The Pure Prairie Living Program for Type 2 Diabetes: Evaluation and Steps to Optimize and Enhance Participant Success

by

Martha Carolina Archundia Herrera

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Department of Agricultural, Food and Nutritional Science
University of Alberta

ABSTRACT

Background: Given the complex etiology of type 2 diabetes (T2D), the Diabetes Canada Clinical Practice Guidelines recommend a multidisciplinary approach for its management, in which self-management education and support, nutrition therapy, physical activity and pharmaceutical therapy play major role. However, people with T2D face difficulties in following these guidelines especially in regards to nutrition therapy. Consequently, lifestyle intervention (LI) programs help guide participants through the overwhelming process of acquiring necessary knowledge and skills. The goal of the work presented in this thesis was to provide strategies that enhance participants' successful adherence to the guidelines through the evaluation and optimization of the Pure Prairie Living Program (PPLP), a LI developed previously. Thus, the primary objective of this thesis was to evaluate the effectiveness of the PPLP in a primary care setting. Guided by results obtained from this randomized controlled trial (RCT), two additional objectives were examined:

i) To analyze to what extent LI programs align with the cornerstones of T2D management and to compare their effect sizes when moving through the scale-up process (efficacy trials to effectiveness trials)

ii) To understand the lived experience of people with T2D when managing their disease, in order to identify optimization strategies for the PPLP and other LI programs.

Methods: The PPLP intervention was a 2-arm, parallel group, RCT. Participants were blinded to group assignment through concealment of allocation until assignment occurred. The program spanned 6 months from recruitment to the final participant visit. Baseline, 3- and 6-month

assessments were carried out in the PPLP intervention group (n = 25) and wait-listed controls (CON, n = 24) to assess anthropometric, metabolic and demographic information. In the intervention arm participants attended and participated in 5 weekly nutrition education session (~ 90 min each). They received the PPLP resource pack that consisted of a copy of the nutrition education presentations each week and a copy of the PPLP workbook to guide them though the educational sessions and provide support, positive reinforcement of concepts and the opportunity for skill acquisition. Lastly, a copy of the Pure Prairie Eating Plan was provided to facilitate and guide participants towards healthy eating options. A detailed summary of intervention activity content, educational sessions and support materials can be found at www.pureprairie.ca. During the 3-month evaluation, two focus groups with the intervention group were carried out. After the 6-month evaluation, the waited listed control group started the education sessions.

For the analysis of LI alignment with the guidelines, a systematic review methodology was adopted guided by PRISMA guidelines. Studies reporting on real-world LI that included at least two of the main pillars of T2D management in accordance with the Diabetes Canada Clinical Practice Guidelines, had gone through scale-up process (efficacy (research setting) to effectiveness (real-world setting)), and reported HbA1c were included. Multiple databases were searched and titles and abstracts, then full texts were reviewed based on the predetermined inclusion and exclusion criteria. For studies meeting the inclusion criteria, research setting pairs were retrieved. Risk of bias components were assessed using the Joanna Briggs Institute templates.

To understand the lived experience of people with T2D an explorative qualitative study design was undertaken guided by COREQ checklist. Purposeful sampling was used to recruit 15

participants who had participated in LI programs and/or had past consultations with any health care provider (HCP) regarding their T2D. One-on-one, semi-structured, open-ended, in-depth interviews were conducted. An essentialist paradigm was adopted to report experiences, meaning and the reality of participants. An inductive approach was used to analyse the data.

Results: The RCT intervention yielded no significant within-group changes in HbA1c at 3-month (-0.04 (-0.27 to 0.17)) and -0.15 (-0.38 to 0.08)) or 6-month (-0.09 (-0.41 to 0.22)) and (0.06 (-0.26 to 0.38)) follow up in either CON or PPLP groups, respectively. Dietary adherence scores improved in the PPLP group ($p < 0.05$) at 3 and 6 months but were not different in the between-group comparison. No changes in diabetes self-efficacy scores were detected. Participants described the program as clear and easy to understand. Knowledge acquired influenced their everyday decision-making but participants faced barriers that prevented them from fully applying what they learned. Healthcare professionals enjoyed delivering the program but described the "back-stage" workload as detrimental.

The main results of the systematic review found that all the studies analyzed reported a decrease in HbA1c values in the intervention group and that a scale-up penalty was detected ranging from 22 to 35%. Furthermore, comprehensive LI that incorporated most of the cornerstones of T2D management reduced HbA1c in research settings and generally sustained those benefits in real-world setting, albeit with a scale-up penalty under some circumstances.

Findings from the qualitative study reflect 5 important results. First, participants' reality of living with and managing T2D can be overwhelming; effective T2D management address individuals' context. Second, T2D management is influenced by and forms part of a complex, evolving system in which a person's behaviour is influenced not only by their personal health

background and history, but also by their external environment where work, family and HCP influence their behaviour towards more positive or negative outcomes. Third, participants cycled through good behaviour and bad behaviour with social factors, resources, the food environment and competing priorities influencing these cycles. Fourth, people with T2D indicated that all the cornerstones of T2D management should be integrated into LI including foot, eye and dental care. Several program characteristics including active learning and hands-on approach were desired for all of the knowledge being taught; furthermore, close follow up and intervention maintenance strategies should be incorporated. Lastly, HCP and researchers should understand who each individual participant is, because through this understanding they can provide appropriate, directed advice that will be effective for each individual context.

Conclusion: While some positive effects of the PPLP intervention were observed, they were not comparable to those previously attained by our group in an academic setting or to what the guidelines recommend, which reflects the challenge of translating LI programs to real-world settings. However, the finding of a modest scale-up penalty does not negate that real-world application of LI programs can result in clinically relevant improvements in T2D outcomes, particularly if interventions support and promote the importance of each cornerstone of T2D management and work with patients to help them increase or maintain their focus or inclusion of each behaviour over the long term. Including input from participants' context, experiences and needs, will provide more sustainable and realistic LI programs. People living with T2D request a more extensive and comprehensive treatment to address the multifaceted etiology of this chronic disease. Shifting of program content, delivery and long-term maintenance is required to address participants' needs.

PREFACE

This thesis is an original work by M Carolina Archundia Herrera and has been written according to the guidelines for a paper format thesis of the Faculty of Graduate Studies and Research at the University of Alberta. The concept of this thesis originated from my supervisor Dr. Catherine Chan. The research project named "A Mixed Methods Evaluation of a Randomized Control Trial to Evaluate the Effectiveness of the Pure Prairie Living Program in Type 2 Diabetes Participants" (ClinicalTrials.gov ID: NCT03043859) was approved by the Human Research Ethics Board at the University of Alberta (Study ID Pro00070736). This research is described in Chapter 4. This research was funded by the Canadian Foundation for Dietetics Research and Danone Institute. The research project named "Identification of contextually appropriate tools and solutions designed to optimize and enhance healthy eating in people with T2D" was approved by the Human Research Ethics Board at the University of Alberta (Pro00092713). This research is described in Chapter 6. This research was funded by Canadian Foundation for Dietetics Research and Danone Institute. I was funded by the National Council of Science and Technology of Mexico (CONACYT).

The research presented in Chapter 2 was published by *Current Obesity Reports* in 2017. This article is part of the Topical Collection on Metabolism. The citation is: Archundia-Herrera, M. C., Subhan, F. B., & Chan, C. B. (2017). Dietary patterns and cardiovascular disease risk in people with type 2 diabetes. *Current Obesity Reports*, *6*(4), 405-413. doi:10.1007/s13679-017-0284-5. M. Carolina Archundia Herrera and Fatheema B. Subhan contributed equally to the work.

The research presented in Chapter 3 was published by *Nutrients* in 2018. This article belongs to the Special Issue Advancement in Dietary Assessment and Self-Monitoring Using Technology. The citation is: Archundia Herrera, M., & Chan, C. B. (2018). Narrative review of new methods for assessing food and energy intake. *Nutrients*, *10*(8), 1064. doi:10.3390/nu10081064. Authors contributions are as follows: Conceptualization, M.C.A.H. and C.B.C.; Methodology, M.C.A.H.; Data Curation, M.C.A.H.; Writing-Original Draft Preparation, M.C.A.H.; Writing-Review & Editing, C.B.C.

The research presented in Chapter 4 was published by *Healthcare* in 2020. This article belongs to the Section Nutrition and Public Health. The citation is: Archundia-Herrera, M.C., Subhan, F. B., Sakowsky, C., Watkins, K., & Chan, C. B. A Mixed Methods Evaluation of a Randomized Control Trial to Evaluate the Effectiveness of the Pure Prairie Living Program in Type 2 Diabetes Participants. In *Healthcare* (Vol. 8, No. 2, p. 153). doi:10.3390/healthcare8020153. Authors contributions are as follows: Conceptualization, F.B.S. and C.B.C.; methodology, F.B.S.; formal analysis, M.C.A.H.; investigation, M.C.A.H.; resources, C.S., K.W., and C.B.C.; data curation, M.C.A.H.; writing—original draft preparation, M.C.A.H.; writing—review and editing, M.C.A.H., C.B.C., F.B.S., C.S. and K.W.; visualization, M.C.A.H.; supervision, C.B.C.; project administration, M.C.A.H.; funding acquisition, F.B.S. and C.B.C.

The research presented in Chapter 5 entitled "From research-settings to real-life: A systematic review of intervention approaches for type 2 diabetes management and their effectiveness" will be submitted to *Applied Physiology, Nutrition and Metabolism.* Stepheny C. De Campos Zani (S.Z), Catherine B. Chan (C.B.C) and I designed the study, S.Z. and I designed and ran the search strategy, selected and extracted all the necessary data. I was responsible for tables 1 & 3, S.Z. was responsible for table 2. We each drafted the results and discussion for each of these sections. I wrote the first draft of the introduction, methodology and discussion; this was an iterative process with S.Z. who reviewed and edited the manuscript. S.Z. edited the final tables and appendices. C.B.C. reviewed the manuscript for content appropriateness and flow.

The research presented in Chapter 6 entitled "Identification of contextually appropriate tools and solutions designed to optimize and enhance healthy eating in people with T2D" was designed and carried out by C.B.C. and me with the supervision and guidance of C.B.C. Participants were recruited through a collaboration with Dr. Denise Campbell-Scherer through her 5AsT-Shared Decision Making Study and the Alberta Diabetes Institute.

The other authors have given their permission for the work to appear in this thesis.

DEDICATION

This thesis is dedicated to my beloved family

ACKNOWLEDGMENTS

I would like to start by acknowledging that this work is the result of many people's hard work and dedication. The work in this thesis would not have been possible without the sponsorship of the National Council of Science and Technology of Mexico (CONACYT).

First and foremost, I would like to acknowledge my Supervisor Dr. Catherine Chan for welcoming me into her lab, seeing my potential, and giving me the opportunity to complete my PhD under her outstanding supervision. Dr. Chan, thank you for your excellent guidance, continuous support, trust and teachings but especially for conceiving this interdisciplinary research for me. Likewise, I would like to acknowledge my Committee members Dr. Rhonda Bell and Dr. Denise Campbell-Scherer, whose support and guidance allowed my studies to go the extra mile. Thank you, Dr. Bell, for the helpful comments, motivation, and teaching opportunities and for opening my mind to research outside diabetes. Dr. Campbell-Scherer, your insight and knowledge steered me through this research process, thank you for your advice, time, kind understanding, and for transmitting to me your fascination for high quality research.

I would also like to thank my Candidacy Committee Members Dr. Caroline Richard and Dr. Steven Johnson and my Chair, Dr. Rene Jacobs as well as my Examining Committee Members Dr. Raylene Reimer and Dr. Kate Storey for taking time to be part of this process, for their guidance and for sharing their wealth of knowledge throughout this process with me.

Furthermore, I would also like to acknowledge the dedication and hard work of Sherwood Park Primary Care Network staff, especially to the Registered Dietitians Cathy Sakowsky and Karen Watkins for collaborating with us in the Pure Prairie Living Program and helping throughout the entire project. Additionally, thanks to the Human Nutrition Research Unit at the University of Alberta and a special thank you to all the participants who took part in these studies, without them, none of the information presented here would be possible.

