-Davis et al., (2004) Int #1- Intensive	12		49	37.6	6.5	49	36.6					1.0	2.7
Mayer-Davis et al., (2004) Int #2- Reimbursable	12		47	37.5	6.7	47	37.2					0.3	0.8
Munsch et al., (2003) Int #1- GP BASEL	16 sessions	12 after int end	53	36.2	6.5	41	34.8	6.6	41	34.4	6.8	1.8	5.0
Munsch et al., (2003) Int #2- Clinic BASEL	16 sessions	12 after int end	52	38.5	7.5	33	38.0	7.8	16	37.6	6.4	0.9	2.3
Read et al., (2004)	12		216	39.7	6.9	73	35.5	5.5				4.2	10.6
Willaing et al., (2004)	12		312	33.7		312	32.6					1.1	

	CONTROL GROUP											NET (Intervention- Control)
	Baseline			Post-Intervention			F/U			Difference (Baseline- Post or F/U)		
Author/Date	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	N	$\bar{x}$ BMI (kg/m ²)	SD BMI	Δ BMI (kg/m ²)	% Δ in BMI	NET Δ BMI
Bo et al., (2008)	166	29.8	4.6	166	30.4	4.8				-0.6	-2.0	0.9
Boyd et al., (2006)												
Christ et al., (2004) Int #1- Diet	14	29	1.8	14								
Christ et al., (2004) Int #2- Diet/PA	14	29	1.8	14								
Clark et al., (2003) Int #1-Adherence Group#3	36	34.7	7.3	36	34.9					-0.2	-0.6	1.3
Clark et al., (2003) Int #2- Adherence Group#2	36	34.7	7.3	36	34.9					-0.2	-0.6	0.5
Davies et al., (2008)	387						387					
Jackson et al., (2007)												
Janssen et al., (2009)	243	30.4	4.6	243	30.6	4.8				-0.2	-0.7	1.6
Kramer et al., (2004) Int #1- Phase I												
Kramer et al., (2004) Int #2- Phase II												
Mayer-Davis et al., (2004) Int #1- Intensive	56	35.2	7.5	56	35					0.2	0.6	0.8
Mayer-Davis et al., (2004) Int #2- Reimbursable	56	35.2	7.5	56	35					0.2	0.6	0.1
Munsch et al., (2003) Int #1- GP BASEL	17	32.6	1.8	12	32.3	2	8	32.4	2.7	0.2	0.6	1.6
Munsch et al., (2003) Int #2- Clinic BASEL	17	32.6	1.8	12	32.3	2	8	32.4	2.7	0.2	0.6	0.7
Read et al., (2004)												
Williaing et al., (2004)	191	32.5		191	31.6					0.9	2.8	0.2

Table 6: Quality Assessment Summary Table- Clinically Relevant Weight/BMI Studies

Author/Date	Selection Bias		Study Design		Confounders	Blinding	Data Collection	Withdrawals & Dropouts		Analyses	GLOBAL RATING
	Are the individuals selected to participate likely to be representative of the target population?	Rating	Indicate the study design	Rating	Rating	Rating	Rating	% participants that completed the study	Rating	Intention to treat used?	
Bo et al., (2007)	Very likely	Strong	RCT	Strong	Moderate	Moderate	Strong	80-100%	Strong	N/A (no drop-outs)	STRONG
Boyd et al., (2006)	Somewhat likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Strong	60-79%	Moderate	No	WEAK
Christ et al., (2004)	Can't Tell	Weak	Cohort (2 group)	Moderate	Weak	Moderate	Strong	80-100%	Moderate	N/A (no drop-outs)	WEAK
Clark et al., (2003)	Very likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Moderate	< 60%	Weak	No	WEAK
Davies et al., (2008)	Somewhat likely	Moderate	RCT	Strong	Strong	Moderate	Strong	80-100%	Strong	No	STRONG
Jackson et al., (2007)	Somewhat likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Moderate	< 60%	Weak	No	WEAK
Janssen et al., (2009)	Somewhat likely	Moderate	CCT	Strong	Weak	Moderate	Strong	80-100%	Strong	Yes	MODERATE
Kramer et al., (2009)	Somewhat likely	Weak	Cohort (1 group) x2	Strong	Weak	Moderate	Strong	60-79%	Moderate	Yes	WEAK
Mayer-Davis et al., (2004)	Very likely	Weak	CCT	Strong	Strong	Moderate	Strong	80-100%	Moderate	No	MODERATE
Munsch et al., (2003)	Not likely	Weak	CCT	Strong	Weak	Moderate	Weak	< 60%	Weak	No	WEAK
Read et al., (2004)	Not likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Strong	< 60%	Weak	No	WEAK
Williaing et al., (2004)	Somewhat likely	Moderate	RCT	Strong	Moderate	Moderate	Strong	60-79%	Moderate	Yes	MODERATE

These 12 studies were further evaluated in order to gain a better understanding of the context for the results. A key aspect of context was the “representativeness” of study participants. Therefore, we first focused on aspects of QA related to these sources of potential bias. A given intervention may be efficacious in a small group of highly motivated patients; however, it is the results which can be achieved in the range of patients seen in primary care which we are interested in. How representative a sample is includes the way in which patients were recruited, the sample size, and the percentage of participants who completed the study. Participants were considered very likely to be representative of the target population if they were randomly selected from a comprehensive list of individuals in the target population or if all eligible patients in the target population were recruited. They were deemed somewhat likely to be representative of the target population if they were referred from a source (e.g. by a provider at a clinic), and not likely to be representative if they were self-referred. Because attrition from programs is so high, the potential for bias in the analysis is substantial when results for program completers only are analysed.

Intention-to-treat analysis (ITT) stipulates that all participants are included in the statistical analysis and are analyzed according to the group to which they were assigned; regardless of what treatment they received (Sainani, 2010). Therefore, participants should be “analyzed as a member of their initial randomization group even if they refuse or discontinue the intervention, ‘cross over’ to another randomization group, miss follow-up measurements, or otherwise violate the study protocol” (Sainani, 2010, page 209). In the context of the present review, the main issue is attrition. Therefore, to perform ITT and analyze participants based on the groups to which they were assigned, various techniques

are used to input missing data to “account” for possible results among non-completers. In weight studies it is generally assumed that people maintain their last known or baseline weight. Of course, using ITT and inputting missing data cannot actually correct for the bias, which remains unknown. In spite of this, it does provide a method for understanding the possible range of typical results (Montori & Guyatt, 2001). If a study in the present review did not perform ITT, however attrition was less than 20%, this was considered acceptable as the completers would be representative enough of the original sample, based on sampling theory and in line with the QA tool categories. After interpreting results based on these aspects of the quality assessment, 6 of the 12 clinically relevant studies (8% of studies which reported BMI or weight) were considered promising or potentially promising. Reasoning for how each study was categorized is discussed below.

5.3.4 Studies likely to be Promising

The three studies described below demonstrated clinically significant results and strong study designs, therefore they were deemed likely to be promising for weight management in primary care. The criteria for a study to be “likely to be promising” includes the following:

- $\geq 80\%$ participant completion or ITT analysis used
AND RCT or CCT design
AND $n \geq 70$
OR
- $\geq 80\%$ completion AND $n \geq 10,000$

5.3.4.1 Davies et al., (2008)

Davies et al. conducted an RCT to evaluate the effectiveness of a diabetes education and self-management program for patients with newly diagnosed type 2 diabetes. Thirteen primary care practices were randomized to the intervention (structured group education programme) or control group. Most practices in both arms offered access to some kind of diabetes education such as one-on-one counseling with the practice nurse or dietitian, or referral to ad hoc group education initiatives. All practices were provided with a pack including evidence-based clinical guidelines in the form of treatment algorithms, notes on “breaking bad news”, and patient resources. Practices in the control arm were provided with the resources which enabled them to offer contact time with healthcare professionals equivalent to that provided by the intervention arm (used as they saw fit within their usual care routine). Within 12 weeks of diagnosis, patients in the intervention group attended a six hour long session focused on lifestyle factors and self-management, delivered by two registered health care professionals (in one day or two half days). The intervention was only intended as the “first step in an ongoing cycle of diabetes care.” Additionally, the healthcare professionals in the intervention practices received formal program delivery training, and were supported by a quality assurance component to ensure consistent delivery.

Mean weight at baseline was 91.8kg and 91.6kg for the intervention and control groups respectively. Weight was measured at 4, 8, and 12 months follow-up. At 12 months, mean weight loss was 3.2% in the intervention practices, and 2.0% in the control practices, yielding a net weight loss of 1.2%. Weight loss was significantly different between groups ($p=0.027$). Net weight loss was slightly higher at 12 months compared to

4 and 8 months follow-up, demonstrating that weight loss was maintained beyond the 6 months plateau period.

Aside from the study by Bo et al. (2007), this was the only other study which scored a strong quality assessment rating. Patients diagnosed with type 2 diabetes were referred within 4 weeks, and 74% agreed to participate. Although intention-to-treat analysis was not used, at 12 months, only 9% of patients were lost to follow-up. As this study achieved a moderate response rate, a large sample size (intervention n=437, control n=387), and low attrition rate, the program seems both acceptable and feasible in a primary care setting. As mentioned above, the control practices were resourced so that patients could receive an “enhanced” usual care. The control arm served as a robust comparator to the intervention arm; therefore, net percentage weight loss was unlikely to be artificially inflated. However, the control group still achieved moderate weight loss so strategies used for usual care also deserve attention. Overall, the combination of this initial group session (including training for providers) followed by enhanced ongoing diabetes care seems quite promising.

5.3.4.2 Janssen, Gorter, Stolk, & Rutten (2009)

This study is part of the international ADDITION study, which is an RCT for patients with screen-detected diabetes. In this study (ADDITION Netherlands- RCT), 56,978 non-diabetic registered patients aged 50-70 years, were invited to participate in a population-based screening program. After the screening, 586 new patients with diabetes were detected. This study was an RCT with practice-level randomization to an intensified treatment (n= 255) or to routine care (n= 243). The intervention practices addressed a change in the organization of care by offering provider decision support. GPs were

trained on treatment protocols (treatment of glucose, blood pressure, lipids, and lifestyle education) during a three hour session. Additionally, the diabetes nurses attended two hour training sessions (every 3 months) on the management of treatment algorithms and providing lifestyle education. When patients were first diagnosed, they were seen by their GP and subsequently visited the diabetes nurse at least 2, 4, 6, 8, and 12 weeks after diagnosis (until target levels were reached). Following this, patients were seen by the GP or nurse every 3 months until one year after screening. After one year, if targets were not reached, patients were referred to an internist. Patients in the control group received routine care from their GPs. These GPs followed treatment guidelines for medications but did not receive any detailed instructions about providing lifestyle education to patients.

At baseline, the mean BMI in the intervention and control groups was 31.2kg/m^2 and 30.4kg/m^2 respectively. After 12 months, the intervention group achieved a decrease of 1.4 BMI units. The control group gained 0.2 BMI units, inflating the net decrease in BMI to 1.6 units. Changes in BMI were significantly different between groups ($p<0.001$). This demonstrates that the provider education and frequent counseling sessions were effective in achieving weight loss, while routine care did not benefit patients.

The sample in this study is likely to be representative of the target population for several reasons. Approximately 500 GPs in the region were invited to participate, and 79 practices of those who were willing, were randomly selected to participate. All patients from these practices were invited to be screened for diabetes and the response rate was quite high at 85%. In the Netherlands, the entire population is registered with a GP, so patients who were screened were likely to be representative of the entire population. Additionally 99% of participants completed the study and intention-to-treat analysis was

used. Overall, this program is likely promising as it appears to be both feasible and effective.

5.3.4.3 Willaing, Ladelund, Jorgensen, Simonsen, & Nielsen (2004)

In this RCT, 60 GPs were randomized to give patients nutritional counseling (control group) or to refer patients to a dietitian (RD group). Patients were recruited if they were obese ($\text{BMI} \geq 30 \text{ kg/m}^2$), had abdominal obesity, dyslipidemia, or type 2 diabetes. Patients in the control group ($n=191$) received usual care provided by the GP, which consisted of general healthy eating advice. The initial session was approximately 30 minutes and the follow-up appointments were ~12 minutes long. Additionally, GPs attended a one day training session on motivational interviewing. Patients in the RD group ($n= 312$) received individual counseling which focused on good nutrition, grocery shopping, cooking methods, meal planning and exercise. The initial session was ~60 minutes and follow-up sessions were ~30 minutes.

At baseline mean BMI in the RD group was 33.7 kg/m^2 , and after the 12 month intervention, they achieved a decrease of 1.1 BMI units. At baseline, mean BMI for the control group was 32.5 kg/m^2 and they achieved a decrease of 0.9 BMI units. Therefore, net BMI change only 0.2 units (change in BMI was not significantly different between groups, $p=0.22$). This study demonstrated that brief GP counseling was nearly as effective as referral to an RD for comprehensive counseling sessions.

Although ITT analysis was used, authors also reported results for completers only (67%). Interestingly, if only completers are accounted for, patients in the RD group lost an additional 0.5 BMI units (1.6 BMI units), while there was no difference for those in the GP group (0.9 BMI units). These results indicate there was more variability among

the RD group, including a subgroup of patients who were able to adopt more changes and achieve greater weight loss. Overall, it appears the weight management strategies used in both groups appear to be promising.

5.3.5 Potentially Promising Studies

The three studies described below demonstrated clinically significant results; and had overall higher QA ratings. The criteria for a study to be “potentially promising” includes the following:

- Did not meet the criteria for studies “likely to be promising”
- Any study design (e.g. RCT, CCT, cohort)
- $\geq 80\%$ participant completion or ITT analysis used

AND $n \geq 35$

OR

- Strong quality assessment rating but results which are not clinically relevant

5.3.5.1 Mayer Davis et al., (2004)

The purpose of this RCT was to evaluate the effectiveness of two lifestyle interventions for diabetic patients living in rural communities. Patients from two primary health care centers aged 45 years or older, who had a clinical diagnosis of diabetes (may be on oral hypoglycemic agents or insulin therapy), and a BMI of 25 kg/m^2 or greater during the previous year, were eligible to participate. Patients were randomized into the “intensive-lifestyle” group ($n=49$), the “reimbursable-lifestyle” group ($n=47$), or the control group ($n=56$). The intensive-lifestyle intervention was modeled after the NIH Diabetes Prevention Program (DPP). Modifications to the DPP included greater use of

group sessions, simplification of written materials, encouraging low to moderate intensity PA for very sedentary individuals, and incorporating regionally/culturally appropriate aspects and examples. In this group, participants received counseling on nutrition and physical activity from the study nutritionist weekly for the first 4 months, every other week for the following 2 months, and once a month for 6 additional months. These sessions were conducted in a pattern of three group sessions, and one individual session. The reimbursable-lifestyle intervention was a condensed version, including a total of 4 one hour sessions (3 group, 1 individual) conducted over the course of 12 months. This intervention was created so that the time allotted for its delivery was similar to the number of hours reimbursed annually by Medicare for diabetes education. Control group participants only received one individual session with the nutritionist at the beginning of the study period. The two study nutritionists received training for the intervention protocols. Additionally, they had weekly conference calls with the university-based study nutritionist to ensure continual high quality program delivery, including appropriate responses to group or individual needs.

At baseline, mean weight was 99.5kg (BMI 37.6kg/m²), 100.0kg (BMI 37.5kg/m²), and 93.0kg (BMI 35.2kg/m²) for the intensive-lifestyle, reimbursable-lifestyle, and control groups respectively. After the 12 month program, the intensive-lifestyle group achieved a weight loss of 2.2% ($p<0.003$) and a decrease of 1.0 BMI unit ($p<0.001$), while the reimbursable-lifestyle only achieved a decrease of 0.3 BMI units (not significant; no weight loss reported). The control group only achieved a weight loss of 0.3% ($p=0.055$), and a decrease of 0.2 BMI units (not significant), therefore net weight

loss for the intensive-lifestyle group was 1.9%. Net decrease in BMI was 0.8 units and 0.1 units for the intensive-lifestyle and reimbursable-lifestyle groups respectively.

It is likely that the sample was representative of the target population as all eligible participants were identified through a diabetes registry and subsequently contacted; however, the response rate was quite low at 21.5%. Although intention-to-treat analysis was not used, a relatively large percentage of participants (81%) still remained at the end of the study. Moreover, as an RCT, the study design was strong; however, the sample size was still quite small. Overall, the strategies used in the intensive-lifestyle intervention may be promising.

5.3.5.2 Kramer et al., (2009)

The aim of this cohort study was to modify the “Diabetes Prevention Program (DPP)” for implementation in a community setting (Group Lifestyle Balance program). Overweight or obese ($\text{BMI} \geq 25 \text{ kg/m}^2$) patients with metabolic syndrome but without type 2 diabetes, were eligible to participate. The program was evaluated in two phases. Phase 1 assessed it in four primary care practices (two urban, two rural) between 2005 and 2006 ($n=51$), while Phase 2 further assessed the program in two additional primary care practices, and in patients referred to the Diabetes Prevention Support Centre between 2007 and 2008 ($n=42$). Modifications to the DPP included group rather than individual delivery, reduction from 16 to 12 sessions, focusing on healthy food choices rather than the food pyramid specifically, and more emphasis on the use of pedometers. Patients attended weekly 1-hour sessions, received handouts, books, a pedometer, and self-monitoring charts for food intake and physical activity. Moreover, the Diabetes Prevention Support Centre was established in an effort to replicate the support structure

provided to DPP lifestyle coaches. All providers attended at 2-day training workshop to provide an overview of the background and results of the DPP, rationale for nutrition and physical activity goals, and an overview of the Group Lifestyle Balance program and its implementation. In Phase 1, health care providers included nurses, a health care educator, and an exercise specialist, while Phase 2 sessions were facilitated by an RD, an exercise specialist, and an RN.