I would also like to acknowledge Dr. Champbell-Scherer's Lab members who were incredibly welcoming and helpful, Dr. Thea Luig and Dr. Nicole Ofosu thanks for your guidance through my Qualitative journey and Melanie Heatherington thank you for all your support.

A Special thank you to Dr. Fatheema Subhan and Stepheny Zani for collaborating with me in this project and to my fellow lab mates in Dr. Chan's Lab, past and present, thank you for enriching this graduate school journey.

Special thanks to my beloved husband Cesar and to my family, my parents Mario and Marina and my sisters Stephany and Carla you are my rocks and my roots. Finally, thanks to my special group of friends Jill, Krista, Ropa and Eduardo, I cherish so many memories of our time together throughout this journey. To all of you thank you!

For all that has been – Thanks…for all that will be – Yes".

Dag Hammarskjöld

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LIST OF ABBREVIATIONS

24HR	24-h recalls
ADA	American Diabetes Association
APNM	Applied Physiology, Nutrition and Metabolism
AIM	Automatic ingestion monitor
BCW	Behaviour Change Wheel
BMI	Body mass index
CDA	Canadian Diabetes Association
CRP	C-reactive protein
CMD	Cardiometabolic diseases
CVD	Cardiovascular disease
CCM	Chronic Care Model
CALERIE	Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy
CI	Confidence Interval
CON	Control
CCS	Counts of chews and swallows
CINAHL	Cumulative Index to Nursing and Allied Health Literature
DC	Diabetes Canada
DSES	Diabetes self efficacy scale
DCM	Diabetic cardiomyopathy
DBP	Diastolic blood pressure
DASH	Dietary Approaches to Stop Hypertension
DP+R	Digital Photography + Recall method
DPP-IV	Dipeptidyl peptidase 4
DLW	Doubly labelled water
DXA	Dual energy x-ray absorptiometry
EMR	Electronic medical record
EE	Energy Expenditure
EI	Energy intake
EVOO	Extra virgin olive oil

FFQ	Food frequency questionnaires
FR	Food records
F&V	Fruit and vegetables
GLP-1	Glucagon like peptide-1
HbA1c	Glycated haemoglobin
GI	Glycaemic index
HCP	Health care provider
HDL-C	High-density lipoprotein cholesterol
JD	Japanese diet
KT	Knowledge translation
KTD	Korean traditional diet
LI	Lifestyle interventions
LTC	Long term care
LDL-C	Low-density lipoprotein cholesterol
MetS	Metabolic syndrome
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NO	Nitric oxide
NCDs	Non-communicable diseases
NIDDM	Non-insulin dependent diabetes
PDAQ	Perceived dietary adherence questionnaire
PA	Physical activity
PANDA	Physical Activity and Nutrition for Diabetes in Alberta
PCN	Primary Care Network
PPEP	Pure Prairie Eating Plan
PPLP	Pure Prairie Living Program
EQ-VAS	Quality of life - visual analogue scale
RCT	Randomized control trial
ROS	Reactive oxygen species
RDs	Registered dietitians
RFPM	Remote food photography method

PREDIMED	REvención con DIeta MEDiterránea
SBP	Systolic blood pressure
SMBG	Self monitoring blood glucose
SME	Self-management education
SMS	Self-management support
SLGT2	Sodium glucose cotransporters 2
SPSS	Statistical Package for the Social Sciences
NHANES	The National Health and Nutrition Examination Survey
TDEEDLW	Total daily energy expenditure assessed by doubly labelled water
TDR	Total diet replacement
TC	Total-cholesterol
TMD	Traditional Mediterranean diet
TG	Triglycerides
T2D	Type 2 diabetes
USDA	United States Department of Agriculture
VD	Vegetarian diet
VLDL	Very-low density lipoproteins
WHR	Waist-to-hip ratio

Chapter 1: General Introduction and Thesis Objectives

1.1. Introduction

Population rates of obesity have increased steadily over recent decades resulting in alarmingly high prevalence (Ward et al., 2019). This rise in obesity goes in hand with an increase in its related comorbidities, in particular of our interest, type 2 diabetes (T2D). To date, the global estimated prevalence of T2D is projected to increase by 25% in 10 years and by 51% in 25 years (Saeedi et al., 2019); ergo no country has been able to steady or decrease its prevalence. Given its chronic nature, a major global economic burden on health systems is foreseen (Bommer et al., 2018).

T2D etiology is impacted by a combination of factors in which chronic positive calorie balance plays a major role (Taylor, 2008). Even though the specific role different types of nutrients play in energy balance is still up for debate (Ludwig & Ebbeling, 2018), the importance and the major role eating patterns and overall eating behaviours play in metabolic disorders has been established (Taylor, 2008, Ludwig & Ebbeling, 2018). For example, as stated in the carbohydrate-insulin model, a positive calorie balance (especially when these calories come from added sugar and other processed and refined carbohydrates), results in a constant hyperinsulinaemic state, promotes fat anabolism and a cascade of signals, resulting in removal of available fuels from the blood, triggering an increased hunger response and slowing metabolic rate. Thus, according to this model, overeating or increased hunger is a consequence of increasing adiposity, not the primary cause (Ludwig & Ebbeling, 2018). Furthermore, based on the twin-cycle hypothesis, this positive energy balance results in a high influx of fat into the liver, leading to increased accumulation of liver fat with consequent resistance to insulin action, leading to an inability to restrain liver glucose output adequately, thus blood glucose levels are elevated (liver cycle) (Singhal, Caumo, Carey, Cobelli, & Taylor, 2002). Additionally, the high influx of fat into the liver leads to excess very-low density lipoproteins (VLDL)-triglyceride output resulting in high ectopic fat availability. In the pancreas this excess impairs insulin action further, stimulating hyperglycaemia, which in turn further increases insulin secretion rates

(pancreatic cycle). These vicious cycles in the liver and pancreas stimulate each other, causing β-cell function impairment in the long run (Taylor, 2008).

In addition to an already complicated process, bodies of evidence have linked unhealthy diet with alterations in gut microbiota, which induce metabolic disturbances including lipid and glucose metabolism (Khan, Nieuwdorp, & Bäckhed, 2014), increased intestinal permeability inducing metabolic endotoxaemia and low-grade inflammation (Marchesi et al., 2016), body weight gain through complex gut-brain axis (Choi, Daoust, Pilon, Marette, & Tremblay, 2020) and alterations in mitochondria biogenesis (Vezza, Abad-Jiménez, Marti-Cabrera, Rocha, & Víctor, 2020). This situation is further exacerbated by sedentary behaviour (Bao et al., 2014).

Given the etiology of T2D, a multidisciplinary approach is recommended for its management, in which eating patterns, physical activity (PA) and medication adherence play a major role (CDG, 2018). Health behaviour change can be more easily accomplished when health-behaviour theories or models are used to facilitate lifestyle changes in participants to manage and prevent complications (Elder, Ayala, & Harris, 1999). The Nutrition Therapy recommendations published in the 2018 Diabetes Canada Clinical Practice Guidelines (CDG, 2018) prioritizes the adoption of "diabetes-friendly eating habits", which include the adoption of healthy eating patterns focused on including whole grains, legumes, fruit and vegetables and avoiding refined foods, processed food and sugar-sweetened beverages (Sievenpiper, Chan, Dworatzek, Freeze, & Williams, 2018). These recommendations are consistent with the recently published update of Canada's Food Guide (Health Canada, 2019), which further emphasises the importance of the food environment, cultural preferences (eating with others) and food skills (food preparation and cooking) in order to prevent the acute and long term complications and comorbidities of diabetes, thus improving the quality of life of afflicted people.

Despite these guidelines, our research group found that Canadians with T2D tend not to meet their respective age-sex-specific recommendations for fruit and vegetables and have higher than recommended intakes of saturated fat and sodium attributed to fast food consumption (Raj et al., 2018). Overall, they tend not to meet dietary (Asaad, Soria-Contreras, Bell, & Chan, 2016) and physical activity recommendations (Berry, Anders, Chan, & Bell, 2012), where inconsistencies between perceived adherence to recommendations and consumption of foods has been reported

(participants indicating high adherence to guidelines but dietary recalls showing far less consumption of fruits and vegetables) (Asaad, & Chan, 2012). The obstacles to meeting nutritional recommendations are multilayered issues (Berry et al., 2012), which include the basics of understanding the nutritional lingo, acquisition of a wide variety of knowledge and abilities including but not limited to: menu planning, grocery lists, understanding and estimating portion size and developing cooking skills (Lim et al., 2019); through the very difficult task of not becoming lost in the vast variety of fake "healthy foods" options and, misleading information; a journey often ending in failure and frustration.

Based on this context of barriers to meeting nutrition therapy guidelines reported by people with T2D, our group has worked on a multiphase project aimed at developing approaches that aid in improving people's adherence to the guidelines by promoting behavioural change, skills development and healthy eating so that those with diabetes can independently manage their chronic disease over the long run (**Figure 1.1**).

> **Phase 1 → Understanding the problem:** In this initial phase, research was carried out to understand and develop strategies designed to increase adherence to LI in people with T2D from the perspectives of participants, researchers (Berry et al., 2012) and healthcare profesionals (Berry, Anders, Chan, & Bell, 2012) with the overall goal to provide long-term benefits to participants with T2D and the healthcare system. Increasing awareness, education and ongoing support were strategies recommended to be included in nutrition and physical activity programs (Berry et al., 2012). Further qualitative research was carried out to understand the barriers diabetes educators face when translating the guidelines and what they believe are some of the reasons for this lack of adherence of those with T2D. The main theme indicates that the lack of adherence to lifestyle recommendations is "complex and interwoven" and is influenced by prior knowledge and skills and affected by social, environmental, cultural and personal factors (Berry, Anders, Chan, & Bell, 2012). In this sense, patient empowerment, which includes patients advocating for their own health, was seen as necessary for long-term effective self-management (Berry, Anders, Chan, & Bell, 2012).

Phase 2.0 →Tool development: Increasing awareness, education and ongoing support were strategies identified to be considering in future programs. Given the complexity of T2D treatment, in which multiple nutrition recommendations are expected to be integrated into participants' everyday lives, a 4-week menu plan focused on Albertans was developed. It translated the Canadian Diabetes Association (CDA) nutrition therapy guidelines into a concrete menu plan and a recipe book "Pure Prairie Eating Plan" (PPEP) based on the 4A Framework: food Availability, Accessibility, Acceptability and Adequacy (Chan & Bell, 2013). On average, the daily menus incorporated 2000kcal (54% carbohydrates, 19% protein, 27% fat). A list of foods produced in Alberta and resources including recipes, cooking tips, weekly grocery lists and ways to adjust menus were incorporated (Chan & Bell, 2013). Alongside, the Perceived Dietary Adherence Questionnaire (PDAQ) was developed and validated to assess dietary adherence to CDA guidelines (Asaad et al., 2015).

Phase 3.0 → Pilot study. A pilot study (pre-post single-arm design) was conducted in participants with T2D (n = 15) to evaluate the PPEP menu plan feasibility and efficacy for improving health outcomes. Participants followed the menu plan (developed in phase 1) for 12 weeks and attended 6 one-on-one education sessions. The first 4 education sessions (40–60 min) were held weekly, in which the first 2 sessions focused on familiarising participants with the guidelines and the third and fourth sessions were individualized to each participant's situation. Participants attended 2 additional monthly sessions (booster sessions) in which concepts of goal setting, self-monitoring and feedback were incorporated (Soria-Contreras, Bell, McCargar, & Chan, 2014). Improved HbA1c (-1.0% ± 0.86%, $p < 0.05$) and dietary adherence score ($p < 0.05$) demonstrated that the PPEP could be a simple and practical approach for improving adherence to nutritional recommendation guidelines (Soria-Contreras et al., 2014), encouraging a larger trial.

Phase 3.1 → Clinical Trial. The Physical Activity and Nutrition for Diabetes in Alberta (PANDA) quasi-experimental, single-arm trial, conducted in a research setting, focused on helping people incorporate CDA nutrition therapy guidelines into their daily lives by incorporating the tools developed in phase 2 (PPEP and PDAQ) plus group education

sessions into the PANDA program with the primary objective of evaluating the effectiveness of the intervention on blood glucose and dietary adherence among patients with T2D (Asaad, Soria-Contreras, Bell, & Chan, 2016). The Social Cognitive Theory was used as a theoretical model to guide the overall behaviour change intervention. After screening, 73 participants were enrolled in the program. Participants attended 5 weekly education sessions (90–120 min) facilitated by M.Sc in human nutrition, and one grocery store tour guided by the same facilitator. At 3-month follow-up, HbA1c was reduced by 0.7% (95% CI 0.4% to 1.0%) ($p<0.05$). Improvements in secondary outcomes including PDAQ scores, serum lipids, blood pressure and self-efficacy were observed. These results showed beneficial effects in management of T2D among participants (Asaad, Soria-Contreras, Bell, & Chan, 2016).

Phase 4.0 →Translational research. Pilot. Considering that the end goal of research findings is not complete until the knowledge acquired is fully applied in real world settings (Garfield et al., 2003) and considering the need for comprehensive diabetes translational research, the research team aimed to test whether the clinical research setting findings could be replicated in a real-world setting. Hence, a pilot study was run at the South Edmonton Primary Care Network (PCN) and, in collaboration with the site personnel, PANDA was adapted to ensure suitability of the program in the new context, where the key features remained as the basis of the program. The Pure Prairie Living Program (PPLP) was piloted with 26 individuals. Results from the 17 participants completing the program showed significantly increased PDAQ scores and diabetes self-efficacy along with weight loss but no improvement in HbA1c.

Therefore, to align with and continue the current line of research, the overall aim of this thesis was to evaluate the effectiveness of the PPLP to improve and facilitate healthy eating in adults with T2D in Alberta and to optimize its potential by identifying contextually appropriate tools and solutions to facilitate this process from the participants' perspective. To develop the background and understand relevant and current knowledge in nutrition, a literature review was conducted to review the beneficial effects on cardiovascular health of several dietary patterns for people with T2D. Given the important role dietary patterns play in diabetes management, a review on new methods to analyse energy intake was also conducted.

The initial research question addressed in this thesis was: Compared with usual care provided to wait-listed controls, can the PPLP improve clinical outcomes and increase dietary adherence in adults with T2D when delivered in a primary healthcare setting? Thus, the objective was to partner with healthcare professionals (HCP) in primary care to conduct and evaluate outcomes of a RCT of the PPLP. Within the RCT, the outcomes of interest were:

1) A comparison of HbA1c in the wait-listed controls with the intervention group, which received the PPLP, at 3 and 6 months follow-up.

2) A comparison of other cardiovascular risk factors in the wait-listed controls with the intervention group, which received the PPLP, at 3 and 6 months follow-up.

3) A comparison of dietary adherence to recommendations in the wait-listed controls with the intervention group, which received the PPLP, at 3 and 6 months follow-up.

4) An exploration of barriers and facilitators to implementing the PPLP from the perspective of both program participants and HCP.

Following completion of the RCT, and guided by the results, two additional objectives were developed:

1. To analyse to what extent LI programs align with the cornerstones of T2D management and to compare their effect sizes when moving through the scale-up process (efficacy trials to effectiveness trials).
2. To understand the lived experience of people with T2D when managing their disease, in order to identify optimization strategies for the PPLP and other LI programs

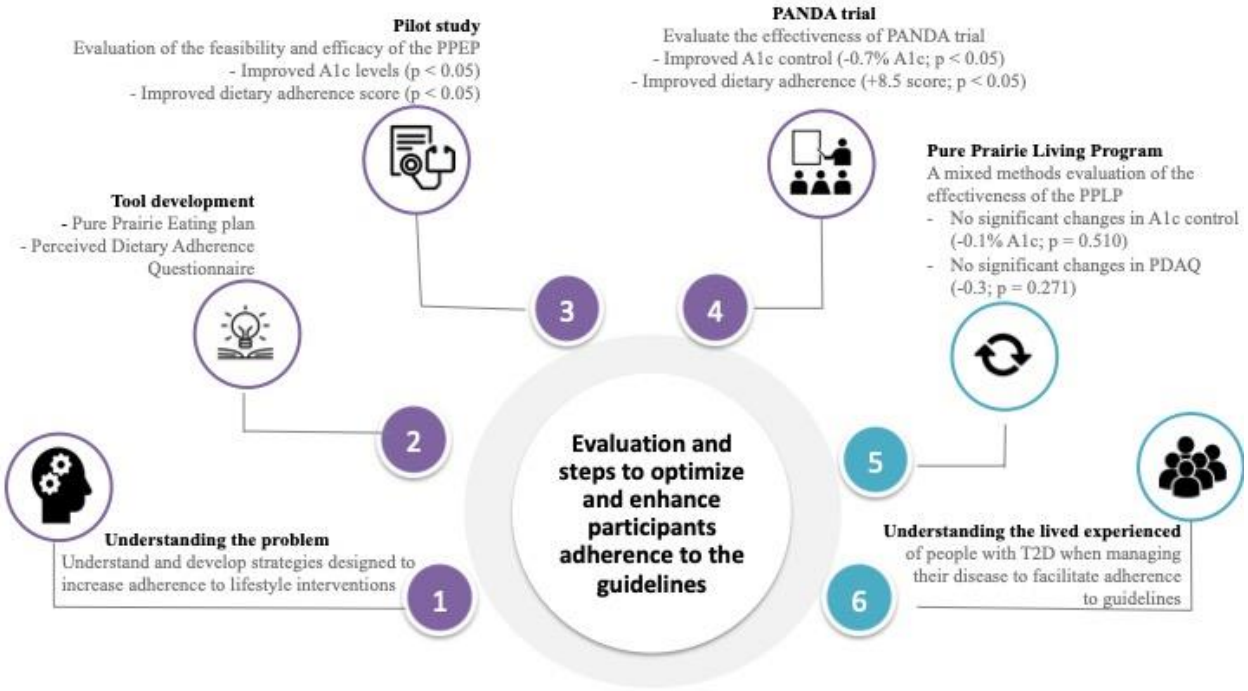

Figure 1.1. Previous (1 – 4) and future (5 – 6) research phases related to the Pure Prairie Living Program.

A brief description of each chapter follows.

Chapter 2: Dietary patterns and cardiovascular disease risk in people with type 2 diabetes. In this chapter, dietary patterns are reviewed as a key factor in the management of T2D. The primary objective is to highlight and identify dietary patterns with beneficial effects on the cardiovascular health of adults with T2D. The chapter is structured to first provide an overview of the scope of dietary patterns followed by a review of the particular benefits of various dietary patterns on different cardiovascular disease mechanisms. Next, a summary of these health benefits is presented. Lastly, the implications of using dietary patterns for the management and reduction of risk of T2D is considered.

This Chapter has been published as Archundia-Herrera, M. C., Subhan, F. B., & Chan, C. B. (2017). **Curr. Obes. Rep.** 6(4), 405-413.

Chapter 3: Narrative review of new methods for assessing food and energy intake. In this chapter, the relationship between dietary patters and health is acknowledged, recognizing the health risks related to poor diet and chronic disease. Accurate assessment of dietary energy intake is addressed as essential for understanding the link between health and chronic diseases as well as the efficacy of dietary interventions. However, current methods for assessing dietary intake have considerable constraints. In this chapter, new methodologies/technologies developed to mitigate present weaknesses are reviewed. Strengths and limitations of new approaches are analyzed based on ease of use, practical limitations, and statistical evaluation of reliability and validity.

This Chapter has been published as Archundia Herrera, M.C., & Chan, C. B. (2018). **Nutrients**, 10(8), 1064.

Chapter 4: A mixed-methods evaluation of a randomized control trial to evaluate the effectiveness of the Pure Prairie Living Program in type 2 diabetes participants. The primary objective of this chapter was to evaluate the effectiveness of a lifestyle intervention, named the PPLP tailored to Albertans with type 2 diabetes, in improving health outcomes (HbA1c levels, lipid panel and blood pressure) and promoting better nutrition choices (dietary adherence to the guidelines, diabetes self-efficacy) in a PCN setting. To evaluate thoroughly the PPLP intervention beyond clinical parameters, a mixed-methods approach was undertaken to understand the perceived effectiveness and limitations of the PPLP contextualized by HCP and study participants. This Chapter addresses the first aim of the thesis.

The data from this Chapter has been published (Archundia-Herrera, M.C., Subhan, F. B., Sakowsky, C., Watkins, K., & Chan, C. B., (2020). **Healthcare** 8(2):153).

Chapter 5: From research-settings to real-life: A systematic review of intervention approaches for type 2 diabetes management and their effectiveness. Given the major increase of T2D in recent decades, guidelines have been developed to support T2D management. Self-management education and support, nutrition therapy, physical activity and pharmacological guidance comprise the four cornerstones of diabetes management. Additionally, the use of multidisciplinary teams whom incorporate components of the Chronic Care Model framework when providing care for people with T2D is encouraged. Considering the complexity

of complying with the guidelines, structured lifestyle intervention (LI) programs integrate the guidelines into feasible programs that have validated feasibility and efficacy to help prevent progression to diabetes, and improve overall glycemic control. However, uncertainty remains regarding their effectiveness, especially over the long run. Thus, the objective of this chapter is to analyze and compare the efficacy and effectiveness of lifestyle interventions that aim to manage T2D when conducted in research versus real-world settings. (This chapter addresses the second aim, specific objective 1.)

The data from this Chapter is being prepared to be submitted to Applied Physiology, Nutrition and Metabolism (APNM) journal.

Chapter 6: Identification of contextually appropriate tools and solutions designed to facilitate healthy eating in people with T2D. This chapter builds on and contributes to our previous findings from the RCT, addressing specific objective 4. Participants enjoyed participating in the PPLP program and found the information useful but couldn't translate their knowledge into actions, thus failing to modify their health behaviours in the long run. Whereas previous studies have focused on investigating the importance of following a healthy eating pattern to reduce and manage T2D complications, others have focused on identifying the barriers when following these recommendations. However, little is known about how to facilitate this process, especially from the participants' perspective. There is a lack of studies that examine individual experiences, in relation to their everyday context, to identify facilitators for healthy eating. As such, this chapter provides additional insights about the processes participants with T2D go through when asked to modify their eating behaviour towards a healthy eating pattern. Understanding participants' context and environment is crucial to facilitating healthy eating behaviour change. (This chapter addresses the second aim, specific objective 2.)

Chapter 2: Dietary Patterns and Cardiovascular Disease Risk in People with Type 2 Diabetes

2.1. Introduction

Over 70% of deaths occurring globally in 2015 were attributed to non-communicable diseases (NCDs), of which cardiovascular disease (CVD) accounted for 45% and type 2 diabetes (T2D) for 4% (WHO, 2017). CVD and T2D represent substantial economic burdens, with a projected global cost of US$1,044 billion and US$745 billion, respectively, by 2030 (Bloom et al., 2011). Further, the global prevalence of T2D has risen from 4.7% to 8.5% in the last two decades (WHO, 2016), a rise that has been accompanied by an increase in 4 major risk factors: poor diet, physical inactivity, tobacco and alcohol use, which represent the hallmark of NCDs (WHO, 2017).

T2D is a chronic metabolic condition characterised by the presence of high blood sugar, insulin resistance and relative insufficiency of insulin secretion by the pancreas (Cheng, 2013). It accounts for 90% of people with T2D, and most often occurs in adults and elderly but recently its prevalence has increased in younger people. Medical nutrition therapy and lifestyle changes with or without anti-hyperglycemic medical treatment are essential for effective management of T2D. Poor control of T2D is associated with increased risk for premature mortality and comorbidities including heart attack, stroke, kidney failure, blindness, non-traumatic limb amputation and depression (CDA, 2011).