Mean weight at baseline was 98.2kg (BMI 36.6kg/m²) and 94.7kg (BMI 34.6kg/m²) for Phase 1 and 2 respectively. After the 3 month program, Phase 1 participants achieved a 2.1% weight loss ($p<0.001$) and a decrease of 0.9 BMI units ($p<0.001$), while Phase 2 participants achieved a 4.8% weight loss ($p <0.001$) and a decrease of 1.5 BMI units ($p < 0.001$). At 12 months follow-up (available for Phase 2 only), participants in Phase 2 maintained a weight loss of 4.4% ($p<0.001$) and a decrease of 1.4 BMI units ($p <0.001$).

Only 65% of Phase 1 and 71% of Phase 2 patients completed the study, however, intention-to-treat analysis was used. The sample size however was still quite small, there was no control group, and only 3 month follow-up data was available for Phase 1. Overall the study was potentially promising.

5.3.5.3 Bo et al., (2007)

This study was a 1-year RCT conducted to evaluate the effectiveness of a moderate lifestyle intervention aimed at reducing metabolic abnormalities in the general population. Three-hundred and seventy-five patients from 6 family physicians were randomized into the intervention or control group. All participants received general healthy lifestyle information from their GPs, according to usual clinical practice. The GPs

attended at least three meetings which were on standard practice lifestyle recommendations and the preventive efficacy of lifestyle change. In addition to this, the intervention group received detailed verbal and written individualized recommendations from nutritionists, endocrinology specialists, and internal medicine specialists over a 12 month period. This included one 60 minute one-on-one session, followed by 4 group sessions (~ 60 min) covering diet, exercise, and behaviour modification.

At baseline, mean weight for the intervention group was 81.7kg (BMI 29.7kg/m²). The baseline mean weight for the control group was very similar at 81.3kg (BMI 29.8kg/m²). After 12 months, the intervention group only achieved a weight loss of 0.9% ($p=0.049$) and a decrease of 0.3 BMI units ($p=0.017$). However, net weight loss was 3.2% as the control group gained weight (2.3% weight gain, $p<0.001$; and 0.6 BMI units, $p<0.001$). This is one of two articles which achieved an overall strong QA rating of all 176 intervention studies.

It is very likely that the sample represented the target population as all patients aged 45-64 from 6 family physicians, representative of the local Health Districts, were contacted. A metabolic screen was carried out on 88.3% of these patients, and all of those who were eligible ($n= 375$) agreed to participate. Additionally, no participants were lost to follow-up, making results more generalizable. The authors wanted to point out the inefficacy of usual care by GPs as most metabolic variables worsened and weight increased. Although weight loss was very modest, the study design was strong, results were not artificially inflated, and the intervention appears to be feasible; therefore the strategies used in this study may be promising.

5.3.6 Characteristics of Potentially Promising and Promising Studies

5.3.6.1 Changes in Weight and BMI

All but one study found that on average, participants were able to achieve clinically significant weight loss. The study by Bo et al., 2007 did not report clinically relevant weight loss; however, its design was the strongest of all 176 intervention studies; therefore it deserves to be mentioned. With such a design, it is less likely that weight loss was due to confounding variables, and more likely that the results were realistic. For all six studies, baseline weights and BMIs were relevant to the range of patients seen in primary care. Weight ranged from 81.7kg to 100.0kg and BMI ranged from 29.7kg/m² to 37.6kg/m². Weight loss ranged from 0.9%-4.4% and change in BMI ranged from a decrease of 0.3-1.5 units. For the five studies with control groups, net weight loss ranged from 1.2% to 3.2% and net BMI change ranged from 0.8 to 1.6 units, however, in two studies, these were inflated as the control groups gained weight.

5.3.6.2 Appraising the Quality of Evidence

Unlike the six studies which were not found to be promising (discussed below), the weight losses achieved in these six studies were more likely to be caused by the intervention (as opposed to confounding variables). The study designs were stronger, as four out of six studies were randomized controlled trials. All six studies recruited samples which were very likely or somewhat likely to be representative of the target population. Furthermore, all but one study had an attrition rate of less than 10% or intention-to-treat analysis was used; therefore, the results were more likely to be reflective of the entire sample. Lastly, 12 month follow-up data were available for all studies (except one cohort of one study), demonstrating that this weight loss was maintained past the 3-6 month

plateau period. Sample sizes were also fairly large for all four RCTs. Overall, these studies used stronger study designs and most still achieved clinically significant results; therefore they are at least potentially promising, and weight loss strategies used merit further attention.

5.3.6.3 Delivery Channels and Providers

Compared to all 12 clinically relevant weight loss studies, these six studies included more one-on-one counseling (5/6 vs. 7/12), less group counseling (4/6 vs. 9/12), and more provider education (5/6 vs. 6/12). The promising studies included more provider education at level 1 (2/5 vs. 2/6) and level 3 (2/5 vs. 2/6), but less at level 2 (1/5 vs. 2/6). More importantly, compared to all 73 studies which reported weight or BMI, these studies used slightly more one-on-one counseling (5/6 vs. 77%), more group counseling (4/6 vs. 40%), and more than twice as much provider education (5/6 vs. 40%). The promising studies included less provider education at level 1 (2/5 vs. 45%) and level 2 (1/5 vs. 31%), but more at level 3 (2/5 vs. 28%). As with the 12 clinically relevant studies, telephone counseling, mailed materials, computer/web-based counseling, were not used. Furthermore, compared to the 12 clinically relevant weight loss studies, RDs (5/6 vs. 7/12) were more often included, other allied health care professionals (1/6 vs. 3/12) and other educators (1/6 vs. 3/12) were included less often, and the same percentage of MD/RN/NPs only (1/6 vs. 2/12) were included. Compared to the 73 studies which reported weight or BMI, promising studies involved RDs more than twice as often (5/6 vs. 41%). However, other allied health professionals (1/6 vs. 40%), MD/RN/NPs only (1/6 vs. 27%), and other educators (1/6 vs. 23%) were involved less often. Lastly, no lay persons were included.

Overall, key features of promising interventions for weight management in primary care include one-on-one counselling, group counselling, provider education, and involving RDs. These strategies appear to contribute to clinically significant improvements in weight/BMI.

Table 7: Comparison of Delivery Channels- Weight/BMI Studies

	Studies that Reported BMI/Weight N= 73	Clinically Relevant Studies N= 12	Potentially Promising/Promising Studies N= 6
One-on-one Counselling Included	56/73 (77%)	7/12 (58%)	5/6 (83%)
Group Counselling Included	29/73 (40%)	9/12 (75%)	4/6 (67%)
Telephone Counselling Included	20/73 (27%)	0/12 (0%)	0/6 (0%)
Computer/Internet Counselling Included	1/73 (1%)	0/12 (0%)	0/6 (0%)
Mailed Materials Included	3/73 (4%)	0/12 (0%)	0/6 (0%)

Table 8: Comparison of Providers- Weight/BMI Studies

	Studies that Reported BMI/Weight N= 73	Clinically Relevant Studies N= 12	Potentially Promising/Promising Studies N= 6
RD Included	30/73 (41%)	7/12 (58%)	5/6 (83%)
MD/RN/NP Only	20/73 (27%)	2/12 (17%)	1/6 (17%)
Other Allied Health Included	29/73 (40%)	3/12 (25%)	1/6 (17%)
Lay Persons Included	2/73 (3%)	0/12 (0%)	0/6 (0%)
Other Educators Included	17/73 (23%)	3/12 (25%)	1/6 (17%)

Table 9: Comparison of Provider Education- Weight/BMI Studies

	Studies that Reported BMI/Weight N= 73	Clinically Relevant Studies N= 12	Potentially Promising/Promising Studies N= 6
Total Provider Education	29/73 (40%)	6/12 (50%)	5/6 (83%)
Provider Education Level 1	13/29 (45%)	2/6 (33%)	2/6 40%
Provider Education Level 2	9/29 (31%)	2/6 (33%)	1/5 20%
Provider Education Level 3	8/29 (28%)	2/6 (33%)	2/5 40%

5.3.7 Overview of Studies Not Likely to be Promising

Studies were deemed “not likely to be promising” if they did not meet the criteria for studies “likely to be promising” or “potentially promising”. The six studies which were not likely to be promising found that on average, their participants achieved clinically relevant weight loss. Most of the studies demonstrated a mean weight loss of > 5% with two of them exceeding 10% weight loss. It appears the more clinically and statistically significant the results, the weaker the quality of evidence. At first glance, they appeared to be quite promising; however upon further evaluation, three of the studies recruited samples that were not likely to be representative of the target population. Also, samples were small for all but one study. Furthermore, four of the studies only used a one group cohort design, while the other two studies used non-equivalent control groups. Therefore a number of confounders may have influenced weight loss results. Additionally, in four studies, attrition was >40% and intention-to-treat analysis was not used. This biases results as weight loss was only reflective of the more motivated and

successful completers. Overall, although clinically significant results were achieved, weight management strategies used in these studies are not likely to be promising.

5.4 Hemoglobin A1c Studies

5.4.1 Defining Clinical Relevance

Out of the 176 intervention studies, 72 reported mean hemoglobin A1c (A1c) levels at baseline and follow-up. To explore which of these 72 studies used promising or potentially promising strategies for glycemic control, they were first selected based on whether participants achieved a clinically relevant reduction in A1c levels. For the purposes of this review, clinically relevant was defined as a mean decrease in A1c levels of $\geq 1\%$ for the group. Modest decreases in A1c levels have been found to contribute to reductions in the development and progression of microvascular and macrovascular complications (The California Medi-Cal Type 2 Diabetes Study Group, 2004).

Studies have shown that individual “decreases in HbA1c of approximately 1% to 2% are associated with a 21% to 76% reduction in the incidence of retinopathy, a 34% to 56% reduction in the incidence of nephropathy, and a 25% to 60% reduction in the incidence of peripheral neuropathy” (UKPDS, 1998a and The Diabetes Control and Complications Trial Research Group, 1993 as cited in Bray et al., 2005).

The UK Prospective Diabetes Study Group also found that for every 1% decrease in A1c maintained over 10 years, the relative risk of microvascular complications, diabetes-related death, and myocardial infarction declined by 32%, 21%, and 14% respectively (UKPDS Group, 1998a; UKPDS Group, 1998b). Furthermore, this change in A1c appears to be realistic for the studies included in the present review. Numerous studies

evaluating diabetes management programs located in primary care have been able to achieve decreases of A1c levels between 1% to 2% (Rothman et al., 2005). For these reasons, a reduction of $\geq 1\%$ A1c was chosen as the cut-point for studies to be considered clinically relevant.

5.4.2 Characteristics of Clinically Relevant Studies

Using the above criterion, 25% of studies (18 studies) which reported A1c levels, demonstrated clinically relevant results.

Table 10 shows the main findings for all 72 studies (the 18 clinically relevant studies are bolded).

Table 10: Summary of Results- All A1c Studies

				INTERVENTION GROUP			NET (Intervention- Control)
				Baseline		Baseline-Post or F/U	
Author/Date	Overall Quality	Intervention Length (months)	Follow-up (months)	N	Mean A1c (%)	Mean Δ A1c (%)	NET Δ A1c (%)
Adolfsson et al., (2007)	Moderate	12		42	7.4	0.1	0.4
Andrews & Holland (2003)	Weak	3		119	9.1	1.2	
Boegner et al., (2008)	Weak	1-2 sessions	6	427	7.6	0.2	
Boyd et al., (2006)	Weak	12		48	8.6	1.7	
Bray et al., (2005)	Weak	6	12	112	8.2	1.1	1.4
The California Medi-Cal Type 2 Diabetes Study Group (2004)	Moderate	12	36	171	9.5	1.8	0.6
Celeste-Harris & Maryniuk (2006)	Weak	up to 6	6	110	8.1	0.6	
Ciardullo et al., (2003)	Weak	unknown	avg. 23 (6-50)	5260	7.6	0.2	
Cleveringa et al., (2007)	Weak	up to 12	12	7893	7.0	0.2	
Cooper et al., (2008)	Weak	2	6	23	8.4	-0.1	0.9
Cusack et al., (2008)	Weak	avg. 32.5 (2-77)		64	6.8	0.0	
Dale et al., (2009) Int #1- Peer	Weak	up to 6 (1 session + 1-6 phone)	6	90	8.4	0.4	-0.4

				INTERVENTION GROUP			NET (Intervention- Control)
				Baseline		Baseline-Post or F/U	
Author/Date	Overall Quality	Intervention Length (months)	Follow-up (months)	N	Mean A1c (%)	Mean Δ A1c (%)	NET Δ A1c (%)
Dale et al., (2009) Int #2- Diabetes Specialist Nurse	Weak	up to 6 (1 session + 1-6 phone)	6	44	8.9	0.9	0.1
Daley et al., (2008)	Weak	6		50	7.6	0.7	
Davidson et al., (2006)	Weak	12		367	8.8	1.8	
Davies et al., (2008)	Strong	1 session+	4, 8, 12	437	8.3	1.5	0.3
Denver et al., (2003)	Moderate	6		60	8.2	0.0	0.0
Dijkstra et al., (2005)	Weak	up to 12	12	458	8.1	0.3	0.5
Doucette et al., (2009)	Moderate	up to 12 (1-4 sessions)	12	36	8.0	0.3	0.4
El Fakiri et al., (2008)	Weak	9	12	137	6.5	0.0	0.0
Eriksson et al., (2006)	Weak	9	12	75	6.4	0.5	0.0
Gabbay et al., (2006)	Moderate	12		150	7.5	0.0	0.0
Gambino et al., (2009)	Weak	$\pm$ 15		87	7.3	0.2	
Georgiou et al., (2006)	Weak	24		2731	7.4	0.2	
Gilmer et al., (2005)	Moderate	up to 18 (avg. 5 sessions)	6-18	188	8.5	1.2	0.7
Glasgow et al., (2005)	Moderate	12		469	7.3	0.2	0.0
Hornsten et al., (2005)	Moderate	9	12	44	5.7	0.3	0.9
Hummel et al., (2003)	Weak	up to 24		752	7.8	0.1	
Ismail et al., (2006)	Weak	12	72	464	9.0	0.8	0.6
Janssen et al., (2009)	Moderate	12		255	7.3	1.1	0.2
Kinmonth et al., (2008) Int #1- Telephone	Moderate	12		124	5.2	-0.2	-0.1
Kinmonth et al., (2008)	Moderate	12		120	5.2	-0.1	0.0

				INTERVENTION GROUP			NET (Intervention- Control)
				Baseline		Baseline-Post or F/U	
Author/Date	Overall Quality	Intervention Length (months)	Follow-up (months)	N	Mean A1c (%)	Mean Δ A1c (%)	NET Δ A1c (%)
Int #2- In Person							
Kirk et al., (2004)	Moderate	9	12	35	8.3	0.2	0.5
Kirsh et al., (2007)	Weak	up to 5 (1-7 sessions)	12	44	10.4	1.4	1.7
Krein et al., (2004)	Moderate	up to 18	avg. 19	123	9.3	0.0	-0.2
Lairson et al., (2008)	Moderate	up to 12	12	435	7.6	0.1	0.2
Larsen et al., (2003)	Weak	48 (cross-sectional)		5785	8.1	0.8	
Lawton et al., (2009)	Moderate	9	12, 24	544	5.6	-0.1	0.1
Lemon et al., (2004)	Weak	up to 6 (1-6 sessions)	6	244	8.7	1.7	
Lin et al., (2007)	Weak	up to 36 ($\geq$ 2 sessions)		33	7.8	0.6	0.3
Litaker et al., (2003)	Moderate	up to 12	12	79	8.4	0.6	0.5
LookAHEAD Research Group (2007)	Moderate	12		2496	7.3	0.7	0.6
Luzio et al., (2005) Int #1- Aachen	Weak	up to 4	4	93	7.1	0.3	
Luzio et al., (2005) Int #2- Cardiff	Weak	up to 6	6	74	7.7	0.6	
Ma et al., (2009)	Moderate	15		212	7.6	0.0	0.3
Maljanian et al., (2005)	Moderate	3	12	176	8.1	1.2	0.1
Mayer-Davis et al., (2004) Int #1- Intensive	Moderate	12		49	10.2	1.6	0.5
Mayer-Davis et al., (2004) Int #2- Reimbursable	Moderate	12		47	9.7	0.8	-0.3
Mensink et al., (2003)	Weak	12		55	5.9	0.0	-0.1
Meulepas et al., (2008)	Moderate	12		427	7.3	0.2	0.3

				INTERVENTION GROUP			NET (Intervention- Control)
				Baseline		Baseline-Post or F/U	
Author/Date	Overall Quality	Intervention Length (months)	Follow-up (months)	N	Mean A1c (%)	Mean Δ A1c (%)	NET Δ A1c (%)
O'Reilly et al., (2007)	Weak	avg.12		401	8.1	1.0	
Osterbrink et al., (2005)	Weak	2	38-40	449	7.9	0.6	
Piatt et al., (2006) Int #1- CCM	Weak	12		27	7.6	0.6	0.5
Piatt et al., (2006) Int #2 Provider Education Only	Weak	12		32	7.3	9.0	-0.1
Powers et al., (2007)	Moderate	24		102	7.5	0.2	0.4
Ragucci et al., (2005)	Weak	up to 8 (≥ 1 session)	12 after 1st session	142	9.5	1.7	
Read et al., (2004)	Weak	12		54	7.8	0.7	
Rothe et al., (2008) Int #1- Cross-sectional	Weak	36		202,293	7.1	0.3	
Rothe et al., (2008) Int #2- Subcohort1	Weak	up to 36	36	105,204	7.1	0.2	
Rothe et al., (2008) Int #3- Subcohort2	Weak	up to 36	36	32,314	8.8	1.3	
Rothman et al., (2005)	Moderate	up to 12	12	112	11.0	2.5	0.9
Schillinger et al., (2009) Int #1- ATSM	Moderate	9	12	112	9.3	0.6	-0.2
Schillinger et al., (2009) Int #2- GMV	Moderate	9	12	113	9.4	0.4	-0.4
Scott et al., (2006)	Moderate	3	6, 9	76	8.8	1.7	1.0
Shea et al., (2006)	Moderate	up to 12	12	829	7.4	0.3	0.1
Shephard et al., (2005)	Weak	up to 12		54	7.6	0.5	
Simmons et al., (2004)	Weak	unknown	12	222	9.4	0.3	0.4
Smith et al., (2004)	Moderate	up to 18	18	96	6.9	-0.1	0.0

				INTERVENTION GROUP			NET (Intervention- Control)
				Baseline		Baseline-Post or F/U	
Author/Date	Overall Quality	Intervention Length (months)	Follow-up (months)	N	Mean A1c (%)	Mean Δ A1c (%)	NET Δ A1c (%)
Steed et al., (2005)	Weak	1.5	3	65	8.2	0.1	0.0
Steuten et al., (2007)	Weak	up to 24	24	473	7.5	0.2	
Sturt et al., (2008)	Moderate	3	6.5	114	8.9	0.5	0.1
Taylor et al., (2003)	Moderate	11	12	61	9.5	1.1	0.3
Taylor et al., (2005)	Moderate	3	3-5	20	7.7	0.3	1.0
Thoolen et al., (2007) Int #1- Intensive + Course	Moderate	3	12	39	4.0	0.0	0.0
Thoolen et al., (2007) Int #2- Intensive + Control	Moderate	3	12	52	4.0	0.0	0.0
Thoolen et al., (2007) Int #3- Usual + Course	Moderate	3	12	50	4.6	0.0	0.0
Tonstad et al., (2007)	Weak	6		29	5.7	0.1	0.1
Tranche et al., (2005)	Weak	12		3466	6.9	0.4	
Tudor-Locke et al., (2004)	Weak	4		24	7.6	0.4	0.0
Van Bruggen et al., (2008)	Moderate	up to 12	12	822	7.0	0.1	0.0
Varroud-Vial et al., (2004)	Weak	up to 12	12	192	7.5	0.3	0.9
Zwar et al., (2007)	Weak	12+		230	7.4	0.1	

¹ All studies bolded author/date demonstrated clinically relevant decrease in A1c levels ($\geq 1\%$ decrease in A1c levels); OR were strong studies.