As the prevalence of T2D has risen, the proportion of CVD attributable to T2D has also increased in the last 50 years (Fox et al., 2007). People with T2D have two-fold excess risk for a wide range of vascular diseases (Sarwar et al., 2010). The pathophysiology of CVD and T2D is complex and multifactorial, physically affecting macro- and microvasculature as well as different cellular and molecular mechanisms in the human body (Dokken, 2008). A crucial part of T2D management and CVD prevention involves the adoption of ideal health behaviours (non-smoking, healthy weight, healthy diet, physical activity) and ideal health factors (blood pressure, cholesterol and blood glucose); from these, cardiovascular health status can be designated as poor, intermediate or ideal in the general population (Lloyd-Jones et al., 2010).

The American Heart Association's "healthy diet" definition focuses on whole foods and dietary patterns rather than specific nutrients (Lloyd-Jones et al., 2010). These recommendations parallel the most recent 2015 Dietary Guidelines for Americans, with the primary focus moving from single nutrient recommendations towards beneficial dietary patterns (Dietary Guidelines Advisory Committee, 2015). This shift in focus requires healthcare professionals and researchers to re-orient their practices and research objectives. Therefore, the primary objective of this review is to discuss and integrate current knowledge on dietary patterns and their potential health outcomes for minimizing CVD risk of adults with T2D. The review is organized by features of pathophysiology of CVD manifestation including i) macrovasculature, ii) microvasculature, iii) inflammation and oxidative stress, iv) hypercoagulation, and v) heart failure (Dokken, 2008), which impact individuals' cardiovascular health and in turn affect their quality of life. The benefits of dietary patterns and their impact on these disease mechanisms are addressed in this review. Patterns that focus on macronutrients rather than foods e.g., low carbohydrate diets are not included.

2.2. Methods

We searched MEDLINE and PubMed databases for prospective cohort studies, randomized controlled trials (RCT) and systematic reviews using the following key word, "diabetes mellitus, type 2, T2D or non-insulin dependent diabetes or NIDDM, "cardiovascular disease*", diet, "diet therp*" or "diet modification*" or "dietary patterns" or nutrition. Human studies in English language, published between 2012 to June 2017, describing dietary patterns and comparing various interventions were included. Primary outcomes included cardiovascular risk factors in adults (≥18 years) with T2D. The results from the studies extracted were heterogeneous in terms of the dietary interventions, length of follow-up, participant demographics, data collection and data reporting. Hence a narrative review approach was adopted in drafting this manuscript.

2.3. Results

2.3.1. Focus shift from single nutrients to dietary patterns

The 2015-2020 Dietary Guidelines for Americans focuses on describing the common characteristics of healthy diet patterns (McGuire, 2016). Even though new approach sounds "simplistic" or "logical", almost a century of scientific research had to evolve. The first link of a

disease with a specific dietary nutrient deficiency was observed in 1747 by Capitan James Lind (Lind, 1753). Preventing deficiencies was the focus of recommendations until 1980 (Dietary guidelines for Americans, 1980), when a shift occurred to include avoidance of single nutrient overconsumption (fat, saturated fat, cholesterol, sugar, sodium), due to possible links to chronic diseases in specific CVD and T2D (Dietary guidelines for Americans, 1980). These recommendations led to decreased consumption of fat intake; however a dramatic growth in the prevalence of obesity, CVD and T2D was concurrently observed (Mokdad et al., 1999). Recent evidence established that metabolic health is less influenced by single nutrients and more by intake of specific foods and overall dietary patterns, which have synergistic effects (Mozaffarian, Appel, & Van Horn, 2011). The amount of fat or carbohydrate consumed is now regarded as less important than the type of fat or carbohydrate (Hu, Manson, & Willett, 2001). This transition has galvanized the study of different dietary patterns and their effects on cardiovascular health in people with T2D as summarised in Table 2.1. It is generally accepted that dietary patterns have a strong impact on specific cardiovascular risk factors. Evidence from the general population indicates that intake of a typical "westernized diet", which includes consuming red and processed meat, sugar-sweetened foods and drinks, and fried foods is generally associated with insulin resistance, hyperlipidemia and pro-inflammatory state thus increasing T2D and CVD risks, while intake of a prudent diet characterized by intake of vegetables, fruits, whole grains, fish and low-fat dairy products is associated with a reduced risk from all-cause mortality and CVD (Rodríguez-Monforte, Flores-Mateo, & Sánchez, 2015).

2.3.2. Dietary patterns that protect the macro-vasculature

In general, patients with T2D and CVD have an impaired lipid profile or dyslipidemia (Dokken, 2008). Small, low-density lipoprotein cholesterol (LDL-C) is highly susceptible to oxidation and glycation resulting in increased atherogenic properties (Carmena, Duriez, & Fruchart, 2004). T2D individuals present decreased levels of high-density lipoprotein cholesterol (HDL-C) contributing to the development of atherosclerosis (Duell, Oram, & Bierman, 1991), given that HDL-C plays a main function in reverse cholesterol transport or cholesterol efflux (Rader, Alexander, Weibel, Billheimer, & Rothblat, 2009), crucial for protection from atherosclerosis (Rosenson et al., 2012). Thus, a therapeutic goal is to create a healthier balance of LDL-C and HDL-C in people with T2D in order to prevent CVD complications. The Korean Traditional Diet

(KTD), Traditional Mediterranean Diet (TMD), Dietary Approaches to Stop Hypertension (DASH) Diet and Low Glycemic Index (GI) Diet were identified as providing macrovascular benefits. Vegetarian diets (VD) were also protective against certain CVD although the number of T2D patients studied is small (**Table 2.1**).

Consumption of a KTD for 12 weeks in older adults with T2D improved including anthropometric parameters and total serum cholesterol, LDL-C, triglyceride (TG) and glycated haemoglobin (HbA1c) in addition to lowering heart rate and diastolic blood pressure (DBP), all of which reduce the risk of atherosclerosis (Jung et al., 2014). The KTD pattern is based on steam-cooked rice and soups; vegetables; fish or meat; sesame oil, soy sauce, and fermented plant products. It excludes bread and dairy products but does not restrict caloric or sodium intake (Jung et al., 2014). Participants on KTD dramatically increased their fibre consumption by ~22g/day, which might explain the improvement in their lipid profile (Jung et al., 2014), because similar effects were seen in other high fibre diet patterns, such as a study reporting improved glycemic control, abdominal obesity, hypertension, metabolic syndrome and inflammatory markers in Japanese T2D patients (Fujii et al., 2013), or improved endothelial function in T2D patients on a 8-week high fibre brown rice diet (Kondo et al., 2017). Observational studies concur that consumption of high fibre whole grain diets reduces CVD risk (Liu et al., 1999) and meta-analysis of prospective studies evaluating the association between dietary fibre and diabetes risk found an inverse association, with a 6% reduced risk for every 2g/day increase in fibre intake (Yao et al., 2014). There is a growing appreciation that modulation of the gut microbiota by fiber plays a role in its beneficial effects on CVD risk (Sawicki et al., 2017).

The improvement in HbA1c levels shown after following a TKD was not found with other dietary patterns discussed above (Díez-Espino et al., 2011; Kondo et al., 2017). A unique aspect of the TKD is the high amount of fermented food consumed. Fermented soy products are high in isoflavones that impact hepatic glucose and lipid metabolism to reduce blood glucose and HbA1c levels (Ae Park et al., 2006). Fermented chilli, for example, is rich in capsaicin, flavonoids and other bioactive compounds, and is reported to be an appetite suppressant leading to a decrease in TG, apolipoprotein B levels and visceral adiposity (Cha et al., 2013). The combined benefits of fibre and isoflavones point to the synergistic effects of constituents of the dietary pattern.

A more well-known, well-balanced dietary pattern is the TMD, characterised in part for its high fibre content. Adherents to the TMD consume olive oil (main lipid source) (Martínez-González et al., 2012). Trials of the TMD reported an overall improvement in cardiovascular risk factors including lipid profile and waist-hip ratio (Widmer, Flammer, Lerman, & Lerman, 2015). Furthermore, the TMD not only increased HDL-C concentrations but improved several HDL-C functions including cholesterol efflux capacity (Hernáez et al., 2017), a more clinically relevant measurement than the HDL-C concentration (Rohatgi et al., 2014). Additional benefits of the TMD relative to other CVD endpoints are discussed further below.

The DASH diet was originally designed to help people with hypertension. However, ~50% of people with T2D suffer from hypertension, which contributes to both macrovascular and microvascular damage, hence the DASH diet is suitable for effective T2D management (Cheng, 2013). The DASH diet includes low intake of total fat, sweets, added sugars, sugar-containing beverages and sodium, and high intake of fruit and vegetables (F&V), whole grains, fish, poultry, nuts and fat-free or low-fat dairy foods. In an 8-week RCT of T2D adults with hypertension, following the DASH diet was associated with significant reduction in body weight, waist circumference, fasting blood glucose, HbA1c, and LDL-C and an increase in HDL-C (Azadbakht, Fard, et al., 2011) consistent with earlier literature (Appel et al., 2003; Ledikwe et al., 2007; Maruthur, Wang, & Appel, 2009; Saneei, Salehi-Abargouei, Esmaillzadeh, & Azadbakht, 2014; Siervo et al., 2015).

Additional dietary patterns have also been beneficially associated with CVD health outcomes in people with T2D. In a meta-analysis of RCTs (>6 month duration) conducted in T2D adults, low GI diets improved HDL-C and HbA1c levels in comparison to control diets (variously high fibre cereal diet, the American Diabetes Association (ADA) diet and low carbohydrate diet (Ajala, English, & Pinkney, 2013). Although the beneficial effects of VD in people with T2D *per se* have not been examined recently, meta-analysis of 11 studies of which 2 included T2D patients found significant lowering of total LDL-C but also reduced HDL-C compared with omnivorous diets (Wang et al., 2015). A review of prospective cohort studies not focused on people with T2D reported that in comparison to non-vegetarians, vegetarians had 26-68% lower risk of mortality from ischemic heart, cardiovascular, and cerebrovascular diseases, along with lower incident hypertension and T2D (Le & Sabaté, 2014). A recent systematic review and meta-

analysis of ~90 cross-sectional and prospective studies reported that vegetarian and vegan diets in comparison to omnivorous diets, significantly reduced BMI, total cholesterol, LDL-cholesterol, and glucose levels. Vegetarian diets also offered protection against incident and/or ischemic heart disease mortality, however there was no significant difference in total cardiovascular and cerebrovascular diseases (Dinu, Abbate, Gensini, Casini, & Sofi, 2017). Higher intake of total/soluble fibre, nuts, soy, plant sterols and lower levels of saturated fat as observed in VD could exert a beneficial effect on the lipid profile (Craig & Mangels, 2009).

2.3.3. Dietary patterns that protect the microvasculature

Nephropathy, retinopathy and neuropathy encompass the more common microvascular complications in T2D (Brownlee, 2001). Damage to the small vessels results from a hyper-constricted state as a consequence of decreased bioavailability of nitric oxide (NO) and increased secretion of endothelin-1 (Brownlee, 2001). Further, chronic hyperglycemia promotes membrane thickening (Hayden, Sowers, & Tyagi, 2005) resulting in impaired selective transport and increased permeability of large molecules resulting in endothelial dysfunction (Besic, Jeraj, Spirkoska, Jezovnik, & Poredoš, 2017).

The "REvención con DIeta MEDiterránea" PREDIMED study, a nutritional intervention based on the TMD with daily supplementation of extra virgin olive oil (EVOO) or nuts and a frequent use of "sofrito" sauce for the dressing of dishes, reported a 43% relative risk reduction for retinopathy in those supplemented with EVOO and high adherence to the TMD compared to the lowest adherence after a 6 year follow-up (Díaz-López et al., 2015). These benefits were attributed to the bioactive compounds and nutrients found in EVOO (Díaz-López et al., 2015). While the anti-inflammatory, anti-atherogenic and hypoglycemic properties of EVOO have been well documented (Rigacci & Stefani, 2016), its benefits to the microvascular are not fully understood. However, since a chronic hyperglycemic state results in excessive reactive oxygen species (ROS) production, which are implicated in microvascular co-morbidities (Tiwari, Pandey, Abidi, & Rizvi, 2013), the TMD and EVOO may decrease ROS (Díaz-López et al., 2015). Future research to understand the effects of dietary patterns/macronutrient composition on ROS, NO bioavailability and impaired microvascular permeability is warranted, as are studies of other dietary patterns examining microvascular endpoints.