² All studies with author/date which are not bolded did not demonstrate clinically relevant decrease in A1c levels

³ References to studies that did not demonstrate clinically relevant results are found in Appendix O

⁴ avg.= average

Seventy-two percent of these 18 studies were conducted in the US and the remaining five studies were conducted in the UK, Netherlands, Canada and Germany. All 18 studies were targeted at patients with type 2 diabetes. Compared to the 72 studies which reported A1c, these 18 clinically relevant studies included more one-on-one counselling (17/18 vs. 86%) and more group counseling (11/18 vs. 39%). However, no mailed materials (0/18 vs. 4%) or computer/web-based counseling (0/18 vs. 6%) were used. A similar percentage of studies included telephone counseling (6/18 vs. 35%) and provider education (8/18 vs. 42%). As mentioned in the “weight/BMI” section, provider education was divided into three levels, based on the amount of detail reported in the study (with higher levels indicating more detail). There were slightly fewer clinically relevant studies which included provider education at level 1 (3/8 vs. 43%), slightly more studies which included provider education at level 2 (3/8 vs. 27%), and a similar percentage of studies which included provider education at level 3 (2/8 vs. 30%). Furthermore, more studies included RDs (10/18 vs. 36%), other allied health professionals (11/18 vs. 51%), and other educators (4/18 vs. 13%). Few studies involved MD/RN/NPs only (3/18 vs. 31%) and lay persons (1/18 vs. 4%). Table 11 and Table 11a describe further study characteristics and details on the intervention.

Table 11: Study Characteristics- Clinically Relevant A1c Studies

Author/ Date	Study Design	Target Group	Patients	Social Cognitive Theory	Health Belief Model	Transtheoretical Model	Theory of Planned Behaviour	Other Theory	No Theory Used
Andrews & Holland (2003)	Cohort (1 group)	"No exclusion criteria were applied." The programme "was suitable for anyone to attend."	n=119 No control group						Yes
Boyd et al., (2006)	Cohort (1 group)	"low-income patients with type 2 diabetes."	n=48 No control group						Yes
Bray et al., (2005)	RCT	"Adult diabetics at high risk for suboptimal patient outcomes."	Intervention: n=112 Control group: n=48						Yes
The California Medi-Cal Type 2 Diabetes Study Group, (2004)	RCT	Individuals with type 2 diabetes	Intervention group: n=186 Control group: n=172						Yes
Davidson et al., (2006)	Cohort (1 group)	Adults with diabetes	N= 367						Yes
Davies MJ, (2008)	RCT	Adults with newly-diagnosed diabetes	Control group: n=387 Intervention group: n=437					Yes	
Gilmer et al., (2005)	Cohort (1 group + 1 retro control group)	Low-income persons with diabetes	Project Dulce group: n=188 Control group: n=160						Yes

Author/ Date	Study Design	Target Group	Patients	Social Cognitive Theory	Health Belief Model	Transtheoretical Model	Theory of Planned Behaviour	Other Theory	No Theory Used
Janssen et al., (2009)	RCT	Patients with diabetes.	Intervention: n=255 Control group: n=243						Yes
Kirsh et al., (2007)	(1 group + 1 retro control group)	"Targeted patients included those with type 2 diabetes enrolled in the primary care clinic at the highest risk for cardiovascular morbidity."	Intervention group: n=44 Control group: n=35					Yes	
Lemon et al., (2004)	Cohort (1 group)	"Adults with Type 2 Diabetes."	n=244						Yes
Maljanian et al., (2005)	Repeated measures randomized controlled trial	Adults with type 1 or 2 diabetes.	Intervention: n=176 Control: n=160						Yes
Mayer-Davis et al., (2004)	RCT (2 int groups)	Patients 45 years or older with diabetes, BMI of ≥ 25 (kg/m ²) during the previous calendar year.	Intensive lifestyle group: n=49 Reimbursable lifestyle group: n=47 Control group: n=56						Yes
O'Reilly et al., (2007)	Cohort (1 group)	Patients with diabetes.	n=401 No control group						Yes

Author/ Date	Study Design	Target Group	Patients	Social Cognitive Theory	Health Belief Model	Transtheoretical Model	Theory of Planned Behaviour	Other Theory	No Theory Used
Ragucci et al., 2005	Cohort (1 group)	"Patients with diabetes."	n= 142 No control group						Yes
Rothe et al., (2008)	Interrupted time series	Patients with diabetes.	Group A1: n=202,293 Group A2: n=291,771 Group B: n=105,204 Another sub-cohort with poor glycemic control: n= 32,314.						Yes
Rothman et al., (2005)	RCT	Patients with type 2 diabetes.	Intervention: n=112 Control: n=105						Yes
Scott et al., (2006)	RCT	Patients with type 2 diabetes.	Intervention group: n=76 Control group: n=73						Yes
Taylor et al., (2003)	RCT	"patients with longstanding diabetes, one or more major medical comorbid conditions, and HbA1c >10%."	Intervention: n=84 Control group: n=85						Yes

Table 11a: Intervention Details for Clinically Relevant A1c Studies

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Andrews & Holland (2003)	"A diabetes specialist nurse (DSN), a specialist diabetes dietitian, a podiatrist, and a doctor ran the programmes...An EXTEND exercise therapist was responsible for organising and delivering individually tailored exercise in a group setting."	Group sessions with both a physical activity component and educational component. "All participants were offered the opportunity of having individual consultations with the DSN and dietitian if necessary."	Participants "attended one morning a week for 12 weeks. Each session was made up of 1 hour of activity followed by half an hour of education."	3 months (immediate post-intervention)
Boyd et al., (2006)	Exercise coach (pharmacist, RN, licensed practical nurse, or medical assistant).	Group exercise class involving motivation, encouragement, and initiating goal setting.	"All patients received free exercise classes twice per week lasting up to 12 months." Each exercise class was approximately 1 hour.	12 months (immediate post-intervention)
Bray et al., (2005)	Certified nurse specialist (CNS), physician, and office staff member.	Group educational sessions followed by a brief visit with physician.	"Patients were assigned to a group of 3 to 12 patients who met for a series of four 2-hour group sessions over approximately 6 months."	6 months (immediate-post intervention), and 12 months
The California Medi-Cal Type 2 Diabetes Study Group, (2004)	Registered nurses, registered dietitians, endocrinologists, and diabetes educators.	Individualized treatment algorithms, one-on-one, face-to-face counselling. Counselling via telephone was provided between visits as needed.	Intervention lasted at least one year. Various case management interventions with varying frequency requirements (e.g. nutrition education management- every visit; assessment of PA- at least quarterly; foot care- at least quarterly, etc.)	HbA1c was measured every 6 months until 36 months, but all other variables were only measured at baseline and at 36 months.

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Davidson et al., (2006)	"Specially trained nurse following detailed diabetes treatment algorithms and supervised by...an endocrinologist."	Appears to be one on one, face to face counselling.	One year intervention. Patients' "process and outcome measures during the year before entering the DMCP were compared with those after 1 year of enrollment." No information provided on length of counselling sessions or frequency of visits.	12 month follow-up (immediate post-intervention)
Davies et al., (2008)	"Registered healthcare professionals" (practice nurse or dietitian).	Structured group education programme. Likely had one on one counselling following this programme.	"The programme was six hours long, deliverable in either one day or two half day equivalents." Patients were offered access to diabetes education afterwards (not part of main intervention).	4, 8, and 12 months follow-up. No immediate-post-intervention measurement reported.
Gilmer et al., (2005)	A nurse-led team that consisted of a registered nurse/certified diabetes educator (RN/CDE), bilingual/bicultural medical assistant, bilingual/bicultural dietitian, and peer educators (i.e. promotoras).	One-on-one, face-to-face counselling with telephone contact and group self-management training.	Variable duration (up to 18 months). "Patients have an initial (50-min) visit with a nurse and are asked to return for additional (50 or 25 min, as required) visits with the nurse and for a (25-min) visit with a dietitian. On average, participants have 5 visits with the nurse, and 50% consult with a dietitian. Telephone contact is used for appointment reminders and to answer specific questions." Group education classes were an 8-week curriculum and the average attendance per participant was 4 classes.	12 months (immediate post-intervention)

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Janssen et al., (2009)	Physicians and diabetes nurses.	One-on-one, face to face counselling during office visits.	After diagnosis of type 2 diabetes, patients "were first seen by their GP" and then had subsequent visits with the diabetes nurse "2, 4, 6, 8, and 12 weeks after diagnosis until target levels were reached. Thereafter, patients were requested to visit the GP or nurse every 3 months. One year after screening, an extensive visit to the GP took place."	12 months (immediate post-intervention)
Kirsh et al., (2007)	"A diabetes specialist,...a certified diabetic educator who is also an experienced diabetes nurse practitioner...one general internist, one nurse practitioner, one pharmD, one clinical health psychologist and one nurse."	Shared Medical Appointment (SMA)- "groups of patients (8-20) are seen by a multidisciplinary team...Patients were asked to be active participants in their care via participation in group and individual learning."	Variable duration (up to 5 months). The intervention took place from April 2005 to September 2005. Included patients were those who could participate in at least one SMA session (1-2 hour appts). Patients were also provided with 5-10 minutes of time with individual providers (MD, NP, PharmD).	Approximately 12 months (immediate-post intervention). Patients participated in at least one SMA session between April 2005 and September 2005. "The follow-up measures were obtained by using the values nearest to August 2006."
Lemon et al., (2004)	Registered Dietitians	One-on-one, face-to-face counselling.	Variable. "During the entire 6-month study period, RDs spent an average of 111+/-55 minutes (range 4 to 490 minutes) with each subject and met with subjects an average of 2.1+/-1.0 times (range 1 to 6 times)."	6 months follow-up. No immediate-post-intervention measurement reported.

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Maljanian et al., (2005)	The telephone calls were scripted by the investigators and delivered in English or Spanish by a trained research nurse. Face-to-face counselling provided by RN and nutritionist.	Individual telephone counselling. Both the intervention and control group also attended educational classes and face to face individual visits.	12 week intervention, 1 phone call per week. The first phone call was 15-20 minutes in length, and subsequent phone calls were 5-7 minutes. Three 4-hr educational classes and individual visits.	3 months (immediate post-intervention) and 12 months.
Mayer-Davis, 2004	Study nutritionists	Individual and group counselling; face to face.	1 year intervention; "Intensive-lifestyle participants met weekly with the study nutritionist for delivery of the first 4 months of the core curriculum (intensive), every other week for the next 2 months (transition), and once a month for the remaining 6 months (maintenance)."	12 months (immediate post-intervention).
O'Reilly et al., (2007)	Diabetes specialist nurse and other healthcare professionals "who attended the GHC diabetes education day". Implied that a Dietitian and other allied health care providers involved.	Delivery of patient education not specified-likely face to face individual counselling.	On average, the intervention was 12 months. No information was provided on length of counselling sessions or frequency of visits.	Approximately 12 months (immediate post-intervention).
Ragucci et al., (2005)	Clinical pharmacist	One on one, face to face counseling.	Variable (up to 8 months). "Patients were included in the analysis if they had at least one diabetes education and management visit with a clinical pharmacist from April 1-December 31, 2002." In most instances, patients were seen for 3-4 visits.	12 months after each patient's first session. No immediate-post-intervention measurement reported.

Author/Date	Provider(s)	Delivery Channels	Duration, Length, Frequency	Length of Post-Intervention F/U
Rothe et al., (2008)	General practitioners and diabetes specialized practitioners.	Individual physician counselling with structured patient education programs.	"291,771 patients were included in the SDMP. Cross-sectional data were evaluated at the beginning of 2000 (group A1) and at the end of 2002 (group A2). A subcohort of 105,204 patients was followed over a period of 3 years (group B)." Another subcohort of patients with poorly controlled diabetes was followed over 3 years. Variable duration for subcohorts (up to 36 month).	Group A- approx. 36 months (immediate-post intervention). Group B- 36 month (no immediate post intervention measurement).
Rothman et al., (2005)	"3 clinical pharmacist practitioners...2 were certified diabetes educators...Patients also "had access to a diabetes care coordinator who was trained by the clinical pharmacist to address issues related to health behaviour and health education." Also received usual care by physician.	One on one, face to face counselling in addition to telephone contact.	Variable duration (up to 12 months). "The diabetes management team made a median of 45 contacts or care-related activities, a total of 460 minutes (38 minutes per month) for each intervention patient. This included time spent caring for patients and collecting data related to study evaluation."	12 months. No immediate-post-intervention measurement reported.
Scott et al., (2006)	Clinical pharmacist, physician, dietitian, and nurse.	Individual appointments, group-sessions and telephone follow-up when necessary.	"The initial three months consisted of appointments every two weeks, group-session appointments, and telephone follow-up when necessary...Group sessions lasted for two hours and consisted of six to eight patients."	3 months (immediate post-intervention), 6 months, and 9 months
Taylor et al., (2003)	Registered Nurse	Individual face to face counselling sessions, group sessions, and telephone follow-ups.	11 month intervention. An initial 90-minute individual meeting was scheduled. "All intervention patients were asked to attend a 1- to 2-hour group class (4-10 participants/group) that met once a week for 4 weeks...All patients received an initial telephone call. Subsequent calls were scheduled for 5, 8, 12, 16, 20, 28, 36, and 44 weeks into the program and were designed to average 15 minutes."	12 months (no immediate post-intervention measurement.

5.4.3 Interpreting by Appraising the Quality of Evidence

Detailed tabular results for the 18 studies with quality assessment results are shown in Tables 12 and 13. A1c results are shown in Table 12 and QA results in Table 13.