2.3.4. Dietary patterns that reduce inflammation and oxidative stress

During the progression of T2D and cardio-metabolic comorbidities, increased oxidative stress and inflammation has been consistently reported (Brownlee, 2005; Dokken, 2008; Faria & Persaud, 2017; Tiwari et al., 2013). The chronic hyperglycemic state characteristic of T2D involves the activation of the immune system via production of pro-inflammatory cytokines (Lau et al., 2017). This long-term, chronic inflammation exacerbates vascular injury and promotes mitochondrial production of ROS (Faria & Persaud, 2017) culminating in cardiac tissue damage (Brownlee, 2005).

Effects of the TMD on inflammation and oxidative stress were investigated in the ATTICA cohort study in a 10-year follow-up (Koloverou et al., 2016). Authors observed improvements in biomarkers of oxidative stress, inflammation and coagulation, concluding that high adherence to the TMD decreased oxidative stress and subclinical inflammation with resultant 60% decrease in T2D risk, whereas a medium level of adherence reduced the risk by 50% (Koloverou et al., 2016). The greatest benefit was observed in individuals who shifted from low to medium adherence, particularly in those with greater waist circumference (Koloverou et al., 2016).

Other dietary patterns also have anti-inflammatory properties. Increasing F&V intake enhanced the antioxidant capacity in subjects with T2D after an 8-week intervention (Daniels et al., 2014). Blood carotenoid levels were associated with enhanced antioxidant properties of HDL-C, consequently boosting its anti-atherogenic properties (Daniels et al., 2014). The DASH diet likewise reduced inflammation and oxidative stress in people with T2D as evidenced by significant reduction in C-reactive protein (CRP), fibrinogen, and liver enzymes in T2D adults after 8 weeks (Azadbakht, Surkan, Esmaillzadeh, & Willett, 2011). In a RCT of pregnant women (24-28 week gestation) with gestational diabetes, intake of DASH diet for 4 weeks improved fasting plasma glucose and insulin, HOMA-IR, total antioxidant capacity and total glutathione levels in comparison with the control diet, however no significant differences in CRP levels were observed (Asemi, Samimi, Tabassi, Sabihi, & Esmaillzadeh, 2013).

2.3.5. Dietary patterns that reduce hypercoagulability

Heart attack and stroke as a result of clots are a leading cause of mortality in people with T2D (Vazzana, Ranalli, Cuccurullo, & Davì, 2012). Hyperglycemia and insulin resistance lead to

increased levels of thrombin generation by platelets, IL-6 expression inducing hepatocyte production of fibrinogen and tissue factor expression resulting hypercoagulation (Vazzana et al., 2012). Several antithrombotic drugs aimed at different coagulation and platelet activation targets moderate these problems (Gosavi & Mukherjee, 2013) but they can also be managed through diet (Ijiri Y, 2016; Rajaram, 2003; Violi, Pignatelli, & Basili, 2010). At present, few studies have examined the relationship between dietary patterns *per se* and pro-thrombotic parameters in overt T2D. Supplementation of 300g of F&V with no other changes to usual dietary intake for 8 weeks was associated with improved blood viscosity, erythrocyte sedimentation rate and fibrinogen and hematocrit levels in adults with T2D (Salau, Adeyanju, Odufuwa, & Osilesi, 2012). Similar improvements in plasmin-dependent fibrinolytic pathway were reported in a 3-week controlled feeding trial of low fat and high-complex carbohydrate diet (35-45 g dietary fibre per 1000 kcal, with the majority of protein derived from plant sources) with significant reductions in plasminogen, tissue plasminogen activator, plasminogen activator inhibitor and lipid and lipoprotein profiles (Mehrabian, Peter, Barnard, & Lusis, 1990). Further, in an 8-year follow-up study of T2D adults with no previous coronary heart disease history, higher intake of F&V and total dietary fiber was associated with a significantly lower risk of stroke (Tanaka et al., 2013).

2.3.6. Dietary patterns associated with reduced heart failure

Even though the prevalence of T2D has risen during the past two decades, cardiovascular and cardiac deaths have declined in T2D patients (Tsujimoto, Kajio, & Sugiyama, 2018) as a result of advances in medication (Ford et al., 2007) and healthcare systems' efficacy of T2D care (Tricco et al., 2012). The general features of T2D physiopathology such as impaired glucose tolerance, dyslipidemia, elevated inflammation and oxidative stress increase the risk of left ventricular hypertrophy, myocardial fibrosis and diastolic/systolic dysfunction associated with diabetic cardiomyopathy (DCM) (Bauters et al., 2003), which is the final pathway of heart failure. T2D patients with ischemic heart diseases or hypertension are at higher risk of DCM (Jansson, Svärdsudd, & Andersson, 2014). Hence, in order to improve heart failure outcomes it is recommend that people with T2D achieve and maintain blood pressure of <130/80 mm Hg (Cheng, 2013; Hackam et al., 2010).

An 8-week RCT of DASH diet was sufficient to lower systolic and diastolic blood pressure (Azadbakht, Fard, et al., 2011), while DASH diet plus physical activity also showed effective blood pressure reduction (Paula et al., 2015). Interestingly, the consumption of F&V typical of the DASH diet was associated with reduced blood pressure in patients with T2D, possibly playing a protective role in part through increased intake of vitamin K (De Paula et al., 2012) because insufficient levels of vitamin K are associated with increased vascular calcification (Tsugawa, 2015). The KTD for 12 weeks also reduced heart rate and DBP (Jung et al., 2014). Further, results from the PREDIMED study indicate that 1 year of following the TMD (TMD + EVOO or TMD + nuts) in comparison to a low fat diet decreased both a biomarker of heart failure and oxidized low density lipoprotein in patients with increased CVD risk (Fito et al., 2014).

2.4. Discussion

This review presents the cardiovascular pathogenesis associated with T2D and provides evidence that balanced dietary patterns can be effective in managing T2D and limiting the risk of cardiovascular comorbidities. Balanced dietary patterns, which include adequate amount of a variety of foods to provide the macro- and micronutrients to meet and individual's daily nutrient requirements are essential for proper functioning of the body and overall health (WHO, 2017). For example, diets such as the TMD and DASH diets are protective against chronic diseases including T2D and cardiovascular diseases (Ledikwe et al., 2007; Mente, de Koning, Shannon, & Anand, 2009; Sofi, Macchi, Abbate, Gensini, & Casini, 2014). Several mechanisms come together to explain these benefits: whole grains, F&V are sources of dietary fibre beneficial in improving hyperglycemia, dyslipidemia and hematological parameters including hypercoagulability, thus supporting optimal macrovascular health (Tanaka et al., 2013). Further, these foods are rich sources of micronutrients including vitamins, minerals and phytochemicals, all of which regulate metabolic, anti-inflammatory and anti-oxidant pathways to improve microvascular status. A recent prospective cohort study from several countries with a median follow-up of 7.4 years, reported that lower risk of major CVD can be attained even with a relatively moderate consumption of 375-500 g/day (3-4 servings) of fruit, vegetables and legumes (Miller et al., 2017). Similarly, these positive health outcomes are reported in individuals who consume VD, which limit or exclude foods of animal origin (Wang et al., 2015).

Careful planning and a varied plant-based diet with supplementation of limiting micronutrients such as homocysteine, folate and calcium (Craig & Mangels, 2009) makes VD suitable for management of CVD risks in T2D. Very few studies have examined the effects of low GI diet in reducing cardiovascular complications in T2D per se, although there is extensive evidence indicating effectiveness in weight and blood pressure management in the general population (Radulian, Rusu, Dragomir, & Posea, 2009). Given that low GI foods tend to fall into the categories of F&V, whole grains and legumes, it can be anticipated that following such diet will have CVD risk benefits for people with T2D.

Recent studies focusing on traditional dietary practices such as TKD have shown improved cardiovascular benefits in people T2D. These diets promote traditional, local foods and ingredients with an emphasis on grains, vegetables, seafood and fermented plant-based products. The fiber, probiotics, and phytochemicals found in these foods plausibly explain their cardio-protective effects. It should be also noted that the TMD and VD are also rooted in traditional practices. Newer evidence supports beneficial effects of other local dietary practices, such as the traditional Japanese diet; people from Japan are known to have high life expectancy (89 years) (WHO, 2015) and this can be attributed to their dietary and lifestyle practices. A traditional Japanese diet (JD) is high in grains and vegetables (including seaweeds), with moderate amounts of fish and soy but minimal dairy and fruit intake. Green tea and fermented soy products are also staples of the diet (Kurotani et al., 2016). A prospective cohort study with a 15-year follow-up period indicated that adherence to Japanese dietary guidelines was associated with a lower risk of total mortality, mortality from cardiovascular disease and cerebrovascular disease (Kurotani et al., 2016).

One commonality in the diets presented in this review is a complex dietary pattern including a variety of foods with a large focus on plant-based products such as whole grains, F&V, legumes (TMD, DASH, VD, GI), seafood and/or poultry (TMD, DASH, TKD, JD, GI). Further, a newer conceptual framework termed “cooking behaviour” which includes: cooking frequency (frequency of cooking at home versus restaurant eating or take-out), techniques and methods of cooking impacting the nutritional quality of food (e.g., low fat cooking methods, avoiding high temperature cooking and heavy browning of food), minimal usage of added sugars, sweeteners, animal fats, processed foods and red meat and flavouring of foods (use of herbs and spices and

avoiding salt) may play an important role in improving dietary intake and prevention of chronic disease risk such as CVD and obesity (Raber et al., 2016). Many of the characteristics discussed above are a cultural norm of the diets reviewed in this paper (MD, TKD, JD). Additionally, in these diets the major source of fat is plant- or seafood-based, providing essential fatty acids, poly/mono–unsaturated fatty acids, which demonstrate anti-atherogenic properties and other health benefits (Estruch et al., 2013; Guasch-Ferré et al., 2014; Hoffman & Gerber, 2013). Liu *et al.* (2017) presented evidence that rather than total fat, it is far more important to consider the overall dietary patterns and type of foods (particularly carbohydrate and fat) consumed, for improving cardiovascular health (Liu et al., 2017). However, public confusion of dietary recommendations particularly regarding fats remains problematic (Diekman & Malcolm, 2009). The 2015 Dietary Guidelines Advisory Committee led the shift toward moving from single nutrients to focusing on dietary patterns and types of foods (McGuire, 2015) with the potential benefit of reducing confusion and misperceptions of what a healthy dietary pattern should include.

The dietary patterns described in this review will also have the effect of increasing nutrient density while lowering caloric density achieved by moderate intake of dairy, lean protein lower in saturated fats, and restriction of processed meats and added sugars. A recent study reported people who experienced a long-term change to a higher-quality diet reduced their risk of death from any cause over 12 years regardless of the approach taken (risk reduction 14% by alternate healthy eating index score, 11% by alternate Mediterranean diet score, and 9% by DASH score) (Sotos-Prieto et al., 2017) providing evidence to support the shift from focusing on single nutrients/diets to healthy eating patterns since these diets, even though different, constitute balanced patterns and incorporate cooking methods associated with healthy eating patterns (De Paula et al., 2012; Díaz-López et al., 2015; Dinu et al., 2017; Hu et al., 2015; Jung et al., 2014; Kurotani et al., 2016; Salau et al., 2012). Furthermore, associations between dietary environment factors (portion size and increased availability) (Herman, Polivy, Vartanian, & Pliner, 2016; Zobel, Hansen, Rossing, & von Scholten, 2016), as well as increased dietary variability might also play an important role as risk factors for obesity (Hardman, Ferriday, Kyle, Rogers, & Brunstrom, 2015). Thus, the role of nutrition in T2D and CVD risk goes beyond the collection of

nutrients ingested and include many personal and environmental factors that need to be taken into consideration, both in research and in practice.