Table 12: A1c Results Table- Clinically Relevant Studies

			INTERVENTION GROUP										
			Baseline			Post-Intervention			F/U			Difference (Baseline-Post or F/U)	
Author/Date	Intervention Length (mo)	F/U (mo)	N	$\bar{x}$ A1c (%)	SD A1c	N	$\bar{x}$ A1c (%)	SD A1c	N	$\bar{x}$ A1c (%)	SD A1c	$\bar{x}$ Δ A1c (%)	% Δ A1c
Andrews & Holland (2003)	3		119	9.1	0.9	96	7.9	0.2				1.2	13.2
Boyd et al., (2006)	12		48	8.6		35	6.9					1.7	19.8
Bray et al., (2005)	6	12	112	8.2	2.6				112	7.1	2.3	1.1	13.4
California Medi-Cal Type 2 Diabetes Study Group, (2004)	12+	Up to 36	171	9.5	0.1	171	8.2	0.1	171	7.7	0.2	1.8	18.9
Davidson et al., (2006)	12		367	8.8		361	7.0					1.8	20.5
Davies et al., (2008)	1 session +	4, 8, 12	437	8.3	2.2				417	6.8		1.5	18.1
Gilmer et al., (2005)	up to 18 (avg. 5 sessions)	6-18	188	8.5	2.4				188	7.3		1.2	14.1
Janssen et al., (2009)	12		255	7.3	1.6	255	6.2	0.6				1.1	15.1
Kirsh et al., (2007)	up to 5 (1-7 sessions)	12	44	10.4					44	9.0		1.4	13.5
Lemon et al., (2004)	up to 6 (1-6 sessions)	6	244	8.7	2.0				184	7.0		1.7	19.5
Maljanian et al., (2005)	3	12	176	8.1	1.9	148	6.9	1.4	148	6.9	1.5	1.2	14.8

			INTERVENTION GROUP										
			Baseline			Post-Intervention			F/U			Difference (Baseline-Post or F/U)	
Mayer-Davis et al., (2004) Int #1- Intensive	Moderate	12	49	10.2	2.5	49	8.6					1.6	15.7
Mayer-Davis et al., (2004) Int #2- Reimbursable	Moderate	12	47	9.7	3.1	47	8.9					0.8	8.2
O'Reilly et al., (2007)	avg. 12		401	8.1	0.1				401	7.1	0.1	1.0	12.3
Ragucci et al., (2005)	Up to 8 (≥ 1 session)	12 after 1 st session	142	9.5					142	7.8		1.7	17.9
Rothe et al., (2008) Int #1- Cross-sectional	~36		202,293	7.1	1.4	291,771	6.8	1.1				0.3	4.2
Rothe et al., (2008) Int#2- Subcohort1	up to 36	36	105,204	7.1	1.4	105,204			6.9	1.1		0.2	2.8
Rothe U et al., (2008) Int #3- Subcohort2	up to 36	36	32,314	8.8	1.2	32,314			7.5	1.2		1.3	14.8
Rothman et al., (2005)	up to 12	12	112	11.0	2.0	105			99	8.5		2.5	22.7
Scott et al., (2006)	3	6, 9	76	8.8		69	7.1		64	7.1		1.7	19.3
Taylor et al., (2003)	11	12	84	9.5	0.3				61	8.4		1.1	11.6

Author/Date	CONTROL GROUP											NET % Change in A1c (Intervention- Control)
	Baseline			Post-Intervention			F/U			Difference (Baseline- Post or F/U)		
	N	$\bar{x}$ A1c (%)	SD A1c	N	$\bar{x}$ A1c (%)	SD A1c	N	$\bar{x}$ A1c (%)	SD A1c	$\bar{x}$ Δ A1c (%)	% Δ A1c	
Andrews & Holland (2003)												
Boyd et al., (2006)												
Bray et al., (2005)	48	8.3	2.0				48	8.6	2.4	-0.3	-3.6	1.4
California Medi-Cal Type 2 Diabetes Study Group, (2004)	146	9.7	0.1	146	8.9	0.1	146	8.5	0.2	1.2	12.4	0.6
Davidson et al., (2006)												
Davies et al., (2008)	387	7.9	2.0				387	6.7		1.2	15.2	0.3
Gilmer et al., (2005)	160	8.7	2.3				160	8.2		0.5	5.7	0.7
Janssen et al., (2009)	243	7.4	1.7	243	6.5	0.9				0.9	12.2	0.2
Kirsh et al., (2007)	35	9.8					35	10.1		-0.3	-3.1	1.7
Lemon et al., (2004)												
Maljanian et al., (2005)	160	7.7	1.7	126	6.6	1.1	126	6.6	1.1	1.1	14.3	0.1
Mayer-Davis et al., (2004) Int #1- Intensive	56	9.6	2.9	56	8.5					1.1	11.5	0.5
Mayer-Davis et al., (2004) Int #2- Reimbursable	56	9.6	2.9	56	8.5					1.1	11.5	-0.3
O'Reilly et al., (2007)												
Ragucci et al., (2005)												
Rothe et al., (2008) Int #1- cross-sectional												
Rothe et al., (2008) Int#2- sub-cohort1												
Rothe U et al., (2008) Int #3- sub-cohort2												
Rothman et al., (2005)	105	11.0	3.0	99			95	9.4		1.6	14.5	0.9
Scott et al., (2006)	73	8.7		71	7.8		63	8.0		0.7	8.0	1.0
Taylor et al., (2003)	85	9.5	0.3				61	9.2		0.3	3.2	0.8

Table 13: Quality Assessment Summary Table- Clinically Relevant A1c Studies

Author/Date	Selection Bias		Study Design		Confounders	Blinding	Data Collection	Withdrawals & Drop Outs		Analyses	GLOBAL RATING
	Are the individuals selected to participate likely to be representative of the target population?	RATING	Indicate the study design	RATING	RATING	RATING	RATING	% of participants that completed the study	RATING	Intention to treat used?	
Andrews & Holland (2003)	Not likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Strong	80-100%	Moderate	No	WEAK
Boyd et al., (2006)	Somewhat likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Strong	60-79%	Moderate	No	WEAK
Bray et al., (2005)	Somewhat likely	Moderate	CCT	Strong	Weak	Weak	Strong	80-100%	Moderate	N/A (no drop-outs)	WEAK
California Medi-Cal Type 2 Diabetes Study Group, (2004)	Somewhat likely	Moderate	CCT	Strong	Strong	Moderate	Strong	80-100%	Moderate	Yes	MODERATE
Davidson et al., (2006)	Very likely	Weak	Cohort (1 group)	Moderate	Weak	Weak	Weak	60-79%	Moderate	No	WEAK
Davies et al., (2008)	Somewhat likely	Moderate	RCT	Strong	Strong	Moderate	Strong	80-100%	Moderate	No	MODERATE
Gilmer et al., (2005)	Somewhat likely	Moderate	Cohort (1 group) + retro control	Moderate	Moderate	Moderate	Strong	80-100%	Moderate	No	MODERATE
Janssen et al., (2009)	Somewhat likely	Moderate	CCT	Strong	Weak	Moderate	Strong	80-100%	Strong	Yes	MODERATE
Kirsh et al., (2007)	Somewhat likely	Weak	Cohort (1 group) + retro control	Moderate	Weak	Moderate	Strong	80-100%	Moderate	N/A (inc. all)	WEAK
Lemon et al., (2004)	Somewhat likely	Moderate	Cohort (1 group)	Moderate	Weak	Weak	Moderate	60-79%	Moderate	No	WEAK

Author/Date	Selection Bias		Study Design		Confounders	Blinding	Data Collection	Withdrawals & Drop Outs		Analyses	GLOBAL RATING
	Are the individuals selected to participate likely to be representative of the target population?	RATING	Indicate the study design	RATING	RATING	RATING	RATING	% of participants that completed the study	RATING	Intention to treat used?	
Maljanian et al., (2005)	Somewhat likely	Moderate	CCT	Strong	Moderate	Moderate	Strong	< 60%	Weak	No	MODERATE
Mayer-Davis et al., (2004)	Very likely	Weak	CCT	Strong	Strong	Moderate	Strong	80-100%	Moderate	No	MODERATE
O'Reilly D et al., (2007)	Can't Tell	Weak	Cohort (1 group)	Moderate	Weak	Weak	Strong	N/A	Moderate	No (retro)	WEAK
Ragucci et al., (2004)	Somewhat likely	Moderate	Cohort (1 group)	Moderate	Weak	Weak	Strong	60-79%	Moderate	No	WEAK
Rothe et al., (2008)	Very likely	Moderate	Interrupted Time Series	Moderate	Weak	Weak	Strong	N/A	Moderate	N/A (ITS)	WEAK
Rothman et al., (2005)	Somewhat likely	Moderate	RCT	Strong	Strong	Moderate	Moderate	80-100%	Moderate	No	MODERATE
Scott et al., (2006)	Somewhat likely	Moderate	RCT	Strong	Moderate	Weak	Strong	80-100%	Moderate	No	MODERATE
Taylor et al., (2003)	Somewhat likely	Weak	CCT	Strong	Moderate	Moderate	Strong	60-79%	Moderate	No	MODERATE

The 18 studies which demonstrated clinically significant reductions in A1c levels were further evaluated. After interpreting results based on relevant aspects of quality assessment (same as weight/BMI section), 11 of the 18 clinically relevant studies (15% of studies which reported A1c) were considered promising or potentially promising for glycemic control in primary care. The reasoning for how each study was categorized is discussed below.

5.4.4 Studies likely to be Promising

The seven studies described below demonstrated clinically significant results and strong study designs, therefore they were deemed likely to be promising for glycemic control in primary care. As with the studies that reported weight/BMI, the criteria for a study to be “likely to be promising” includes the following:

- $\geq 80\%$ participant completion or ITT analysis used

AND RCT or CCT design

AND $n \geq 70$

OR

- $\geq 80\%$ completion AND $n \geq 10,000$

5.4.4.1 Davies et al., (2008)

This study has also been discussed in the “weight/BMI” section but briefly, this RCT was conducted to evaluate the effectiveness of a diabetes education and self-management program for patients with newly diagnosed type 2 diabetes (may have been on oral hypoglycemic agents). Thirteen primary care practices were randomized to the intervention group (structured group education programme, $n=437$) or control group ($n=387$). Practices in both groups were provided with the same resources and had access

to equivalent health care professionals, therefore the control group served as a robust comparator. In addition to this, the healthcare professionals in the intervention practices received formal program delivery training, and within 12 weeks of diagnosis, patients attended a six hour long session on lifestyle factors.

At baseline, mean A1c for the intervention and control groups were 8.3% and 7.9% respectively. At 12 months follow-up, mean A1c was reduced to 6.8% in the intervention group and 6.7% in the control group. Net change was only 0.3%, and changes in A1c were not statistically significant between groups ($p=0.52$). Similar to the weight loss results, patients in the control group also demonstrated clinically relevant changes. As mentioned previously, this study received a strong quality assessment rating, indicating results are likely accurate, and the program is feasible. Strategies from both the control group and the additional group education session should be considered promising.

5.4.4.2 California Medi-Cal Type 2 Diabetes Group (2004)

The purpose of this RCT was to determine if intensified diabetes case management could improve glycemic control among low-income ethnic minority populations. Adults with poorly controlled type 2 diabetes ($A1c > 7.5\%$) were recruited from clinical sites in three counties that served racial/ethnic minority, low-income Medi-Cal (Medicaid) patients. Patients were then randomized to the control group ($n= 171$) or intervention group ($n= 146$). Control group patients continued to receive usual care from their primary care providers. Meanwhile, the intervention for the treatment group was more comprehensive and addressed several changes in the organization of care by redesigning the delivery system, offering provider decision support, and helping patients develop personal skills. The intervention group received diabetes case management

provided by RNs and RDs working closely with an endocrinologist. Evidence-based practice guidelines and treatment algorithms were used for glucose and medication management (oral hypoglycemic agents and insulin therapy). Patients in the intervention group were also provided with a glucose meter and individualized education on its use and data recording. Additionally, they were educated on diet, exercise, and self-care (self-care education and management used throughout the study). Counselling strategies considered patients' level of education, literacy, functional understanding, treatment goals, general health status, cultural beliefs, and support network. The intervention lasted at least 12 months.

A1c levels were measured quarterly in the intervention group and every 6 months in the control group (for up to 36 months). All participants with a baseline measure and at least one follow-up A1c measure, were included in the longitudinal analysis (mean duration of follow-up was 25.3 months). At baseline, mean A1c levels for the intervention and control groups were 9.5% and 9.7% respectively. Based on patients' latest follow-up data, the intervention group achieved an impressive reduction of 1.8% (mean 7.7%). However, the control group also achieved a clinically relevant reduction of 1.2%, making the net change 0.6%. The reduction in A1c levels, however, was still significantly different between groups ($p < 0.01$). This demonstrates that usual care seems to be effective at improving glycemic control, while the intensified diabetes case management furthers this improvement.

Eligible patients were identified by a chart review, making the response rate not applicable. Additionally, it cannot be determined whether all or only some eligible patients were chosen. Other aspects of the study design however were stronger. It was an

RCT in which 89% of participants completed the study and intention-to-treat analysis was used. Overall, the strategies seem feasible and effective, indicating this study is likely to be promising.

5.4.4.3 Rothman et al., (2005)

The purpose of this RCT was to evaluate the effectiveness of a pharmacist-led, primary care based disease management program for vulnerable patients with diabetes. The study was conducted at the University of North Carolina General Internal Medicine Practice. Primary care providers referred adult patients with poorly controlled type 2 diabetes ($A1c \geq 8.0\%$). Participants were randomly assigned to the control group ($n=105$) or the intervention group ($n=112$). Prior to randomization, all participants attended a one hour management session delivered by a clinical pharmacist practitioner. This included diabetes education and treatment recommendations which were given to the patients' primary care provider. The control group then received usual care from their primary care provider only. In addition to usual care, the intervention group received intensive diabetes management delivered by three clinical pharmacist practitioners (2 were CDEs). This intervention included addressing changes to the organization of care by offering provider decision support, and implementing information systems. Intensive educational sessions, evidence-based algorithms, and proactive management of clinical outcomes were used to help reduce cardiovascular risk factors and improve glycemic control. Pharmacists were in contact with patients every 2 to 4 weeks (or more frequently if necessary), either by phone or face-to-face (up to 12 months). A Microsoft Access database was developed to track patient outcomes and improve care. Additionally, the intervention group had access to a diabetes care coordinator, trained by the pharmacists,

to address health behaviour and health education issues. To encourage patient follow-ups, the coordinator called patients to remind them of appointments and assess if they required further treatments.

At baseline, mean A1c levels were 11.0% for both the intervention and control groups. At 12 months follow-up, the intervention group achieved an impressive 2.5% reduction in A1c levels (mean = 8.5%). The control group also achieved a clinically significant reduction of 1.6% (mean = 9.4%), therefore net change was 0.9%. The change in A1c levels between groups was still statistically significant, $p=0.05$. This demonstrates that usual care in conjunction with a 1-hour management session, may be sufficient to achieve a clinically relevant change, while the addition of the pharmacist-led intensive diabetes management further improves glycemic control.

Although intention-to-treat analysis was not used, 89% of participants completed the study. As participants were referred from their primary care providers and the response rate was 86%, the sample is more likely to be representative of the target population. The sample was only moderate in size but an RCT is a strong design. Overall, both the strategies used for usual care and the intensive program are likely to be promising.

5.4.4.4 Scott, Boyd, Stephan, Augustine, & Reardon (2006)

The purpose of this RCT was to evaluate the outcomes of pharmacist-managed diabetes care services in the Siouxland Community Health Centre (SCHC). Primary care providers referred adult SCHC members with type 2 diabetes (may have been on oral hypoglycemic agents or insulin therapy) to the clinical pharmacist or nurse to learn about the study. Participants were randomized to a pharmacist managed diabetes care program

(intervention group, $n=76$) or standard diabetes care managed by a nurse (control group, $n=73$). The control group received usual care from health care providers which included distributing patient education materials and monitoring blood glucose levels. Providers then used their own discretion to educate, refer and manage these patients. Participants in both groups received a free blood glucose monitor, blood glucose strips, and a \$5.00 gift certificate to the grocery store. Over three months, the intervention group attended individual appointments every two weeks (focusing on disease management, lifestyle changes, and goal-setting), 2 hour group sessions, and received telephone follow-ups when necessary. During group sessions, a pharmacist, dietitian, and nurse were present to review nutrition and basic diabetes management skills. The clinical pharmacist's role also included reminding patients of appointments.

At baseline, the mean A1c levels for the intervention and control groups were 8.8% and 8.7% respectively. At 9 months follow-up, the intervention group achieved a notable 1.7% (mean = 7.1%, $p=0.003$) reduction in A1c levels. As the control group achieved a 0.7% (mean = 8.0%) reduction in A1c levels, the net change was 1.0% ($p<0.05$). This demonstrated that although standard care was somewhat effective, the pharmacist managed diabetes care program was still more successful at improving glycemic control.

It appears that all eligible patients were referred by their primary care providers and the response rate was 94%, therefore it is likely that the sample is representative of the target population. Although intention-to-treat analysis was not used, 88% of participants completed the study, increasing the likelihood that completers are still

representative enough of the entire sample. The study only included a modest sample size but used a strong study design (RCT). Overall, this study is likely to be promising.

5.4.4.5 Janssen et al., (2009)

This study was described in the “weight/BMI” section. Briefly, ADDITION Netherlands (RCT) is part of the international ADDITION study. Seventy-nine GP practices were randomized to intensified treatment (n=255) or routine care (n=243). Patients with screen-detected type 2 diabetes (may have been on oral hypoglycemic agents or insulin therapy) were invited. The intervention practices addressed a change in the organization of care by offering provider decision support. GPs in the intervention arm received a 3 hour training session on the treatment protocol (treatment of glucose, blood pressure, lipids, lifestyle education and medications), while the diabetes nurses attended two hour training sessions (every 3 months) on the management of treatment algorithms and providing lifestyle education. Patients in the intervention group were first seen by their GP, subsequently visited the diabetes nurse at least 2, 4, 6, 8, and 12 weeks after diagnosis, and then seen by their GP or nurse every 3 months until one year after screening. Patients in the control group received routine care from their GPs. These GPs did not receive any detailed instructions about providing lifestyle education to patients.

At baseline, mean A1c was 7.3% in the intervention group and 7.4% in the control group. After 12 months, A1c levels decreased by 1.1% in the intervention group and 0.9% in the control group, therefore net change was only 0.2%. However, the change in A1c levels was still statistically significant between groups ($p=0.03$). As previously discussed, the sample in this study is likely representative of the target population and 99% of the participants completed the study. Although routine care resulted in slight

weight gain, it appears to be almost as effective for reducing A1c levels as intensive care. Strategies used in both groups appear to be promising for glucose control.

5.4.4.6 Bray, Thompson, Wynn, Cummings, & Whetstone (2005)

The purpose of this CCT was to assess the clinical effectiveness of combining care management and interdisciplinary visits for minority (predominantly African American) patients with diabetes. The study took place in two rural primary care practices. In the intervention practice, adult patients were recruited if they had type 2 diabetes, and were at high risk of suboptimal outcomes (i.e. A1c >7.0%, BP > 135/85 mm Hg, or physical examination or laboratory evidence of high risk of end-organ disease). In the control practice, participants were randomly selected from a printout of patients who met the same criteria as those set out for the intervention practice. Data were abstracted from patients' medical records.

Compared to all other clinically relevant studies, this study demonstrated the most changes in the organization of care by improving the delivery system design, offering provider decision support, implementing information systems, and helping patients build personal skills. In the intervention practice, the care redesign process included nurse-led planned care visits using evidence-based clinical management, patient education and support for self-management, making decision support tools available for providers, and implementing a new clinical information system (patient registry). A major aspect of this redesign was the nurse-led care management. The certified nurse specialist (CNS) made weekly 12 month visits and facilitated diabetes education, patient flow, and management. At each visit, patients were seen by the CNS (action plans/progress), completed one (of four) 2-hour group educational sessions, and were individually evaluated by the

physician. The educational sessions were led by an interdisciplinary team (nurse, physician, pharmacist, and nutritionist) and focused on an overview of diabetes, nutrition, medication, and self-management/goal-setting. These patient education visits took place over 6 months. Additionally, the care redesign included implementing an electronic patient registry system. The clinic staff and CNS also used a new procedure to remind patients of their appointments and recall those who missed their visits.

At baseline, mean A1c levels for the intervention (n= 112) and control (n= 48) practices were 8.2% and 8.3% respectively. At 12 months follow-up, the mean A1c level in the intervention practice decreased to 7.1% (mean change = 1.1%, $p<0.0001$); however in the control practice, the mean A1c level increased to 8.6% (mean change = +0.3%, $p<0.05$), making the net change 1.4%. These changes in A1c levels were significantly different between groups ($p<0.05$). This indicates that the care redesign process was successful at improving glycemic control over usual care in the control practice. The study design seems fairly strong as it was a clinical controlled trial with a moderate sample size, and 100% participant completion. This demonstrates that the new processes used in the intervention practice were likely acceptable and feasible. Therefore, the strategies used in the care redesign appear be promising.

5.4.4.7 Rothe et al., (2008)

The purpose of this study (interrupted time series) was to evaluate the Saxon Diabetes Management Program (SDMP), a statewide diabetes management program. This program addressed changes in organization of care mainly by supplying providers with decisions support tools, and helping patients develop personal skills. The SDMP had four core elements: 1. Integrated practice guidelines; 2. Integrated diabetes management

structure; 3. Integrated quality management as a basis for evaluation, and 4. Education.

The practice guidelines were developed by the Saxon Diabetes Committee to define therapy targets and criteria for timely referral to health care providers. The multidisciplinary health management system was between GPs and DSPs. The continuous quality management system comprised of regular training and workshops delivered by DSPs (2-4 times a year) to GPs (including discussing guidelines and international advances). GPs and DSPs received quarterly quality reports based on the collected data/outcome indicators. Lastly the SDMP provided structured education programs specifically tailored to different diabetic populations (e.g. newly diagnosed, young, elderly etc). For example, for younger type 2 diabetics, the program (MEDIAS) is based on patient empowerment and self-management concepts.

This study observed the entire target population: all diabetic patients (may have been on oral hypoglycemic agents or insulin therapy) who received medical care at any SDMP participating practices. The evaluation consisted of several cross-sectional surveys, the first quarter of 2000 (Group A1, $n=202,293$), then in quarterly intervals until the last quarter of 2002 (Group A2, $n=291,771$). Additionally, a subgroup of 105,204 patients was followed over the entire three years (Group B). Mean A1c for Group A1 (baseline) was 7.1% and mean A1c for Group A2 (~ 3 years later) was 6.8% (mean change 0.3%). At baseline, the mean A1c for Group B was also 7.1% and at 36 months follow-up, they achieved a very similar decrease to 6.9% (mean change 0.2%, $p<0.001$). Patients in Group B with poorly controlled diabetes ($A1c > 7.5\%$, $n = 32,314$) achieved a more significant decrease in A1c, as their A1c levels dropped from 8.8% to 7.5% (mean change 1.3%, $p<0.001$) after 36 months.

Although Groups A and B did not achieve clinically significant reductions, mean A1c levels at baseline were much lower than those seen in most of the other studies that have been discussed. Additionally, the study was well designed. As the study included all SDMP diabetic patients, the sample was exceptionally large and very representative of the target population. In fact the authors calculated that 6.7% of the general Saxon population was included in the study, and the prevalence of diabetes in Germany is estimated to be 6-8%. Moreover, the poorly controlled diabetic sub-cohort had baseline A1c levels typical of patients in other diabetes management studies, and they were able to achieve a clinically relevant reduction in A1c. Therefore the SDMP is likely a promising program.

5.4.5 Potentially Promising Studies

The four studies described below demonstrated clinically significant results; however quality of evidence was moderate, therefore they were deemed potentially promising for glycemic control in primary care. As with the studies which reported weight/BMI, the criteria for a study to be “potentially promising” includes the following:

- Did not meet the criteria for studies “likely to be promising”
- Any study design (e.g. RCT, CCT, cohort)
- $\geq 80\%$ participant completion or ITT analysis used

AND $n \geq 35$

OR

- Strong quality assessment rating but results which are not clinically relevant

5.4.5.1 Mayer-Davis et al., (2004)

This study has been discussed in the “weight/BMI” section. Briefly, it was an RCT conducted to evaluate the effectiveness of two lifestyle interventions aimed at adults with type 2 diabetes (may be on oral hypoglycemic agents or insulin), living in rural communities. Patients were randomized into the “intensive-lifestyle” group (n=49), the “reimbursable-lifestyle” group (n=47), or the control group (n=56). Participants in the intensive-lifestyle group met with the study nutritionist for several group and individual sessions. The reimbursable-lifestyle intervention was a condensed version, including 3 group sessions and 1 individual session conducted over the course of 12 months. Participants in the control group only received 1 individual session. The two study nutritionists received training for the intervention protocols. Additionally, the nutritionists had weekly conference calls with the university-based study nutritionist to ensure continual high quality program delivery, including appropriate responses to group and individual needs.

At baseline, mean A1c was 10.2%, 9.7%, and 9.6% for the intensive-lifestyle, reimbursable lifestyle, and control groups respectively. After the 12 month program, mean A1c was reduced to 8.6% (1.6% change; $p<0.0001$) in the intensive group and 8.9% (0.8% change; $p<0.05$) in the reimbursable group. Unexpectedly, the control group achieved a decrease in A1c of 1.1% ($p<0.0001$), therefore, the net change was 0.5% for the intensive group and -0.3% for the reimbursable group. Considering the difference between the reimbursable-lifestyle group and the control group is that the intervention group participants received three additional group sessions, there were likely other factors affecting the control group results.

As previously discussed, this study was an RCT with a sample likely to be representative of the target population, and 81% completers; however, the response rate was low and the sample size was quite small. The results suggest that both the intensive-lifestyle and control groups were more successful than the reimbursable-lifestyle intervention. Overall, it appears that the strategies used for the intensive intervention and the control group may be promising.

5.4.5.2 Gilmer, Philis-Tsimikas, & Walker (2005)

The San Diego MIA program, County Medical Services (SD-CMS) works with community health centres to provide a limited scope of medical services to low-income adults on a discounted fee-for-service basis. The SD-CMS contracted with Project Dulce to provide a nurse-led culturally specific diabetes management program at 17 of the community health centres. The objective of this cohort study was to evaluate the clinical effectiveness and costs of Project Dulce. This project implemented changes in the organization of care by helping patients build personal skills and redesigning the delivery system. Patients attended an initial session with the nurse (50 min), then follow-up appointments as required (on average 5 sessions). Half of the patients also attended 25 minute sessions with an RD. In addition to these one-on-one visits with the Dulce team (RN/CDE, RD, medical assistant), patients were encouraged to participate in an 8-week group self-management training program delivered by peer educators. The peer educators were recruited from the patient population, have been diagnosed with diabetes, and are of the same cultural/ethnic group as the participants. They completed a 4 month competency-base training and mentoring program in which they were required to complete a series of classes as a patient, followed by instructing a series of classes with

an experienced educator. This program covered diabetes and its complications, diet, exercise, medication, the importance of self-monitoring and also included interactive sessions. This project addresses population needs-based care as it aimed to improve care among low-income, ethnically diverse populations who are disproportionately affected by diabetes and related conditions. A historical comparator group was used by identifying patients enrolled in the SD-CMS during the year before Project Dulce was implemented.

At baseline, mean A1c levels for the intervention group (n=188) and comparator group (n=160) were 8.5% and 8.7% respectively. Based on patients' latest follow-up data (ranging from 6 to 18 months), the intervention group achieved mean decrease of 1.2%, while the control group only achieved a decrease of 0.5%. Therefore the net change in A1c was 0.7% and the change in A1c levels was significantly different between groups ($p<0.001$).

All patients with diabetes enrolled in SD-CMS were eligible to participate in Project Dulce. Of those eligible, 91% agreed to participate. One-hundred and ninety-four patients agreed to participate in Project Dulce, but baseline and follow-up data were reported for 188 participants. Although intention-to-treat analysis was not used, 97% of participants completed the study. The sample was moderate in size and somewhat likely to be representative of the target population; however this was only a one group cohort study (with a historical comparator group). Therefore, overall, this study is potentially promising.

5.4.5.3 Kirsh et al., (2007)

The purpose of this cohort study was to determine if a quality improvement project for diabetic patients at high risk of cardiovascular risk could improve intermediate

outcome measures for diabetes. This study took place in a primary care clinic at an academic medical center in the Veterans Healthcare System. It was targeted at patients with type 2 diabetes (may have been on oral hypoglycemic agents or insulin therapy) at the highest risk for cardiovascular morbidity (i.e. A1c > 9%, SBP > 160 mm Hg, or LDL-c > 130 mg/dl).

The intervention discussed was based on the Chronic Care Model. As such, it addressed several changes in the organization of care by improving the delivery system design, offering provider decision support, implementing information systems, and helping patients develop personal skills. Part of the system redesign included patients attending Shared Medical Appointments (SMA) in which groups of 8-20 patients were seen by a multi-disciplinary team (general internist, nurse practitioner, pharmacist, clinical health psychologist, and nurse) in 1-2 hour appointments. These group office visits were “organized to foster productive interactions between informed activated patients and a prepared proactive team, peer support”, and allowed for greater self-management support. Decision support was provided by having practice guidelines readily available on clinic computer workstations and by including a diabetes specialist team. The clinic integrated a clinical reminder system with feedback on performance. Additionally, an electronic medical record/clinical information system-based diabetes registry was used to identify patients. Patients were included in the analyses if they participated in at least one SMA from April 2005 to September 2005 (ranged from 1-7 sessions; up to 5 months). A retrospectively identified comparator group was also analyzed. It included all patients who participated in at least one SMA the following year; however data obtained prior to SMA participation was used. Usual care was provided by

internal medicine physicians and nurse practitioners. Patients were typically referred to a nurse case manager, pharmacist, dietitian, or diabetes specialty clinic if needed.

At baseline, mean A1c levels for the intervention group (n =44) and comparator group (n =35) were 10.4% and 9.8% respectively. At 12 months follow-up, the A1c levels in the intervention group decreased to 9.0% (mean change 1.4%, $p<0.001$), while mean A1c levels in the comparator group increased to 10.2%, inflating the net change to 1.7% (change in A1c levels significantly different between groups, $p=0.002$). This demonstrates that the quality improvement project including the use of SMAs was effective at improving glycemic control, whereas usual care was not.

This study only used a cohort design with a historical comparator group and small sample size. Despite these weaknesses, this study may still be of interest. All patients who participated in at least one SMA were included in the analysis. Moreover, this study addresses a particularly difficult group of patients relevant to primary care. Therefore it is worth exploring in this scoping review as potentially promising.

5.4.5.4 Andrews & Holland (2003)

The purpose of this cohort study was to evaluate a short exercise programme for patients with diabetes in a clinical setting. Patients were referred by GPs, practice nurses, hospital clinics and self-referrals. Although no exclusion criteria were applied (program suitable for anyone to attend), 59% of participants were hypertensive and 87% were type 2 diabetics (may have been on oral hypoglycemic agents or insulin therapy).

This program addressed a change in organization of care by attempting to redesign the delivery system. By offering a program that was open to anyone (i.e. those with and without established diseases), this program integrated health promotion and

disease prevention. Additionally, an interdisciplinary team was implemented with multiple health care professionals with defined roles and responsibilities. A diabetes specialist nurse (DSN), specialist diabetes dietitian, podiatrist, and doctor ran the programs. An exercise therapist was contracted to organize and deliver individually tailored exercise in a group setting. The DSN and exercise therapist were the only two providers who attended every session, while the others were involved during one or more sessions. The program ran once a week for 12 weeks and each session included 1 hour of activity followed by 30 minutes of education. The activities were based on the EXTEND movement to music principles. Topics covered during the education session included hypoglycemia and exercise, healthy eating, footcare, eye care and exercising safely. The program was meant to be informal and friendly, and peer group support was strongly encouraged. Lastly, patients were offered individual counseling sessions with the DSN and dietitian if necessary.

At baseline, the mean A1c level was 9.1% (n= 119). By the end of the 3 month program, A1c levels dropped to 7.9% (mean change 1.2%, $p<0.05$). Although intention-to-treat analysis was not used, 81% of participants completed the study, therefore increasing the likelihood that completers may still be somewhat representative of the original sample. As some patients were self-referred, the sample may not be representative of the target population. Lastly, it was only a short one group cohort design, therefore, this program is only somewhat promising.

5.4.6 Characteristics of Potentially Promising and Promising Studies

5.4.6.1 Changes in A1c Levels

For all eleven studies discussed thus far, baseline mean A1c levels were relevant to the range of patients seen in primary care; ranging from 7.3% to 11.0%. All of these studies also demonstrated clinically significant reductions in A1c, ranging from 1.1% to 2.5%. For the nine studies which had a control or comparator group, net change in A1c ranged from 0.2% to 1.7%; however for two of these studies, this percentage was inflated as glycemic control worsened in the control or comparator groups.

5.4.6.2 Appraising the Quality of Evidence

Unlike the seven studies which were not found to be promising (discussed below), the A1c reductions achieved in these eleven studies were more likely to be caused by the intervention (as opposed to confounding variables). While three potentially promising studies used one group cohort designs (two with comparator groups); the other eight studies used stronger designs. Seven of them were either RCTs or CCTs, while the last used a population-based cross-sectional design ($n > 200,000$) with a large sub-cohort ($n > 32,000$). Ten out of the eleven studies recruited samples which were very likely or somewhat likely to be representative of the target population. The last study recruited patients through referrals by providers, as well as patient self-referrals; therefore it is difficult to tell if the sample is representative of the target population (*potentially* promising study). Furthermore, all eleven studies had an attrition rate of less than 20%; therefore the results were more likely to be reflective of the entire sample. Lastly, all but two studies had 12 months follow-up data (including two with 36 months follow-up), which demonstrates that overall, the reductions in A1c were maintained past the 3 to 6

month plateau period. Sample sizes were at least fairly large for all studies except for two studies. Overall, these eleven studies used stronger designs and were still able to achieve clinically significant results; therefore, they are considered potentially promising at the least, and the strategies used to improve glycemic control merit further attention.

5.4.6.3 Delivery Channels and Providers

When comparing the 18 clinically relevant studies to these 11 promising studies, the percentage of studies which included one-on-one counselling (11/11 vs. 17/18) and group counselling (7/11 vs. 11/18) was quite similar. The promising studies included less telephone counselling (2/11 vs. 6/18), however, more provider education (6/11 vs. 8/18). The promising studies included slightly less provider education at level 1 (2/6 vs. 3/8) and level 2 (2/6 vs. 3/8), but more at level 3 (2/6 vs. 2/8). Percentages for mailed materials (0/11 vs. 0/18) and computer or web-based counselling (0/11 vs. 0/18) were the same. More importantly, compared to the 72 studies which reported A1c, these 11 promising studies used more group counselling (7/11 vs. 39%), one-on-one counselling (11/11 vs. 86%), and provider education (6/11 vs. 42%). The promising studies included less provider education at level 1 (2/6 vs. 33%), while including slightly more at level 2 (2/6 vs. 30%), and level 3 (2/6 vs. 27%). The promising studies however, included less telephone counselling (2/11 vs. 35%) and no computer and web-based counselling (0/11 vs. 6%) or mailed materials (0/11 vs. 4%)

Furthermore, when compared to the clinically relevant studies, the 11 promising studies involved slightly more RDs (7/11 vs. 10/18), other allied health professionals (8/11 vs. 11/18), other educators (3/11 vs. 4/18), and lay persons (1/11 vs. 1/18), while including less MD/RN/NPs only (1/11 vs. 3/18). Compared to all the studies which

reported A1c, these 11 promising studies more often included RDs (7/11 vs. 36%), other allied health professionals (8/11 vs. 51%), other educators (3/11 vs. 13%), and lay persons (1/11 vs. 4%); however much less often included MD/RN/NPs only (1/11 vs. 31%).

Overall, key features of promising interventions for glycemic control in primary care include one-on-one counselling, group counselling, provider education, involving other allied health care professionals and RDs. These strategies appear to contribute to clinically significant improvements in A1c levels.