2.5. Conclusion

Based on the review of diets presented here (Mediterranean diet, DASH diet, Vegetarian Diet, Traditional Korean Diet, Japanese diet, Low Glycemic Index diet), there is a range of dietary options available to people with T2D to manage CVD risk. However, considering the overall set of scientific evidence is necessary when making cardiovascular health recommendations since adherence to dietary practices is highly individualistic and influenced by various social and environmental factors. Future interventions to educate and build skills in patients and healthcare professionals can help them make informed choices to meet individual needs.

Table 2.1. Characteristics and cardiovascular health benefits of dietary patterns in people with T2D

Author	Characteristics	Cardiovascular Health Benefits In People with T2D*				
		Macrovascular	**Microvascular**	**Inflammation and Oxidative stress**	**Hypercoagulability**	**Heart Failure**
Traditional Mediterranean Diet	Includes a high consumption of olive oil (main lipid source), vegetables, fruits, legumes and fish and poultry, and a low consumption of red or processed meat, butter, fast food, sweets, pastries or sugar-sweetened beverages	Improves lipid profile, HbA1c, blood pressure and endothelial function	Reduction in diabetic retinopathy. Improved endothelial function	Decreases oxidative stress and subclinical inflammation	Insufficient evidence	Decreases a biomarker of heart failure and oxidized low density lipoprotein
Dash Diet	Includes low intake of total fat, sweets, added sugars, sugar-containing beverages and sodium, and a high intake of fruits and vegetables, whole grains, fish, poultry, nuts and fat-free or low-fat dairy foods	Reduction in body weight, waist circumference, fasting blood glucose, HbA1c, and LDL-C and improvement in insulin resistance and HDL-C levels	Insufficient evidence	Reduction in inflammatory markers (CRP), oxidative stress – improvements in total antioxidant capacity and total glutathione levels	Decrease in fibrinogen	Reduction in systolic and diastolic blood pressure.

Low GI Diet	Includes foods high in dietary fiber such as whole grains, vegetables, fruit, lean meat	Improved HDL and HbA1c and reduction in LDL and TG	Insufficient evidence	Insufficient evidence	Insufficient evidence	Insufficient evidence
Traditional Korean Diet	Includes steam-cooked rice and soups, vegetables (raw or cooked), fish or meat, sesame oil, soy sauce, salted and fermented vegetables, fermented soybean and red chilli pastes. Excludes bread, dairy products; does not restrict caloric or sodium intake	Improvement in waist hip ratio, body weight, fat mass, total cholesterol, LDL, TG , heart rate and diastolic BP	Insufficient evidence	Insufficient evidence	Insufficient evidence	Reduces HR and DBP thus reducing the risk of hypertension and myocardial infarction.
Vegetarian Diet	Improves glycemic control, abdominal obesity, hypertension, metabolic syndrome. Lower risks of mortality from ischemic heart disease, cardiovascular disease, and cerebrovascular disease	Improves endothelial function.	Improvement in inflammatory markers	Insufficient evidence	Improvements in blood viscosity, erythrocyte sedimentation rate and fibrinogen and haematocrit levels. Improvement in plasmin-dependent fibrinolytic pathway	Insufficient evidence

*Abbreviations: CRP, C-reactive protein; DBP, diastolic blood pressure; glycated haemoglobin, HbA1c; HR, heart rate; HDL-C, high density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol; T2D, type 2 diabetes; TG, triglyceride.

Chapter 3: Narrative review of new methods for assessing food and energy intake

3.1. Introduction

On a global scale, life expectancy has increased steadily for the past 35 years; however, in association with the global rise of obesity, the number of deaths from most non-communicable causes like T2D rose by 32.1%, increasing the burden on health systems (Wang et al., 2016). During the past two decades, different intensive LI programs have consistently shown that modest but clinically significant weight loss of 5% in individuals with overweight, obesity or T2D can yield a variety of health, disease prevention and treatment benefits (Williamson, 2017). Prescription of a hypocaloric diet (500–750 calories less than baseline), increased physical activity (90–175 min/week) and long term behavior change, are common techniques use in Intensive Lifestyle Intervention (Das et al., 2017; DPP, 2002; Look AHEAD, 2014; Ma., et al., 2016), which also have been described previously as individual techniques for weight control (Blair, 2009; Ryan & Jensen, 2013; Sharma, Patil, & Satyanarayana, 2014).

Assessment of dietary and/or energy intake (EI) is crucial to understand the impact of clinical trials on the management of obesity and its comorbidities (Subar et al., 2015; Williamson, 2017). To date, food records (FR), food frequency questionnaires (FFQ), and 24-h recalls (24HR) are the most common methods used to assess dietary and EI during treatment and follow-up (Johnson, 2002). These self-reported data methodologies have provided valuable information to use as a base to develop public health policy, comprehend and identify consumption of different food groups, understand relationship with diseases and determine eating patterns associated with weight loss, information that until recently could not be obtained in any other way (Subar et al., 2015).

However, a major challenge of these methods is that they rely on self-reported data. Human memory is not 100% accurate in recalling past behavior, consequently these measurements do not directly or objectively measure dietary intake or EI and do not comply with the standards of scientific methodology (Archer, Pavela, & Lavie, 2015; Dhurandhar et al.,

2015). One issue is that the actual process of doing food records can lead individuals to change their food behavior patterns and therefore, misreport information resulting in an inaccurate report of foods, nutrients and energy consumed (Ioannidis, 2013). Using data from The National Health and Nutrition Examination Survey (NHANES) 2003–2012, researchers analyzed the prevalence of under and over-reporting of EI, finding that in the US adult population (≥20 years) 25.1% misreported EI (Murakami & Livingstone, 2015), results consistent with European countries where prevalence of under-reporting ranges from 20% to a high of 45% (Berta Vanrullen, Volatier, Bertaut, Dufour, & Dallongeville, 2014; Gemming, Jiang, Swinburn, Utter, & Mhurchu, 2014; Johansson, Solvoll, Bjorneboe, & Drevon, 1998; Murakami, McCaffrey, & Livingstone, 2013) with a predominance of obese populations under-reporting. Part of the limitation of behavior modification presented in food records can be overcome though the use of 24HR, since they can be unannounced so that the diet is not changed; however, estimation of the usual diet is weakened by recall bias (food omission or forgetfulness, erroneous estimation of portion size) (Basiotis, Welsh, Cronin, Kelsay, & Mertz, 1987). In addition to recall bias, these methods impart a substantial researcher/individual burden and high cost of administration (Thompson, Subar, Loria, Reedy, & Baranowski, 2010). These methodologies used for dietary assessment have been severely criticized to the point of calling the resultant data "pseudoscientific and inadmissible in scientific research", and what "constitutes the single greatest impediment to actual scientific progress in the fields of obesity and nutrition research" (Archer et al., 2015).

Thus, the accuracy of dietary assessments or modifications in dietary or EI is full of challenges and the development of new technologies to try to overcome current limitations has been encouraged (Thompson et al., 2010). The objective of this review is to present the strengths and weaknesses of innovative new tools or methodologies that could replace, improve or complement current self-report dietary assessment instruments.

3.2. Methods

3.2.1. Search for innovative food and EI assessment tools and methodologies

Medline, CINAHL and PsychINFO were searched for English-language articles, using the following keywords separately or in combination: diet, diet records, dietary intake, energy intake, innovate *, meals, measurement, metabolism, method, models, new, nutrition assessment, optimiz *, recent, self-report, technolog *, test reliability, test validity, trend, validation studies. The search resulted in 337 articles (**Figure 3.1**). The output was then narrowed by imposing search criteria of "2012 – October 2016" and "adults". This search resulted in 73 articles. These article titles and abstracts were screened by one author (MCAH) to determine if they fulfilled the eligibility criteria. The articles included had to describe or validate a new method or use new technology tools that could capture food or EI. The methodologies or tools were assessed to determine their benefits and limitations as well as their reliability or validity. Studies using text messaging or mobile phone applications that required manual introduction of information were not considered because using this type of technology imposes the same limitations as the current methods requiring a self-reported measurement with a burdensome of impractical framework for the subject.

Of the 73 articles uncovered with this search, 17 were considered potentially eligible. These articles were cross-listed in PubMed for articles related to the topic, which identified 8 other articles. Reference lists of relevant articles were also hand-searched but no other relevant articles were found. For these 25 articles, review of the full text was used to identify those meeting the criteria ($n = 11$).

3.2.2. Evaluation

A relative evaluation of the innovative technology tools and methodologies was carried out. They were assessed to ensure that the main weaknesses of present methodologies: recall biases, measurement discrepancies, lack of scientific rigor, were being acknowledged. When developing tools to collect dietary information, specific statistical methods must be used to evaluate their reliability and validity in order to test the accuracy of the method and avoid bias (Bountziouka & Panagiotakos, 2010). Thus, utilization of these recommended statistical methods to assess the different tools and methodologies was noted when drafting this manuscript. *Reliability* refers to "the consistency of a measuring instrument" (Bountziouka & Panagiotakos, 2010), in different situations; inter-rater, test-retest, inter-

method and internal consistency. *Validity* refers to "how close the tool can measure the actual (true) value"; in this case, a measure of true EI when compared to the gold standard (Bountziouka & Panagiotakos, 2010).

Benefits and limitations: When describing benefits and limitations of each tool/methodology, the focus was on the following criteria: Easy to administer—Referring to reducing participant burden. Current methods rely on information reported by the subjects recalling what they ate for the past week/month/year, or keeping a diary for various days. This decreases the quality of the reports, and the process itself can make subjects change their eating habits (Rebro, Patterson, Kristal, & Cheney, 1998). Easy to score—Observed and weighed-food records (Hise, Sullivan, Jacobsen, Johnson, & Donnelly, 2002), doubly labelled water (DLW) (Schoeller, 1988), and FFQ (Johnson, 2002), are some of the methods currently used to determine/estimate EI and/or eating behavior. These methods are expensive and time-consuming, making them less feasible to use and hard to score. New methodologies should minimize practitioners' or researchers' burden and expense and capture change over more than one day because assessment of day-to-day variability in food intake is an important limitation of current methodologies. New methodology should overcome these limitations and be able to capture fluctuations in habitual energy and nutrient intake on free-living subjects.

3.3. Results

Table 3.1 summarizes the studies that were included in the review. Five described different types of monitors and sensors; five described camera-scan-sensor-based technologies; and one described a mathematical method. Details of the statistical methods used to assess validity and reliability are noted in **Table 3.2.**

3.3.1. Food/energy intake monitoring devices and tools

Use of body sensors as a direct measurement of human eating behavior is quite recent. Body monitors and sensors have been developed with the hope of improving and facilitating measurement of daily food and EI (Amft & Troster, 2008; Sazonov et al., 2008).

Automated wrist motion tracking

The Automated Wrist Motion Tracking, also called a "bite counter" is worn like a watch and automatically tracks wrist motion for monitoring eating in humans (Dong, Hoover, Scisco, & Muth, 2012). Reliability was tested in both controlled meal and semi-controlled settings. The sensitivity was >85% in both settings. Bites measured by the device were >80% detected compared with bites counted by direct observation. The equations used to measure sensitivity and performance are reported in **Table 3.2** (Dong et al., 2012). A third experiment in free-living situations was performed to examine the correlation between bites detected and EI, with $r = 0.6$. This experiment was only exploratory and was done to seek any possible relationships between these factors for further research (Dong et al., 2012).

Use of this device resulted in improved accuracy of measuring EI in free-living situations compared with 24HR and FFQ, which typically under-report EI in men by 16–20% and 31–36%, and in women by 16–20% and 34–38% respectively (Subar et al., 2003). Participant burden was minimal because the user only needed to turn it on and off before eating, and thereafter, bites were registered automatically by the device; thus, researcher and administrative costs are ameliorated since no food weight or labour-intensive laboratory techniques are needed (Dong et al., 2012; Fontana, Farooq, & Sazonov, 2014; Salley, Hoover, Wilson, & Muth, 2016). Forgetting to use the device, accuracy in different social settings and loss of data when both hands are used to eat are present limitations that the bite counter tool needs to address. Importantly this device's main benefit is its use as a food intake-monitoring and ingestive behavior tracking system in a real-world setting to improve users, researchers and health care providers understanding of food intake behaviors. Furthermore, lessen the burden of manual measurements; however, no input regarding the type or quality of the food consumed is tracked.

The bite-based model of kilocalorie intake

The bite-counter described above was used for the development of a kilocalorie per bite equation (using bite counts, individual demographic and physical characteristics) that allowed EI to be estimated. The relationship obtained was estimated as kilocalories per bite = −0.128 age + 6.167 sex (female = 0) + 0.034 height + 0.035 weight − 12.012 WHR + 22.294; where WHR = waist-to-hip ratio (Salley et al., 2016). The feasibility of using the

formula was then systematically evaluated. Two trials were run using a train and test paradigm, in which the training group was used to develop the model and the test group was used to determine reliability of the regression model.

When comparing the reliability of the formula-predicted EI values to the staff-observed values within the test group the Pearson correlation was $r = 0.374$. For the reliability of the model between training and test groups, the difference in r^2 (which is called the shrinkage value) was 1.4% (Salley et al., 2016). To assess validity, researchers assessed participants' estimation error of EI compared with the equation. The bite-based equation method was more effective at estimating EI than the best human estimation (Salley et al., 2016).

The bite counter along with the bite-based method formula can provide individuals with an EI estimation that is more accurate than an individual's estimation even when EI information is available, which potentially could help improve their adherence to recommended dietary changes. The bite counter also has the benefit of being a non-invasive device, which allows tracking of free-living situations for research and also has the potential to improve the understanding of food ingestion patterns including snacking, night eating, and weekend overeating, as pointed out by Fontana et al., (2014) as one of the benefits of food intake monitoring devices and tools. However, reliability was relatively low and internal and external validity of the method needs to be further elucidated. This tool is for monitoring EI purposes only and does not provide information or feedback on diet quality.

The automatic ingestion monitor (AIM)

The Automatic Ingestion Monitor (AIM) integrated hand gestures, jaw motions and accelerometer sensors to detect food intake in free-living individuals (Fontana et al., 2014). It was designed for objective 24-h monitoring of food intake in free-living conditions without depending on any input from the subjects. The monitor was 90% accurate in its ability to detect specific food intake epochs in free-living individuals compared with self-reported signal (push-button) indicating food intake events, and self-reported food journals (Fontana et al., 2014).

When developing and validating this device, the data were obtained from monitoring free-living situations that included a wide variety of foods and activities, increasing its feasibility for everyday use and research purposes. Its use could provide insight into overall eating behavior patterns where participants burden is minimal. Nonetheless, the use of self-report as the gold-standard method, rather than direct observation, prompts caution regarding reliability. Furthermore, subject compliance with and acceptability of wearing the AIM needs to be established (Fontana et al., 2014). Insight obtained from this and previous studies (Sazonov, 2009) encourages further research to build mathematical models to obtain estimated EI using individualized models on counts of chews and swallows (CCS) (Fontana et al., 2015).

Intelligent food-intake monitor

The intelligent food-intake monitor integrates multi-sensor monitors to track chewing speed, and images of the type and amount of food consumed, giving an overall understanding of eating behavior characteristics (Liu, 2012). The tool was tested for its ability to correctly detect the proportion of food consumed in real life scenarios but results were not reported (Liu, 2012).

The development of the device took into consideration the general process and pattern of food-intake activities to directly target their process (food ingestion, chewing and swallowing). The experiments were conducted in a real-world setting to increase the feasibility of being used in such settings. Valuable information involving eating behavior can be obtained from the use of this device because it doesn't assume that the food on the plate is consumed, thus providing a more reliable measure than capturing images of food alone to assess food consumption, thanks to the integration of chewing and swallowing detection in the process. Further research needs to be conducted to increase participants' comfort levels when using the device to ensure compliance with its use for longer periods. Even though a high level of correlation is reported between ground truth and auditory and vision predictors, no *r*-values were given and no strong statistical bases were presented. Participant characteristics were not supplied (Liu, 2012), leaving to speculation the age

range that could benefit from using this monitor, and whether it would be feasibility to use in older adults, youth and children.

3.3.2. Camera-scan-sensor based technologies or food/energy intake assessment tools

Sixty-four percent of the American population own a smartphone, a 35% increase since 2011 (Pew Research Center, 2015). Since the use of smartphones is steadily increasing in daily life, mobile phone camera-scan-sensors are being proposed to contribute novel approaches to the measurement of food and EI.

Digital photography + recall method (DP+R)

Ptomey et al., (2015) developed and evaluated a pre-post meal photographic method for assessing EI in overweight and obese individuals in a cafeteria setting. Foods consumed outside this setting were assessed by recall methods. Nutrition research staff underwent rigorous training for estimating portion size and EI from pre- and post-meal digital photographs and dietary recalls, with inter-rater reliability >95%. DP+R procedure includes taking notes and delineating standard measurements as guidelines for the portion size assessment (Ptomey et al., 2015). The DP+R during ad libitum eating in a cafeteria was compared to measurement of total daily energy expenditure assessed by doubly labelled water ($TDEE_{DLW}$) method (Ptomey et al., 2015) with no significant differences found; thus, the method was considered valid.

DP+R method is a reliable and validated method for estimating EI in overweight or obese participants in a cafeteria setting. The main advantage over a food record/recall alone is verification of the written record by the photograph. This method was judged to provide an acceptable level of burden for both participant and research team when compared to previous procedures but a considerable burden is still present for the researcher because of the need to enter nutritional information into a database to quantitate EI (Ptomey et al., 2015). The capacity of DP+R to capture change over time is limited since the procedures are done in cafeteria settings, therefore when the subjects stop attending, the change will not be captured. However, the authors point out the possibility of modifying the DP+R

method to use in conjunction with smartphone photos to make the method portable (Ptomey et al., 2015).

Remote food photography method (RFPM)

Participants send images taken on their smartphone wirelessly (Martin et al., 2012) to a Food Photography Application© (Martin et al., 2014), which is linked to the Food and Nutrient Database for Dietary Studies 3.0 (USDA, 2008). Trained raters use the application to oversee the semi-automated process of food and nutrient intake estimation (Martin et al., 2012). In this trial, some participants received prompts to use the application customized to their specific meal times, or generic prompts in the morning, at noon and in the late afternoon.

Analyses were run to evaluate any significant differences between the RFPM and DLW estimation of EI, and if they were influenced by the EI consumed; no significant differences were found when participants received customized reminder messages but device reliability was decreased when participants received generic prompts (Martin et al., 2012). The RFPM and DLW were used to measure EI in free-living individuals during a 6-day period. The error between methods (EI estimated with the RFPM minus EI measured with DLW) was calculated and was smaller in the participants receiving customized prompts (Martin et al., 2012).

The underestimation of EI by RFPM improves drastically compared to self-report methods, particularly when accompanied by customized prompts, allowing monitoring of habitual EI in free-living individuals. The method also offers the opportunity to detect missing data (due to technical problems or no compliance) promptly, and take pertinent action (contact participant) to improve data quality and compliance, thereby reducing recall bias (Martin et al., 2009). The ability of RFPM to provide users feedback about their behavior is another benefit worth mentioning. In general, the user burden is keep to a minimal and 82% of users rated overall satisfaction 5 or higher (based on a six-point scale) (Martin et al., 2014). However, since the method is only semi-automated, it remains expensive to analyze. The RFPM has also been used to estimate EI in children in both research and free-living settings (Martin et al., 2009; Martin et al., 2012; Martin et al., 2014).

Real-time food recognition system

The user points the smartphone camera at the food plate for the food recognition process. After selection of the food from a database and indication of its approximate volume, the calorie and nutrition values are displayed (Kawano & Yanai, 2015). The real-time recognition of foods was approximately 80% correct. This system utilizes a real-time image recognition system, and the processing time only takes 0.065 seconds once the user enters the input. A fully automated interface with a food database completes its system. Evaluation of its usability was carried out, where adjustment of the bounding boxes on the different food items wasn't as positively rated (2.4 out of 5) as for the item recognition itself, which was done automatically without additional user input, obtaining an average score of 4.2 out of 5 (Kawano & Yanai, 2015). However, this tool hasn't been validated and has a limited number of food categories and it does not specify the database used for the nutrition information.

Snap-n-eat

A "snap-shot" (photograph) of participants' plate is captured. The analytical system is based on predefined EI and nutritional density for each food category. Depth images are used to estimate the portion size of the food and the EI and nutritional content are displayed on the user's screen in ~4 s (Zhang, Yu, Siddiquie, Divakaran, & Sawhney, 2015). A classification accuracy (the percentage of the test images of each category correctly classified) of 85% was obtained for 15 different food categories. Snap-n-Eat presents a food recognition system for which users only need to take a snapshot of their food in order for the system to estimate its EI and nutritional content, allowing participants to track their daily food intakes helping to understand their eating habits in a cost and time effective manner. However, in order to be a feasible tool, a scale-up to hundreds of food items and a validation process is needed (Zhang et al., 2015).

GoCARB

The user photographs their food from at least two angles. The food items are segmented and recognised and their carbohydrate content is estimated based on the nutritional information of the United States Department of Agriculture (USDA) Nutrient Database for

Standard Reference (Rhyner et al., 2016). GoCARB's portion sizing and individual food item recognition accuracy ratings were 75% and 85%, respectively (Rhyner et al., 2016). To validate the device, adult participants with type 1 diabetes were asked to calculate the carbohydrate content of the meals by themselves and subsequently with the help of the GoCARB. The error using GoCARB was approximately half of that without any aid (Rhyner et al., 2016). The application is overall better than participants at estimating carbohydrate content of meals. In the GoCARB app the carbohydrate content estimation is done automatically so the burden on researchers and participants is minimal; thus, 90% (17/19) qualify the tool as easy to use and would like to use the application on a regular basis. These measurements were done in a clinical setting that may not represent real-life situations where the meals may have more complex composition than the test meals. The overall nutrient content of the meal is not analyzed, and for individuals with T2D it is important to consider the influence of the overall meal in determining their postprandial glycemia (Rhyner et al., 2016).

3.3.3 Mathematical algorithm

A totally different, novel approach to assess EI is through mathematical algorithms.

Mathematical method

Sanghvi's group (Sanghvi, Redman, Martin, Ravussin, & Hall, 2015) validated a mathematical formula originating from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (Hall & Chow, 2011), to measure long-term changes in free-living EI of humans by using repeated DLW and dual energy x-ray absorptiometry (DXA) measurements collected over 2 years in 140 free-living subjects from the Comprehensive Assessment of Long-term Effects of Reducing Intake of Energy (CALERIE) study (Rochon et al., 2010). The formula inputs were baseline demographic (age, sex, height) and repeated body weight data, which was used to obtain the change in body weight over time and the rolling average. Measured body weight and EI changes for the participants were documented over 2 years at 4 different time intervals. During the course of the study, the test-retest reliability was obtained by comparing the gold standard with the mathematical model, differing by only 40 kcal/day (Sanghvi et al., 2015). The change in EI values

calculated by the mathematical method was compared (paired, 2-sided t-test) to the gold standards DLW/DXA and found to be similar (Sanghvi et al., 2015).

In order for the formula to measure long-term changes in free-living EI, easily acquired initial information regarding age, sex, height and physical activity are required. However, baseline DLW measurements are also needed to establish energy requirements if one wishes to know absolute EI as well as changes in EI over time, limiting its use to researchers with the ability to obtain this parameter (Sanghvi et al., 2015). If all the mathematical parameters are available, the formula is an easy-to-score tool that captures changes over more than one day; however, the model might require adjustments for use in children or older adults. In addition, specific nutrient/food intake information is not known, therefore without co-administration of a diet record or FFQ it would not be possible to obtain this information (Sanghvi et al., 2015). Important limitations must be considered. The study was conducted on normal weight individuals and validation in individuals with obesity was not demonstrated even though the authors were confident the model could be used on this population because the model was built to measure changes in metabolism and body composition.

3.4. Discussion

From a research perspective, the first and foremost goal of evaluating food and EI is to be able to increase our understanding of diet-disease associations. Validated and reliable measures of food and EI are crucial to understand their relationship with health, especially with the overwhelming increase in obesity prevalence (Wang et al., 2016). Individuals with obesity present different problems ranging from the physiological to the psychological aspects, which represent barriers to their treatment. The 4Ms of Obesity Assessment and Management (Mental, Mechanical, Metabolic and Monetary) has been proposed as a framework to help identify the root cause and help obesity treatment (Sharma, 2010).