Table 14: Comparison of Delivery Channels- A1c Studies

	Studies that Reported A1c N= 72	Clinically Relevant Studies N= 18	Potentially Promising/Promising Studies N= 11
One-on-one Counselling Included	61/72 (85%)	17/18 (94%)	11/11 (100%)
Group Counselling Included	28/72 (39%)	11/18 (61%)	7/11 (64%)
Telephone Counselling Included	25/72 (35%)	6/18 (33%)	2/11 (18%)
Computer/Internet Counselling Included	4/72 (6%)	0/18 (0%)	0/11 (0%)
Mailed Materials Included	3/72 (4%)	0/18 (0%)	0/11 (0%)

Table 15: Comparison of Providers- A1c Studies

	Studies that Reported A1c N= 72	Clinically Relevant Studies N= 18	Potentially Promising/Promising Studies N =11
RD Included	26/72 (36%)	10/18 (56%)	7/11 (64%)
MD/RN/NP Only	22/72 (31%)	3/18 (17%)	1/11 (1%)
Other Allied Health Included	37/72 (51%)	11/18 (61%)	8/11 (73%)
Lay Persons Included	3/72 (4%)	1/18 (1%)	1/11 (9%)
Other Educators Included	9/72 (13%)	4/18 (22%)	3/11 (27%)

Table 16: Comparison of Provider Education- A1c Studies

	Studies that Reported A1c N= 72	Clinically Relevant Studies N= 18	Potentially Promising/Promising Studies N=11
Total Provider Education	30/72 (42%)	8/18 (44%)	6/11 (55%)
Provider Education Level 1	13/30 (43%)	3/8 (38%)	(2/6) 33%
Provider Education Level 2	9/30 (30%)	3/8 (38%)	(2/6) 33%
Provider Education Level 3	8/30 (27%)	2/8 (25%)	(2/6) 33%

5.4.7 Overview of Studies Not Likely to be Promising

Studies were deemed “not likely to be promising” if they did not meet the criteria for studies “likely to be promising” or “potentially promising”. The 7 studies not likely to be promising, found that on average, their participants achieved clinically relevant decreases in A1c levels. On average, studies achieved a 1.4% reduction in A1c (ranged from 1.0% to 1.8%). Although they appear to be promising at first, upon further

evaluation this is not likely to be the case. Similar to the studies which reported weight and BMI, results were likely artificially inflated due to poor study designs. For five of the studies, the response rate could not be determined, while the other two studies had response rates of 29% and 37% respectively. Where the response rate could not be calculated, information was not provided on recruitment or recruitment was not necessary (e.g. chart review). This lack of information and recruitment, as well as low response rates, may introduce the issue of selection bias. Additionally, 5 of the 7 studies only used a one group cohort design; therefore a number of confounders may have influenced the results of these studies. For all 7 studies, $\leq 75\%$ of participants completed the study and intention-to-treat analysis was not used. Reductions in A1c were more reflective of the more motivated and successful completers. Overall, although clinically significant results were achieved, glycemic control strategies used in these studies are not likely to be promising.

5.5 Results of Methodological Studies

5.5.1 Quality Assessment Dictionary Addendum

While the quality assessment tool was being piloted, it became apparent that certain aspects of the Quality Assessment Tool for Quantitative Studies Dictionary were still unclear. Since this QA tool was not specifically developed for primary care studies, certain interventions and scenarios which the researchers encountered were not explained in the QA dictionary. For example, the dictionary did not address data that were collected via chart review. Other aspects of the QA dictionary were simply unclear and terms needed to be further defined. For example, what exactly constitutes as ‘valid data

collection methods’, and what if multiple tools are used, some of which were valid and some of which were not. A QA dictionary addendum was therefore developed to address these issues before the official QA process. As a result, studies were assessed more efficiently and consistently. The addendum outlines clarifications for the selection bias, confounders, blinding, data collection, withdrawals and drop-outs, and analyses sections of the QA dictionary. For more details, refer to the QA dictionary addendum in Appendix N.

5.5.2 Quality Assessment Tool Modifications

During the same pilot testing process, modifications were made to the actual Quality Assessment Tool. Changes were made to better fit the range of studies included in the present review. For example, several one-group cohorts were included in the review, therefore, the questions regarding confounders were not applicable and the options N/A were added. Modifications were made to the confounders, withdrawals and drop-outs, intervention integrity, and analyses sections. Details are outlined in the QA dictionary addendum shown in Appendix N.

5.5.3 Issues with Conducting Quality Assessments

Aside from what was discussed above, there are some issues with appraising the quality of evidence that were not under the researchers’ control. The most prominent problem would be the way in which data are reported. The CONSolidated Standards of Reporting Trials (CONSORT) Group developed the CONSORT Statement to improve the reporting of randomized controlled trials, therefore, enabling readers to better understand all aspects of these studies (CONSORT, 2010). The CONSORT Statement is “an evidence-based minimum set of recommendations for reporting RCTs. It offers a

standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.” It includes a 25-item checklist (and flow diagram) which pertains to the various sections of studies. Although over 400 journals support CONSORT, it is not mandatory for all journals and it only applies to RCTs.

For the studies published in journals which do not support CONSORT and for studies which are not RCTs, data are not reported in a standardized manner; some authors may choose to report a given piece of information, while others omit it. The problem arises when that provision of data results in a lower QA rating. These studies are therefore unfairly penalized while those who reported less information are not (although they may share the same flaw). For example, the percentage of participants who completed the study is calculated by dividing the number of participants who completed the study by the number who consented to participate. If a given study only reports the number of participants who have baseline data recorded, the percentage of participants who completed the study would be based on this number instead. Therefore, the QA rating for the withdrawals and drop-outs section may be higher for the study that omitted this information, as the percentage of participants that completed the study would appear to be higher. Moreover, intervention integrity and fidelity are often not well reported. It is important to know if (or the % of) participants actually received the allocated intervention, how consistently the intervention was delivered, or if participants received an unintended intervention. This may affect results as well as give readers a sense of how realistic it is to deliver the intervention as intended. Furthermore, some studies may state that they used a given statistical method; however, they may not report the data that was

generated using that particular method. Several authors stated that intention-to-treat analysis was used; however, upon further examination of results, data for participants who dropped-out were not included in the analysis. It is issues like these which decrease the validity and accuracy of quality assessment results.

6 DISCUSSION

6.1 Discussion- Augmented Scoping Review

6.1.1 World Health Organization Stepwise Chronic Disease Prevention Framework

As previously discussed, the draft obesity management planning framework developed by Brauer et al (2008) was grounded in the WHO's framework for chronic disease prevention. The WHO framework is discussed in more detail in the "literature review" section. Briefly, they describe three steps to policy implementation: Step 1 CORE, Step 2 EXPANDED, and Step 3 DESIRABLE. Only Step 2 and Step 3, however, apply to the present review. Studies included in this review were conducted in developed countries and interventions required additional resources (beyond usual care). Therefore, it is evident that studies were already being conducted in 'expanded' and 'desirable' practices. As a result, we cannot make comparisons between promising basic versus promising ideal strategies. 'Expanded' practices refer to interventions that may be implemented with a realistically projected increase or reallocation of resources. Therefore these projects likely require more funding and may include educational and skill-building workshops/group appointments. 'Desirable' practices refer to interventions which are evidence-based and beyond the reach of existing resources. Interventions may include computerized patient self-assessment, individualized self-management plans, and supplementary self-management support by telephone or internet (WHO, 2005). Overall, it appears that promising weight management and glycemic control interventions used a combination of strategies found in 'expanded' and 'desirable' practices. They often involved educational skill building workshops which are part of step 2, as well as

evidence-based individualized self-management plans, and support by telephone which are a part of step 3.

6.1.2 Ontario's Chronic Disease Prevention and Management Framework

The development of the draft obesity management planning framework was also informed by the Chronic Care Management (CCM) model and other related models. This is discussed in more detail in the “literature review” section. Briefly, the current health care system has been criticized as it is designed to address acute illness rather than chronic disease (MOHLTC, 2007). As such, care tends to be reactive as opposed to proactive. The Ministry of Health and Long-Term Care (MOHLTC) finds that practitioners rely on patients to contact the system and patients are usually passive when receiving treatment, while promoting overall health and preventing disease are not priorities. The Ontario Chronic Disease Prevention and Management (CDPM) Framework was developed by the MOHLTC (2007) as a guide to redesign health care practices and systems to make them more evidence-based, population-based and client-centered. Several key features of this framework were reflected in the weight management and glycemic control studies included in the present review. Two out of the 6 promising weight management studies and 8 out of the 11 promising glycemic control studies incorporated aspects of the CCM and addressed a change in the organization of care on some level. The promising glycemic control studies integrated more features and to a greater extent than the weight management studies.

6.1.2.1 Personal Skills and Self-Management Support

The framework describes four elements for health care organizations, three of which are highly relevant to the most promising interventions discussed in this review.

The first element involves helping patients develop personal skills and providing self-management support. The interventions of many promising studies went beyond providing basic diet and physical activity counseling. After intense training, patients may have acquired the skills manage stress, emotional eating, and tempting situations, as well as grocery shop and cook to better manage their illness. During appointments, counseling and support services, shared decision-making and goal setting were used to help patients learn to self-manage and be active in their own care. Bray et al. (2006), for example, redesigned their care process to include nurse-led care management that included patient education and support for self-management through group visits. Additionally, Kirsh and colleagues (2007) aimed to “foster productive interactions between informed activated patients and a prepared proactive team, as well as peer support.”

6.1.2.2 Delivery System Design

The second feature is improving the design of delivery systems. A few promising studies incorporated case management, including planned interactions and follow-ups. Planned follow-ups are especially important for providing further education, support, and feedback to patients. In the study by Bray et al. (2008), an advanced practice nurse made weekly 12 month visits and facilitated diabetes education, patient flow, and management in the intervention practice. In the study by the California Medi-Cal Type 2 Diabetes Study Group, the intervention group received diabetes case management provided by RNs and RDs working closely with an endocrinologist. Focusing on health promotion and disease prevention is another aspect of delivery redesign. The study conducted by Andrews & Holland (2003), offered a physical activity and education (lifestyle) program which was suitable for anyone to attend (open to referral from all GPs, PNs, hospital

clinics, and self-referral). Lastly, population needs-based care provides tailored interventions to varying target groups. Gilmer et al (2005), for example, aimed to improve care among low-income, ethnically diverse populations who are disproportionately affected by diabetes and related conditions. The study by Rothe et al (2008), provided structured education programs specifically tailored to different diabetic populations (e.g. newly diagnosed, young, elderly etc).

6.1.2.3 Provider Decision Support

Another approach involves supplying providers with decision support tools. Some promising studies offered provider education to help them integrate evidence-based guidelines into daily practice (beyond training on lifestyle counseling or motivational interviewing). In the study by Rothe et al. (2008), GPs regularly attended workshops where they discussed and were trained on guidelines and international advances. Measuring outcomes and giving feedback to the health care providers is another aspect of provider decision support. The workshops offered in the study by Roth et al. (2008) were also part of an integrated quality management system, in which outcome indicators were measured and providers received reports and feedback. Additionally, Kirsh and colleagues (2007) implemented a clinical reminder system with feedback on performance. Provider decision support also includes supplying tools for providers. Most promising studies incorporated treatment algorithms to help providers follow evidence-based guidelines. The study by Rothman et al., (2005), for example, used treatment algorithms to help reduce cardiovascular risk factors and improve glycemic control in diabetic patients. Lastly, giving providers access to specialist expertise would improve patient care. This can be done by referring the patients to the experts outside of the

practice, but is most easily done when practices have interdisciplinary teams. Several studies, for example, referred patients to Registered Dietitians.

6.1.2.4 Information Systems

The last component of the CDPM framework which is relevant to health organizations is including advanced information technology systems. Although many of the intervention studies implemented such systems (e.g. electronic health records, client registries, web support, online links etc.), there were only three promising studies (all for glycemic control) that did so. Strategies in the study by Bray et al (2005) included providing a new clinical information system in the form of a patient registry. Rothman et al (2005) developed a Microsoft Access database to track patient outcomes and proactively improve care. The study by Kirsh et al. (2007) used an electronic medical record/clinical information system-based diabetes registry to identify target patients. In addition, practice guidelines were made readily available on clinic computer workstations. The availability of these guidelines is also a part of offering providers decision support tools.

6.1.2.5 Community Elements

Other aspects of the CDPM framework include ‘developing healthy public policies’, ‘creating supportive environments’, and ‘promoting community action’. Promoting community action is the only feature relevant to the present review-collaborations between the health care sector and community organizations. Boyd et al. (2006) described a project which aimed to form a partnership between the Community Health Centre (SCHC) and the local YMCA to improve access to exercise for low-income patients with type 2 diabetes. Although results were clinically relevant, the study

may not be promising due to the poor quality study design. None of the promising studies included in this review addressed these community elements.

6.1.3 The Quality of Studies Conducted in Primary Care

The vast majority of included intervention studies were rated as weak (61%) in terms of quality of evidence. Sixty-seven studies were rated as moderate (38%) and only two were rated as strong (1%). Studies in primary care and the community are mostly weak in quality because they are inherently difficult to conduct. These studies are more complex as researchers are dealing with a setting in which a service is already being delivered. The quality of primary care studies can be improved but a well conducted RCT would require a large number of practices, patients, and resources; a lot of which, research to date has not been able to incorporate. Reasons for which studies are often weak/areas that need strengthening, are outlined below.

For studies conducted in primary care or the community, it is often not feasible to randomly select patients for participation. Therefore studies were seldom rated as ‘very likely’ to be representative of the population. Similarly, the feasibility of conducting studies relevant to IP-PC often hinders the type of study design that can be used. Many were cohort studies, while fewer were randomized controlled trials. For the one group cohort studies, confounders were often marked as ‘not applicable’, therefore assigning a weak rating for that section. Given the nature of these studies, blinding was usually not possible. Firstly, the assessor may have been the health professional providing the intervention; therefore they were aware of the intervention/exposure status of the patients. Secondly, studies included diet and/or physical activity; therefore, patients may have been aware of the research question. Furthermore, attrition was often high given the type

of patients recruited for the study. Sample sizes are often larger and patients are more representative of patients seen in primary care. They are not comparable to the small group of highly motivated patients participating in highly controlled efficacy studies.

As discussed above, primary care studies are often weak and scoping reviews do not require quality assessments; however, appraising the quality of evidence was found to be a crucial step in the present review. Although studies in the community that are representative of primary care are often weak from a classic RCT perspective, they may remain promising from a practical perspective. Since researchers are searching for novel approaches, studies with weak studies were not immediately discounted; different aspects of the quality assessment were considered.

6.1.4 Contributions to the Existing Literature

In the analysis of complex interventions, potentially interesting studies were first identified based on clinical outcomes. Upon further interpretation, and after appraising the quality of evidence, most studies were discounted due to weak study designs; therefore, new insights were limited. Although a few studies did achieve clinically significant results and used stronger designs, there was no clearly dominant type of effective intervention. Interventions used in promising studies, however, were quite consistent with the CCM model and related models. Four general approaches which were used in these studies include helping patients build personal skills and providing self-management support, improving the design of delivery systems, supplying providers with decision support tools, and implementing information technology systems. Particular strategies which were often in promising interventions include offering counselling, support services, and health information, engaging patients in shared decision-making,

goal-setting and self-management, planning interactions and follow-ups, offering provider education, using decision support tools (e.g. treatment algorithms), and having access to specialist expertise. Promising studies used complex health interventions which included combinations of approaches suggested in the Chronic Care model. As such, it is difficult to determine to what degree each specific feature affected clinical improvements. Nonetheless, it is evident that overall, CCM model approaches are relevant to the success of weight management and glycemic control interventions in primary care. Therefore, the present review supported the incorporation of this model in the obesity management planning framework developed by Brauer et al. (2008).

6.1.5 Next Steps and Future Research

This review has generated a large database of studies relevant to weight management in inter-professional primary care. Although data have been collected and summarized (available upon request), intervention studies which have reported other outcomes, such as blood pressure and lipid levels, still need to be interpreted. Similar to the studies which reported weight/BMI and A1c levels, the analysis will help researchers identify promising strategies for reducing blood pressure and lipid levels in the range of patients seen in primary care. Studies thus far have been first analysed based on clinical outcomes reported (i.e. weight/BMI and A1c); however, there are several other ways the data can be examined. All intervention studies fall under four main categories (unique) which are used as target groups in the draft obesity management planning framework: 1. Generally healthy; 2. High CVD risk; 3. Diabetes; and 4. Other chronic diseases. Looking for promising results based on these categories would be useful as they represent typical target groups found in primary care. Additionally, studies which addressed changes in the

organization of care (no clinical data reported) and patient and/or provider perceptions of improved care have been summarized; however, they have yet to be interpreted. Findings from these studies should be considered in the interpretation as it would provide further insights on potentially promising strategies for the above target groups. Furthermore, categorizing studies based on specific populations of interest would also be valuable. Populations such as low-income individuals, ethnic minorities, rural populations, and children/adolescents are highly relevant to the range of patients seen in primary care practices across Canada.

The findings from this review have highlighted future research directions in the area of weight management in inter-professional primary care. Next steps may include piloting promising strategies identified in the review. Implementation trials need to be conducted to determine the effectiveness of interventions in IP-PC settings across Canada. To date, this review has informed the draft obesity management planning framework developed by Brauer and colleagues (2008). Once the draft has been reviewed and developed in more detail, the final framework will have identified best practice “obesity services” programs for specific target groups within Canadian primary care (Royall, 2010). With all options identified, it will provide clear guidance for the development of new implementation trials in multiple IP-PC settings. This may include contacting authors of studies which demonstrated promising strategies with the possibility of using similar tools (e.g. treatment algorithms, patient resources). These implementation trials will be conducted to address the hypothesis that interventions at the organization and delivery levels can improve obesity prevention, management and treatment effectiveness (Glasgow et al., 2001; Royall, 2010).

Overall, the data collected from this review will be further analysed and the effectiveness of promising strategies should be tested by conducting implementation trials. Insights gained from the present review will help to strengthen the knowledge base and subsequent reviews on this topic. Published documents may be used by health care providers and may inform guideline and policy development to improve weight management in primary care.

6.2 Discussion- Methodological Issues

6.2.1 Applicability of QA Tool in Primary Care

The Quality Assessment Tool for Quantitative Studies developed by the Effective Public Health Practice Project (EPHPP) has now been recognized for public health and health promotion studies in the Cochrane Handbook for Systematic Reviews of Interventions (The Cochrane Collaboration, 2008). This QA tool covers all quantitative study designs, and includes many relevant domains (e.g. selection bias, withdrawals and drop outs, and intention-to-treat) making it suitable for this review. Additionally, no similar tool has been developed specifically for primary care; therefore it appears to be the most appropriate existing tool for the range of studies included in the present review.

While the QA tool was being piloted however, modifications were made to the EPHPP QA tool. Changes had to be made in order to better fit studies conducted in primary care. During this pilot process, it also became apparent that certain aspects of the QA tool dictionary were still unclear. Since this QA tool was not expressly developed for primary care studies, certain interventions and scenarios which the researchers

encountered were not described in the QA dictionary. An addendum was therefore created to address these issues (previously discussed in the results section).

6.2.2 Study Strengths and Limitations

Some limitations should also be taken into account when interpreting the results of this review. Studies which were not published in English were excluded; therefore relevant studies published in other languages may have been missed. However, studies which have been published in countries (e.g. Denmark) where researchers would expect to find promising interventions have been mostly translated into English. Due to time constraints, multiple researchers had to extract data and complete summary tables. Despite providing a coding scheme, there was inevitably some variability between researchers. As mentioned above, there are no QA tools which have been expressly developed for studies in primary care; therefore an addendum, including modifications was created to address any issues that arose during the piloting process. Despite efforts to modify the tool to better fit primary care studies, there were additional issues which came up during the final QA process which were not anticipated. For these issues, it is possible that they were not dealt with consistently by different researchers conducting QA. Furthermore, the exclusion criteria were created in an attempt to exclude any studies which would have been rated as “not likely to be representative of the target population”. Based on the QA results, however, some studies which were not likely to be representative, managed to be included.

As a scoping study, the present review did not incorporate all of the features outlined in the Cochrane Handbook for Systematic Reviews of Interventions. Although the reference lists of all included reviews were systematically screened for potentially

relevant studies (screen by title, abstract and then full-text), the size of the review precluded review of the reference lists of all primary studies. The number of missed primary studies within the 2003-2009 timeframe was likely to be small.

Despite the limitations, this review has made important contributions to the existing body of knowledge. To our knowledge, this augmented scoping review is the first of its kind. To date, no other scoping review has included as many studies, as well as quality assessments on the topic of weight management in inter-professional primary care. Over 26,000 titles and abstracts and 1100 full-text articles were screened.

Researchers of the present review were therefore confident that a comprehensive database of relevant studies was identified. Unlike narrative reviews, scoping reviews require a rigorous and transparent process. Researchers used a systematic approach for the search strategy, study selection, quality assessments, and summarizing of results. All aspects of the study were documented in enough detail to allow the study to be replicated by others. Additionally, conducting quality assessments was not a requirement of scoping reviews; however, the researchers felt that doing so would enhance the analysis.

Appraising the quality of evidence allowed researchers to assess studies for biases and better interpret results. All important tools (e.g. screening tools, QA tool) were piloted and critical decisions were individually made by two researchers who then came to consensus (e.g. selecting studies and conducting quality assessments). Moreover, it is important to recognize that an augmented scoping review was conducted as it best fit the objective of the present review. There is no single ideal type of literature review, rather, each type of review method offers a set of tools best suited to different purposes and research questions (Arksey & O'Malley, 2005). In order to discover new and innovative

strategies, it was necessary to broaden the scope of the review. As a result, studies were heterogeneous and complex. Although this may be seen as a limitation, researchers may also recognize it as a strength. The present review full-filled its purpose of identifying promising weight management strategies for program development in inter-professional primary care.

7 CONCLUSIONS

Based on this large augmented scoping review, it seems that the number of studies which have discovered new and promising approaches for weight management and glycemic control in primary care is quite limited. Of studies which reported weight/BMI, only 8% appear to be promising after net effect of treatment and quality assessments were reviewed. The situation was somewhat more optimistic for studies which reported A1c, as 15% were deemed at least potentially promising after the analysis was completed. Approximately 83% of promising weight management studies and 55% of promising glycemic control studies offered some level of provider education. The large majority of promising interventions also incorporated CCM model approaches and addressed a change in the organization of care (more evident in glycemic control studies). Most prominent were: 1. redesigning the delivery system; 2. offering providers training and/or decision support tools; and 3. helping patients develop personal skills and providing self-management support. Research to date indicates that this approach to chronic disease prevention and management will improve the health of chronically ill individuals and reduce the incidence of chronic disease in the province (MOHLTC, 2007). Based on the characteristics of successful interventions, it appears that key features of both weight management and glycemic control interventions include one-on-one counselling, group counselling, provider education (especially for weight/BMI studies), and involving RDs. It appears that involving other allied health care professionals only emerged as a key feature of glycemic control interventions. The inclusion of these delivery channels and providers may contribute to clinically significant improvements (i.e. $\geq 3\%$ weight loss,

decrease of ≥ 1 BMI unit, decrease of $\geq 1\%$ A1c) where study designs are still relatively strong.

Overall, no clearly superior interventions emerged from the analysis. This review provides direction for further studies that combine promising elements of studies to date. Aside from incorporating key characteristics at the organization and delivery levels, the ideal study must have a strong design. Implementing these strategies and reporting clinically relevant results is of little use if methods are highly biased. Firstly, the setting must be relevant to inter-professional primary care and the sample needs to be representative of the target population. Patients should be randomly selected and the sample size should be relatively large. Secondly, the ideal design would be a randomized controlled trial, in which participants are blinded to group assignment, confounders are controlled for, and data collection methods are both reliable and valid. Lastly, it is ideal if attrition is limited; however, this is not under the researchers control and is often difficult in a primary care setting. Therefore, intention-to-treat analysis should be used to at least “account” for possible results among non-completers (instead of analyzing results of completers only).

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9 APPENDICES

Table of Contents

APPENDIX A: Search Terms and Phrases.....	152
APPENDIX B: Title and Abstract Screening Tool.....	156
APPENDIX C: Full-text Screening Tool.....	158
APPENDIX D: Coding Manual.....	162
APPENDIX E: Intervention Summary Table Template	165
APPENDIX F: Organization of Care Summary Table Template	172
APPENDIX G: Patient and/or Provider Perceptions Summary Table Template	175
APPENDIX H: Summary of Results Template- All BMI/Weight Studies	178
APPENDIX I: Summary of Results Template- All A1c Studies.....	179
APPENDIX J: Weight Results Table Template- Clinically Relevant Studies	180
APPENDIX K: BMI Results Table Template- Clinically Relevant Studies	182
APPENDIX L: A1c Results Table Template- Clinically Relevant Studies	184
APPENDIX M: Quality Assessment Summary Table Template	186
APPENDIX N: Quality Assessment Tool Addendum	187
APPENDIX O: References of Included Articles	190

APPENDIX A Search Terms and Phrases

CONCEPT	PUBMED (Medline)/ COCHRANE	CINAHL	PsycINFO/ SCI-Expanded	TEXTWORDS (OVID)
Obesity/ Overweight	Exp overweight/ (includes obesity) Exp body weight changes/ Body weight/ Exp diabetes mellitus/ Chronic disease/ Exp dyslipidemias/ Hypertension/ Coronary artery disease/ Coronary disease/ Exp cardiovascular diseases/ Body mass index/ Waist-hip ratio/ Bulimia/ (used for binge eating)	Exp obesity/ Body weight/ Body weight changes/ Exp weight gain/ Body mass index/ Waist-hip ratio/ Exp diabetes mellitus/ Exp hyperlipidemia/ Hypertension/ Exp cardiovascular diseases/ Chronic disease/ Bulimia/	Body weight/ Body size/ Exp overweight/ Body mass index/ Weight gain/ Exp diabetes mellitus/ Chronic illness/ Chronicity (disorders)/ Exp cardiovascular disorders/ Binge eating/	Obes\$ Overweight Weight loss Weight adj2 reduc\$ Reduc\$ weight Weight control Weight adj 2 manage\$ Weight maintenance Maintain\$ adj2 weight Body weight Diabet\$ Chronic disease\$ Dyslipidemia Dyslipidaemia Hypercholesterolemia Hypercholsterolaemia Hypertension High blood pressure Heart disease Coronary artery disease CAD Cardiovascular disease\$ Cardiovascular event\$ Binge eating

Non-drug treatments	"prevention and control" pc.fs.(floating subheading) Therapy.fs.(floating subheading) Diet therapy.fs.(floating subheading) Exp nutrition therapy/ Primary prevention/ Secondary prevention/ Exp health promotion/ Exp health education/ not (sex education/ or health education, dental/) Exp exercise/ Exp exercise therapy/ Self-care/ Life style/ Exp behavior therapy/ (includes cognitive therapy) Self efficacy/ Attitude/ Patient attitude/ Attitude to health/	Physical activity/ Nutrition/ Eating behavior/ Preventive health care/ Health promotion/ Exp diet therapy/ Exp health education/ Exp exercise/ Self care/ Life style changes/ Life style/ Exp psychotherapy/	Prevention/ Exp treatment/ Exp counseling/ Diets/ Dietary restraint/ Weight reduction/ Eating behavior/ Food intake/ Health promotion/ Health education/ Preventive medicine/ Exp lifestyle/ Health attitudes/ Health behavior/ Exp exercise/ Weight control/ Exp physical activity/ Exp psychotherapy/ Attitudes/	Prevention Therapy Nutrition education Nutrition adj2 counsel\$ Diet\$ adj2 counsel\$ Dietary approach Diet\$ adj2 manag\$ Health education Patient education Exercise\$ Health program\$ Self-management Physical activity Diet Lifestyle intervention Health promotion Cognitive behave\$ therapy CBT Behav\$ counsel\$ Psychosocial Attitudes Beliefs Self-efficacy
Primary care setting	Exp primary health care/ Physicians, family/ Nurses/ Nurse practitioners/	Primary health care/ Physicians/ Physicians. Family/ Multiskilled health 153ounseling153r/	Primary health care/ Family physicians/ Physicians/ Family medicine/ General practitioners/	Physician\$ General practitioner\$ Nurse\$ Dietitian\$ Dietician\$

	Nurse clinicians/ Allied health personnel/ Exp managed care programs/ Exp patient care team/ Health educators/	Allied health personnel/ Dietitians/ Exp nurses/ Exp group practice/ Exp nursing practice/ Health educators/ Diabetes educators/ Exp multidisciplinary care team/ Family nursing/	Nurses/ Allied health personnel/ Health personnel/ Exp managed care/	Health care provider\$ Health professional\$ Allied health personnel Multidisciplinary approach Primary health care Primary care Organization of care
NOT	exp 154ounse/ or exp 154ounselin region/ or exp central 154ounsel/ or exp latin 154ounsel/ or exp south 154ounsel/ or exp 154ounselin regions/ or exp arctic regions/ or exp asia/ or exp historical geographic locations/ or exp 154ounse ocean islands/ or exp pacific islands/	School health education/ Student health education/ Exp drug therapy/ Exp Africa/ Exp Asia/	Exp drug therapy/ Exp schools/ School-based interventions/	

TEXTWORD STATEMENTS

Obesity/Overweight

obes* OR overweight OR weight loss OR (weight AND reduc*) OR reduc* weight OR weight control OR (weight AND manage*) OR weight maintenance OR (maintain* AND weight) OR body weight OR diabet* OR chronic disease* OR dyslipidemia OR dyslipidaemia OR hypercholesterolemia OR hypercholesterolaemia OR hypertension OR high blood pressure OR heart disease OR coronary artery disease OR CAD OR cardiovascular disease* OR cardiovascular event* OR binge eating

Non-drug treatments

prevention OR therapy OR nutrition education OR (nutrition AND counsel*) OR (diet* AND counsel*) OR dietary approach OR (diet* AND manag*) OR health education OR patient education OR exercise* OR health program* OR self-management OR physical activity OR diet OR lifestyle intervention OR health promotion OR cognitive behave* therapy OR CBT OR 155ounse* counsel* OR psychosocial OR attitudes OR beliefs OR self-efficacy

Primary care setting

Physician* OR general practitioner* OR nurse* OR dietitian* OR dietician* OR health care provider* OR health professional* OR allied health personnel OR multidisciplinary approach OR primary health care OR primary care OR organization of care

APPENDIX B Title and Abstract Screening Tool

INCLUDE IF:

Study

- Quantitative Studies
 - PHC cohort
 - Trial (e.g. RCT)
 - Pre-post study
 - Cross-sectional (e.g. survey based in Canada or potentially relevant in Canadian inter-professional primary care)
- Qualitative Studies
 - Provider and/or patient perceptions of improved care or a change in process of care.

-----AND-----

Setting

- Located in primary care setting or general practitioner (GP) practice
- Referred from multiple GP practices
- Other settings (e.g. private practice, community centre) if the intervention can be replicated or developed in Canadian inter-professional PHC
- Intervention delivered by a health care provider affiliated with PHC
- Studies using a multi-disciplinary approach

-----AND-----

Lifestyle Component

- Diet and/or physical activity therapy
- Results reported as change in body mass (i.e. weight or BMI)
- Results reported as diet and/or physical activity behaviour change
- Results reported as other clinical outcomes (e.g. HbA1c, BP, lipids)
- Results reported as change in quality of life
- Results reported as cost-effectiveness

-----OR-----

Organization of Care

- Change in process, services, practices of care

-----OR-----

Patient and/or Provider Perceptions

- Perceptions of improved care
-

Reviews

- Primary care studies (meeting above criteria) referenced in reviews (narrative, systematic), guidelines or grey literature (e.g. screening/ readiness/ assessment lifestyle intervention studies)

EXCLUDE IF:

- Prior to 2003 for publication of primary study
- Prevalence of risk factors in primary care settings
- Editorials, debates
- Reports that are not editorials or debates
- Interventions not beyond the norm
- Observations of current practice
- Obvious pilot/sample size < 20
- Homogeneous ethnic groups outside of Canada
- Efficacy studies including:
 - Metabolic studies e.g. feeding trials
 - Large cohort studies not from primary care setting e.g. NHANES
 - Large multi-centre diabetes, HT or dyslipidaemia treatment or prevention trials e.g. UKPDS, DCCT, DPP, DASH (except if they are translation programs into PHC)
 - Diet counselling studies focused on differing diets within homogeneous groups or volunteers solicited by advertising, not the range of patients seen in primary health care
 - If participants NOT recruited through PHC (e.g. mass media)
- Drug and surgery interventions

APPENDIX C Full-text Screening Tool

Reviewer: _____ RefMan ID # _____

Author _____ Year Published _____

Title _____

Verify that the study meets the criteria for each of the following characteristics:

Fill out #1 AND #2

1. SETTING

Relevant to Canadian inter-professional PHC ☐

-----*exclude if*-----

NOT relevant ☐

Comments:	

2. LIFESTYLE COMPONENT

Diet AND/OR Physical Activity ☐

OR

Health Behaviour Interventions with Change in Body Mass ☐

-----*exclude if*-----

NO lifestyle component ☐

Comments:	

Fill out appropriate section (#3 OR #4 OR #5)

2. INTERVENTION/THERAPY

Diabetes ☐

CVD/HTN ☐

Other Diseases (e.g. arthritis, COPD) ☐

General Chronic Disease Management (not related to specific conditions) ☐

Obesity Only ☐

Healthy Lifestyle (no disease, not weight loss) ☐

3. ORGANIZATION OF CARE

Related to a change in process of care ☐

-----*exclude if*-----

NOT a change in process of care (i.e. usual) ☐

Comments:	

4. PROVIDER and/or PATIENT PERCEPTIONS

Perceptions re: improved care ☐

-----*exclude if*-----

NOT re: improved care (i.e. usual) ☐

Comments:	

INCLUDE ☐

EXCLUDE-Hold

Part of a larger study- find primary study ☐

Review- check references ☐

Relevant/Background info (Canadian-based population data) ☐

EXCLUDE-Fully ☐

Comments:	

APPENDIX D Coding Manual

#1 Setting (relevant to inter-professional primary care)

- Located in primary care setting or general practitioner (GP) practice
- Referred from multiple GP practices
- Other settings (e.g. private practice, community centre) if the intervention can be replicated or developed in Canadian PHC
- Intervention must be delivered by a health care provider affiliated with PHC (e.g. physician, nurse, dietitian, physiotherapist, peer-helper etc) AND beyond the norm (can help improve treatment implemented in a multi-disciplinary team)
- Studies using a multi-disciplinary approach
- **Exclude if:**
 - Intervention not beyond the norm (e.g. review of nurses role, physician and/or nurse standard practice/counselling)
 - Medical management
 - Cardiac rehab
 - Pharmacy
 - Home care
 - Pediatric specialty clinic
 - Obvious pilot/sample size < 20
 - Homogeneous ethnic groups outside of Canada
 - Efficacy studies including:
 - Metabolic studies e.g. feeding trials
 - Large cohort studies not from primary care setting e.g. NHANES
 - Large multi-centre diabetes, HT or dyslipidemia treatment or prevention trials e.g. UKPDS, DCCT, DPP, DASH (except if they are translation programs into PHC)
 - Diet counselling studies focused on differing diets within homogeneous groups or volunteers solicited by advertising, not the range of patients seen in primary health care
 - If participants NOT recruited through PHC (e.g. mass media)
 - Drug and surgery interventions

-----AND-----

#2 Lifestyle Component

- Lifestyle therapy (i.e. diet and/or physical activity)
- Change in organization of care with a lifestyle component

- Results reported as change in body mass
- Results reported as change in diet and or physical activity (i.e. behaviour change)
- Exclude if:
 - Change in body mass resulting from drug therapy

-----OR-----

#3 Diet and/or PA Intervention/Therapy

- Change in organization of care interventions (categorize by disease)
- If NOT an intervention/therapy, do NOT check off any boxes (i.e. do not categorize by disease); skip to page 4 for final decision

-----OR-----

#4 Organization of Care

- CHANGE in process of care/practice/service
 - i.e. beyond usual care
 - reports outputs (e.g. #screenings for given disease)
- Must be within an inter-professional context
- Only primary studies
- Observational and cross-sectional studies
- If change in organization of care intervention reporting patient outcomes, do NOT fill in this criteria (i.e. criteria #4)
 - These belong in criteria #3 Lifestyle Intervention/Therapy
 - If a study describes BOTH, it still belongs in criteria #3 Lifestyle Intervention/Therapy
- Exclude if:
 - Observations of current practice
 - Not a change in process of care

-----OR-----

#5 Patient and/or Provider Perceptions

- Perceptions re: improved care
- If meet criteria #1 AND #2 AND #5 but part of a larger study, automatically Exclude-HOLD

FINAL DECISION

INCLUDE if:

- Meets criteria #1 AND #2 AND (one of #3 OR #4 OR #5)
-

EXCLUDE-HOLD if:

- Meets criteria #1 AND #2, NOT (one of #3 OR #4 OR #5) but fits one of the categories below
 - Part of larger study- check for primary study
 - Study protocol/design
 - Subset of original study
 - Review- check references
 - If meets criteria #1 AND #2 and is a review (narrative or systematic), automatically exclude-hold in this category
 - Background information
 - Canadian-based population data
 - Canadian guidelines
-

EXCLUDE-FULLY if:

- Does NOT meet criteria #1 OR #2
- Does meet criteria #1 AND #2 but NOT (one of #3 OR #4 OR #5)
- Does meet criteria #1 AND #2 but N/A to #3 OR #4 OR #5
 - Prior to 2003 for publication of primary study
 - Prevalence of risk factors in primary care settings
 - Editorials, debates
 - Reports that are not editorials or debates

NOTE:

- In the comment boxes, justify reasoning for meeting criteria or not (e.g. sample size and recruitment in setting section)
- If criteria #1 AND #2 are not met, do NOT fill out criteria #3 OR #4 OR #5; skip to page 4 and make final decision

APPENDIX E

Intervention Summary Table Template

STUDY		
Title	Write out the full title of the article. Example: Translating the diabetes prevention program to primary care	
Author/Date	First author only. Surname, given name initial, coma, date. Example: Campbell G, 2003	
RefMan ID#	Indicate the reference manager ID #. Example: 1212	
Country of Origin	The country in which the study was conducted. Example: Canada	
Purpose/Objectives	List the purpose or objectives of the study (list multiple objectives; if not provided, list the overall purpose). Example: To compare- (1)the effectiveness of physician advice versus dietitian advice for a fat reduced diet (2)the effectiveness of dietitian advice for a fat-reduced diet (3)dietitian advice for a soluble fiber-enhanced diet	
STUDY DESIGN & PARTICIPANTS		
Study Design	Indicate the study design used for the study. If needed, provide more detail. Example 1: RCT. Example 2: A cross-sectional study within the Second Manifestations of ARterial disease (SMART) study which is a cohort study that has enrolled >7000 patients with major atherosclerotic risk factors.	

Target Group	Use the inclusion criteria to determine the target group (one brief phrase/sentence). In the six rows to follow, indicate "YES" for all that apply (chronic conditions that the participants have- baseline data). If the data is available, in brackets, indicate the percentage of patients with this chronic condition. Example 1: Adults with diabetes. Example 2: Atherosclerotic (CVD) risk factors plus Internet expertise and access to a computer	
Diabetes	Example: Yes (98%)	
CVD/HTN	Example: Yes (84%)	
Other Diseases (e.g. arthritis)		
General Chronic Disease Mngt		
Obesity Only		
Healthy Lifestyle		
Gender	Indicate the % of the gender that is the majority. If it is not reported, give as much information as possible (e.g. the gender is mixed). Example 1: 80% Female. Example 2: Mixed	
Ethnicity	Indicate the percentage of participants from each ethnicity. If it does not add up to 100%, or even percentages are not given, provide as much information as possible. Use NR if no information is provided. Example 1: 88% Caucasian. Example 2: Majority Caucasian	

Education/SES	Indicate the SES of the majority of participants. Provide as much detail as possible (i.e. if there are percentages for difference income brackets). Use NR if no information is provided. Example 1: Primary school (22%) Secondary education (44%) University education (34%). Example 2: Majority upper middle income	
INTERVENTION		
Patients	Indicate the number of participants (patients) that were enrolled (i.e. baseline data collected) in the study. If applicable and given, indicate the number of participants in the intervention group and the control group. Example 1: N=260 Intervention N= 150 Control N= 110. Example 2: N= 50 No control group	
Providers/Institution Selection Bias/Recruitment	If applicable, indicate the number of providers or institutions involved in the study. Also indicate whether the providers are likely to be representative of the target population (e.g. physician's offices in Ontario). Use very likely, somewhat likely, not likely or can't tell based on the QA tool. Indicate how they were recruited AND the percentage of selected providers/institutions that agreed to participate. Example: Very likely to be representative of the target population. Physician's offices were randomly selected from all the physician's offices in Ontario. 10/25= 40% agreed to participate.	
Setting/Usual Team	Indicate where the intervention took place and who the usual team consists of (which providers). You may think of "usual team" as who is involved in the usual	

	care as opposed to the intervention. A dietitian for example may only be hired to for the study, but usual care may only involve a physician and nurse. Example 1: Setting- Three physician's offices. Usual team-physician and registered nurse.	
Theoretical Basis	Select from dropdown list or leave blank for No	
Social Cognitive Theory		
Health Belief Model		
Transtheoretical Model		
Theory of Planned Behaviour		
Other		
No theory used		
Provider(s)	Indicate the provider(s) involved in giving the intervention. Example: Nurse practitioner and Dietitian	
Delivery Channels	Indicate how the intervention was delivered; whether it was individual or group counselling, face to face, telephone, or internet. This may include other details. Example: One on one, face to face counselling.	
Duration, Length, Frequency	Indicate the duration of the intervention, the length and the frequency of each visit. Only include what applies and/or other relevant information (e.g. for internet coaching length of visit would likely not apply.) Example: 16 week intervention 1 hr counselling sessions every 4 weeks.	

Content	Describe the content of the counselling given during the intervention including the resources used. If there were multiple providers, indicate who delivered what content. Provide as much detail as possible. Example: Dietitian- provide counselling and resources (identify resource) on reducing fat in the diet Nurse- provide information on increasing physical activity through the use of pedometers.	
(Control Description)	If applicable, give a brief description of the delivery, provider and content, duration, length and frequency of what is provided to the control group. Follow the above guidelines. Example: Usual care was given to control patients. The nurse saw the patients for one single one hour, face to face one on one counselling session. They were given basic diet and exercise advice and resources.	
Length of Post-Intervention F/U	Indicate the length and frequency (if applicable) of the post-intervention follow-ups. Example: 12 weeks (immediate post-intervention), 16 weeks, and 20 weeks.	
Outcome Measures	If any of the outcome measures below were reported in the study, select "Yes" from the drop-down menu. If they were not reported, either select "No" from the drop-down menu or leave it blank (defaults to "No").	
Weight		
BMI		
HbA1c		

BP		
Lipids		
Behaviour		
Knowledge		
Health Status		
Quality of Life		
Process Measures		
Cost-effectiveness		
Overall QA Rating	Indicate the overall QA rating for this article. Example: Moderate	
RESULTS		
Limitations	<p>Summarize and describe the study limitations.</p> <p>Example: Selection bias may have been an issue as the participants were randomly selected from those who had computer access and who stated they were already interested. It would have been better if participants were simply randomly selected from those who had computer access. Therefore, they may not be as representative of the population. The sample size was very small (N= 50); therefore the results may be less generalizable "This pilot-study was intended as feasibility study" therefore the main outcome of interest was not improvement in vascular profile Since there was no control group (cohort study), the relationship between internet coaching and improved vascular risk is not causal; only an association. It is possible that another factor affected the participants vascular risk profile</p>	

Conclusion	Three to five brief sentences describing the overall message/what the study found. Example: The authors conclude that this web-based individualized risk management intervention was feasible in that most patients checked the website at least once/week. It also appeared to increase awareness of individuals self-management abilities in that an increase in treatment goals was achieved over the 6 months. Of the 50 participants, 23 had a decrease in number of risk factors, 21 had no change and 6 increased the number of risk factors. As there was no control group for comparison, the intervention requires a controlled trial to determine whether it is efficacious for treating high risk patients with CVD.	
REFERENCES		
1	Include any references used to fill in the summary table. This includes the original article and any related sub-studies. List each reference on a new row. Use the American Journal of Clinical Nutrition for referencing style. Example: Study this evaluation was based on: Goessens BM, Visseren FL, de Nooijer J, van den Borne HW, Algra A, Wierdsma J, van der Graaf Y; SMART Study Group. A pilot-study to identify the feasibility of an Internet-based coaching programme for changing the vascular risk profile of high-risk patients. Patient Educ Couns. 2008 Oct;73(1):67-72.	
2		
3		

APPENDIX F

Organization of Care Summary Table Template

STUDY		
Title	Write out the full title of the article Example: Translating the diabetes prevention program to primary care	
Author/Date/RefMan ID#	First author only. Surname, given name initial, coma, date, RefManID# in brackets. Example: Campbell G, 2003(1211)	
Country of Origin	The country in which the study was conducted Example: Canada	
Purpose/Objectives	List the purpose or objectives of the study (list multiple objectives; if not provided, list the overall purpose) Example: To compare- (1)the effectiveness of physician advice versus dietitian advice for a fat reduced diet (2)the effectiveness of dietitian advice for a fat-reduced diet (3)dietitian advice for a soluble fiber-enhanced diet	

PARTICIPANTS		
Participants (Providers & Patients)	Describe who the providers and patients (if info available)	
Practice/Setting	Briefly describe the setting	
METHODS		
Methods (Recruitment & Measures)	Describe the recruitment of the practices. Describe the outcome indicators and how they were measured.	
INTERVENTION		
Activities of the Organization	Describe the intervention at the organizational level e.g. medical records, implementing CCM	
Activities of Disciplines (who they are/ what they did)	Describe what the providers are doing within the organization	
RESULTS		
Indicators of Success & Outcomes		
Facilitators/Barriers to	Summarize facilitators and barriers to implementation	

Implementation	(may need to make a note to refer to the article for details)	
Conclusion		
REFERENCES		
1	<p>Include any references used to fill in the summary table. This includes the original article and any related sub-studies. List each reference on a new row. Use the American Journal of Clinical Nutrition for referencing style.</p> <p>Example: Study this evaluation was based on:</p> <p>Goessens BM, Visseren FL, de Nooijer J, van den Borne HW, Algra A, Wierdsma J, van der Graaf Y; SMART Study Group. A pilot-study to identify the feasibility of an Internet-based coaching programme for changing the vascular risk profile of high-risk patients. Patient Educ Couns. 2008 Oct;73(1):67-72.</p>	
2	<p>Example: Original SMART cohort study that this cross-sectional study was derived from:</p> <p>Simons PC, Algra A, van de Laak MF, Grobbee DE, van der Graaf Y. Second Manifestations of ARterial disease (SMART) study: rationale and design. Eur J Epidemiol 1999;15:773–81.</p>	
3		

APPENDIX G Patient and/or Provider Perception Summary Table Template

STUDY		
Title	Write out the full title of the article Example: Translating the diabetes prevention program to primary care	
Author/Date/RefMan ID#	First author only. Surname, given name initial, coma, date, RefManID# in brackets. Example: Campbell G, 2003(1211)	
Country of Origin	The country in which the study was conducted Example: Canada	
Purpose/Objectives	List the purpose or objectives of the study (list multiple objectives; if not provided, list the overall purpose) Example: To compare- (1)the effectiveness of physician advice versus dietitian advice for a fat reduced diet (2)the effectiveness of dietitian advice for a fat-reduced diet (3)dietitian advice for a soluble fiber-enhanced diet	

PARTICIPANTS		
Participants (Providers & Patients)	Describe who the providers and patients (if info available)	
Practice/Setting	Briefly describe the setting	
METHODS		
Methods (Recruitment & Data Collection)	Describe the recruitment of the patients and/or practices. Describe the data collection methods.	
INTERVENTION		
Intervention	Describe the intervention of interest.	
RESULTS		
Emerging themes	Summarize the major emerging themes (e.g. facilitators and barriers to implementation/behaviour change, patient and/or provider perceptions of interventions)	
Conclusion		

REFERENCES		
1	<p>Include any references used to fill in the summary table. This includes the original article and any related sub-studies. List each reference on a new row. Use the American Journal of Clinical Nutrition for referencing style.</p> <p>Example: Study this evaluation was based on:</p> <p>Goessens BM, Visseren FL, de Nooijer J, van den Borne HW, Algra A, Wierdsma J, van der Graaf Y; SMART Study Group. A pilot-study to identify the feasibility of an Internet-based coaching programme for changing the vascular risk profile of high-risk patients. Patient Educ Couns. 2008 Oct;73(1):67-72.</p>	
2	<p>Example: Original SMART cohort study that this cross-sectional study was derived from:</p> <p>Simons PC, Algra A, van de Laak MF, Grobbee DE, van der Graaf Y. Second Manifestations of ARterial disease (SMART) study: rationale and design. Eur J Epidemiol 1999;15:773–81.</p>	
3		

APPENDIX H Summary of Results Template- All Weight/BMI Studies

[illegible]

APPENDIX I Summary of Results Template- All A1c Studies

[illegible]

APPENDIX J Weight Results Table Template- Clinically Relevant Studies

APPENDIX J Weight Results Table Template- Clinically Relevant Studies

[illegible]

	CONTROL GROUP											
	Baseline			Post-Intervention			F/U			Difference (Baseline-Post or F/U)		
Author/Date	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	N	$\bar{x}$ Wt (kg)	SD Wt	$\bar{x}$ Δ Wt (kg)	% Wt Loss	NET % Wt Loss (Intervention-Control)

APPENDIX K

BMI Results Table Template- Clinically Relevant Studies

[illegible]

[illegible]

APPENDIX L A1c Results Table Template- Clinically Relevant Studies

[illegible]

APPENDIX M Quality Assessment Summary Table Template

[illegible]

APPENDIX N Quality Assessment Tool Addendum

A) Selection Bias

- For (Q1) score "1. Very likely" if all eligible individuals are recruited from the target population (e.g. all individuals in the practice, organization, or community that met inclusion criteria)
- If the design/analysis is at the practice level, then answer (Q1) and (Q2) based on practice recruitment/participation.
- If patients identified through a database/chart abstraction, choose N/A for (Q2)

C) Confounders

- Answer (Q1) based on any true significant differences between groups. If these differences were adjusted for during analysis, still choose "Yes".
- Highlight the confounders which were not controlled for AND those that were not measured.
- For (Q2), identify the number of confounders that were not significantly different at baseline/those that were controlled as a percentage out of a total of 8 confounders (those that were NOT highlighted). e.g. if race and marital status was not reported at baseline, total is 6/8 or 75% [choose 60-79%].
- If no data is provided re: if the differences between groups are significant or not, choose "can't tell" for (Q1). For (Q2), also choose "can't tell", unless less than 60% were even measured, choose, "less than 60%".
- For (Q1) and (Q2), the option *N/A* was added. Please choose this if confounders are not applicable to the study (e.g. cohort one group pre-post). This is important as it will change the rating.

D) Blinding

- For (Q1)
 - Unless, it is explicitly explained OR obvious (e.g. cohort one group pre-post) OR there is some leading information that the assessor was aware of the intervention or exposure status of the participants, choose "Can't Tell" (as opposed to "Yes").
- For (Q2)
 - Unless, it is explicitly explained OR obvious OR there is some leading information that the participants are aware of the research question, choose "Can't Tell" (as opposed to "Yes").
- If cohort one group pre-post, choose "Yes" for (Q1) and "Can't Tell" for (Q2)
- If chart abstraction, choose "Yes" for (Q1) and "No" for (Q2)

E) Data Collection Methods

- For (Q1) and (Q2)- focus on primary outcome measures
 - *Yes*= 80-100% of collections tool were reliable/valid.
 - *No*= < 80% of collection tools were reliable/valid.
- (Q1)3 and (Q2)5 = Weak
- If data is self-reported:
 - For (Q1), may choose “Yes” if the tool has been validated (as per references). Otherwise, choose “Can’t Tell”.
 - For (Q2) choose “Can’t Tell” unless reliability specifically discussed (e.g. Cronbach’s alpha to demonstrate the tool is reliable).
- For chart abstraction,
 - if reported valid outcomes (e.g. clinical outcomes, process measure outcomes, validated tools) choose “Yes” for (Q1)
 - Choose “Can’t Tell” for (Q2) unless they comment on how the data was collected
- Even if there is not a lot of detailed information on how height, weight and other anthropometric data was taken, choose “Yes” (this is more valid and reliable than self-reported).
- If necessary, check references to determine if tools (e.g. questionnaires) were reliable or valid.

F) Withdrawals and Drop-Outs

- For (Q1) the word ‘or’ was removed. It now reads “Were withdrawals and drop-outs reported in terms of *numbers AND reasons* per group?” Therefore, the option ‘Yes’ should only be chosen if both the numbers and the reasons were reported.
- For (Q2), the option ‘*N/A to study design*’ was added. Choose this option when (Q1) = No (i.e. withdrawals and numbers were not reported in terms of numbers AND reasons) AND indicating the % of participants that completed the study is not applicable to the study.
- If chart abstraction, choose N/A for (Q2)

G) Intervention Integrity

- For (Q2) the option “Can’t Tell” was removed and the word ‘measured’ was replaced by ‘*reported*’. Therefore, if the consistency of the intervention was reported, choose ‘Yes’ and if it was not reported than choose ‘No’

H) Analyses

- For (Q4), the option *N/A* was added. Please choose this if intention to treat is not applicable to the study (e.g. retrospective chart abstractions).

must be explicitly stated in the text or show total numbers in tables to demonstrate intention to treat; otherwise choose 'no.

APPENDIX O

References of Included Articles

Intervention Articles

Effects of physical activity counseling in primary care: the Activity Counseling Trial: a randomized controlled trial (2001). *JAMA.*, 286, 677-687.

Closing the gap: effect of diabetes case management on glycemic control among low-income ethnic minority populations: the California Medi-Cal type 2 diabetes study (2004). *Diabetes Care.*, 27, 95-103.

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