The methodologies/tools presented in this review have the potential to aid in the understanding and treatment of obesity within this framework. This review identified 3 main new modalities for estimating food and EI. These include devices that monitor intake through sensors that detect movement of the arm and/or jaw, counts of chews and

swallows, smartphone-based photographic methods linked to food databases and a mathematical formula. In order to come to a consensus of which methodology/technology would be the most highly recommended it is important not to lose sight of why EI is being assessed or monitored. The overall objective should guide opting for one or the other.

In the context of the 4Ms of Obesity Assessment and Management, if the individual being treated is believed to have psychological (Mental) issues influencing their eating behavior, then the main objective is to understand their eating behaviors or food intake patterns in order to detect and/or modify eating habits. Food intake-monitoring devices and tools (Bite Counter, AIM, Intelligent food-intake monitor) would be recommended in this context because they could provide useful insight regarding food intake behaviors (e.g., timing and size of meals). In general, food intake-monitoring devices and tools can count the number of bites an individual takes, track the approximate EI and monitor episodes of food intake. Several benefits to the understanding of food intake behaviors may accrue from these methods. These devices could fill a gap in providing timely monitoring and feedback to individuals wishing to change eating habits, similar to the way the use of pedometers and/or accelerometers has been validated to promote and assess physical activity (Van Remoortel et al., 2012), by establishing and monitoring personal goals achievement, a behavior that according to Social Cognitive Theory, is an effective behavior change strategy (Bandura, 1986) aiding behavioral change.

Therefore, these tools could be used for monitoring, controlling and correcting eating behaviors and portion size in obese or overweight individuals as well as for chronic disease management. However, their effectiveness in eliciting behavior change has yet to be documented. Future work includes the possible addition of a vibrotactile alarm, similar to the technology used on intelligent watches or pedometers so that subjects can self-adjust their eating behavior based on the estimated EI per bite (Dong et al., 2012). Moreover, the commercial cost of these devices has not been established since they are still on the development phase and have not gone further to establish a market cost. Further, wearing some devices may be more acceptable to participants than others.

On the other hand, if the aspect of obesity treatment is within the Metabolic category of the 4Ms, as in the case of individuals with T2D or hypertension, then the intent would shift the focus to understanding specific macro/micronutrient intakes (sugars, salt, fats). Similarly, within the Mechanical category (such as osteoarthritis), weight loss could be desired to reduce pain. For both approaches, camera-scan-sensor (Snap-n-Eat, GoCARB) could be useful. RFPM could be applied in a hospital setting where monitoring individuals' nutrition intake is essential but difficult to do on a routine basis. Registered dietitians and nurses could use this tool to oversee adequate food intake essential for hospitalized individuals' wellbeing. If the overall objective is a focus on measures of long-term changes in EI in free-living individuals undergoing a research or lifestyle intervention, the mathematical method would highly be recommended since its accuracy lies within 40 kcal/day of mean difference with the gold standard, as long as the initial DLW measurement is possible to obtain, which could be a potential limitation.

Overall, the studies included in this review presented new devices designed to improve how EI is measured, analyzed and registered. However, the devices and methods have usually undergone pilot testing in small numbers of participants and various limitations elicit caution. Food intake-monitoring tools have limited ability to assess day-to-day variability in food intake (Dong et al., 2012; Fontana et al., 2014; Salley et al., 2016). They do not take into account the type of food consumed, its EI density nor its consistency; therefore, no information about the macro/micronutrient is obtained, resulting in an inability to capture change in type of food or nutritional intake over time. As mentioned previously, a current limitation with present methodologies used to assess food intake or EI is individual reactivity causing changes in food behavior patterns, thereby resulting in inaccurate reporting. None of the present studies addressed these issues, therefore the question arises: could bias play a role in the use of these devices? That is, would peoples' consumption of food intake be modified by simply wearing these tools? And if so, what would be the differences compared with current methodologies? Certainly, more accurate data of consumption patterns seems possible, but to date none of the devices has gone beyond pilot testing nor addressing potential bias. To our knowledge, the application of these

methodologies to clinical settings or outside of the original developers' laboratories has not been reported.

Regarding smartphone-based apps, additional limitations applying to one or more include, participants forgetting to take the photographs, or not having the smartphone with them (Martin et al., 2012). In general, two major limitations need to be addressed with camera-scan-sensor methods. First, they cannot quantify all food ingredients or beverages. These tools only work with the food items in the database of each individual tool, and their validity is also dependent on the food nutrient value on which the databases are built.

However, with current food record/recall databases, there are acknowledged differences between what a person consumes and what the database contains (Rhyner et al., 2016); even the Canadian Nutrient File or the USDA database cannot keep up with constantly evolving food possibilities. The use of these technologies is not advanced enough to correctly and accurately estimate 100% of food intake since the best achieved accuracy was 85% based on a small number of foods (Zhang et al., 2015). Second, they cannot judge quality since a photograph doesn't convey information about ingredients that are hidden or blended (Martin et al., 2012). Nevertheless, these methods show improvement in estimating, on average, the nutrient content of meals more accurately, easier and faster than individuals' self-report measures (24HR, FFQ, etc.) but caution must be taken when using and analyzing these methods. Bearing in mind the strong link between food intake and health, continuing to document the improved validity and reliability of the food item recognition and nutritional information provided by these tools would undoubtedly lead to better outcome measurement in the fields of obesity and nutrition. However, the feasibility of creating comprehensive databases for food recognition is problematic in an environment of incessantly increasing food possibilities. On the other hand, the ubiquity of smartphone ownership means that affordability and acceptability are of less concern with the main investment being the data processing.

3.5. Conclusions

In conclusion, these innovative dietary assessment tools are able to record food/energy intake more accurately than participants' estimates and are an improvement on important

weaknesses of conventional methods (paper-based records/recalls), particularly regarding the burden of recording by participants and collecting/administering and evaluating/scoring the information by researchers. However, caution is needed when using them since they are still being refined. Future work should look at combining body monitor sensors and camera-scan-sensors to work together in order to counter their strengths and weaknesses. This work should eventually progress outside of research settings and promote the collaboration of dietitians with engineers to co-develop the design, development, evaluation and implementation of these new tools, since this would likely increase their effectiveness, acceptability and validity. Lastly, this research field should take into consideration changing formats of national nutrition recommendations, such as the 2014 Brazilian dietary guidelines, 2015 Dietary Guidelines for Americans and the American Heart Association, which are shifting the focus from single nutrients or kilocalorie counting into healthy eating patterns (Lloyd-Jones et al., 2010; Millen, 2016; Monteiro et al., 2015). Therefore, future development should aim at being able to detect overall eating patterns.

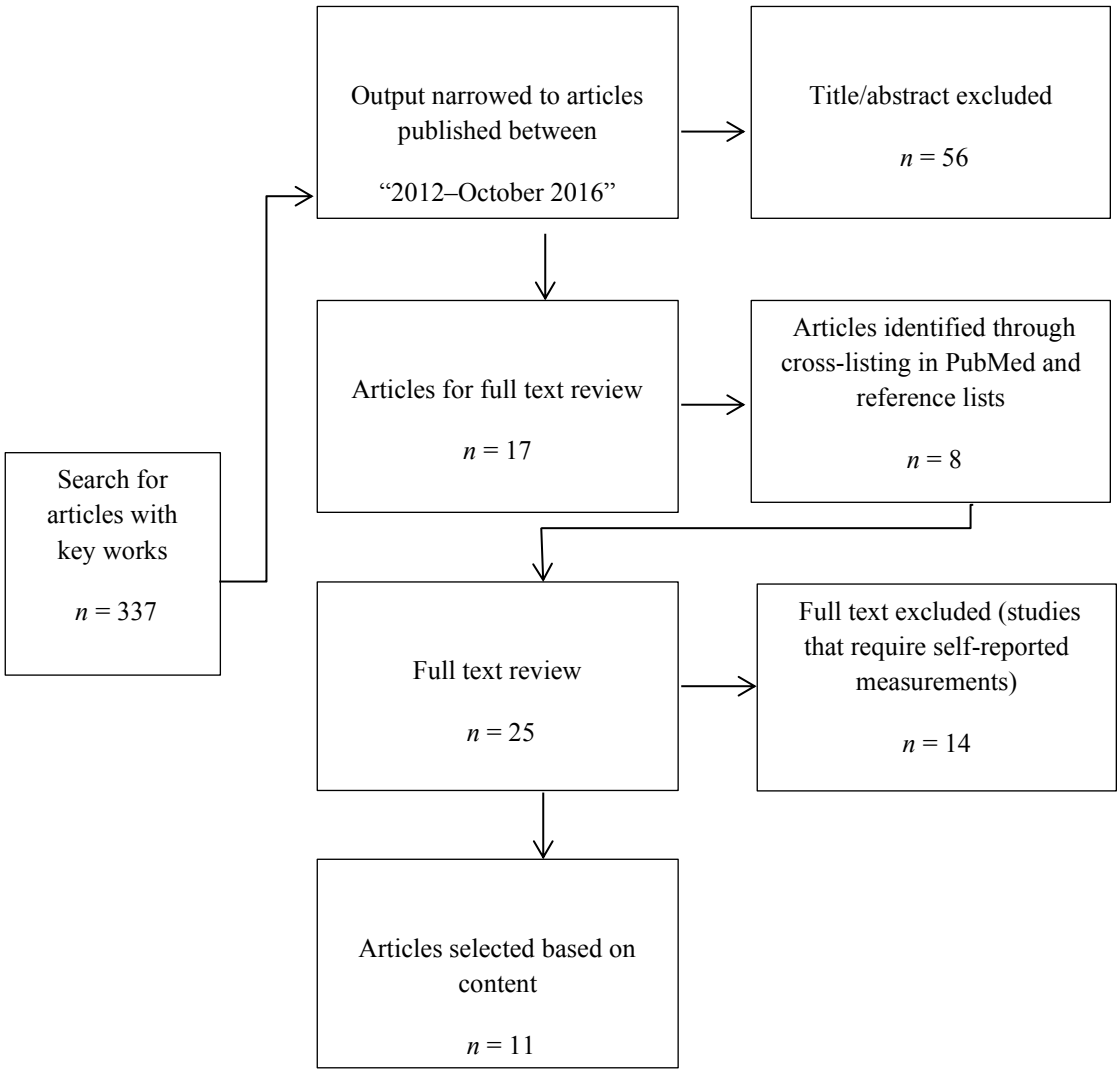

Figure 3.1. Flow diagram of the article selection process and exclusion reasons.

Table 3.1. Summary of new methods for assessing food and energy intake.

Reference	Objective	Brief Description	Key Findings
(Dong et al., 2012)	Evaluate a new method of automated dietary intake monitoring.	The "Bite Counter" device was worn like a watch. Before eating, the user pressed a button to turn it on (and off afterwards). While operating, the device used a micro-electro-mechanical gyroscope to track wrist motion, automatically detecting when the user had taken a bite.	The method worked across a reasonably large number of subjects, and variety of foods, and there was modest correlation with EI on a per-meal level.
(Salley et al., 2016)	Evaluate accuracy of an individualized bite-based equation of kilocalorie intake compared to participant estimates of kilocalorie intake.	Subjects' real kilocalorie intake was compared to predicted kilocalories estimated by: (a) the bite-based equation of kilocalorie intake, (b) participants' kilocalorie estimate when provided with kilocalorie information of the foods eaten, (c) participants' kilocalorie estimate without kilocalorie information.	The bite-based equation measure of kilocalorie intake outperformed human estimates with and without menu kilocalorie information.
(Fontana et al., 2014)	Evaluate the: Automatic Ingestion Monitor (AIM) for objective detection of food intake in free-living individuals.	The AIM integrated three sensor modalities and a pattern recognition method for subject-independent food intake recognition.	The AIM can detected food intake with an average accuracy of 89.8% suggesting that it can be used to monitor eating behavior in free-living individuals. AIM could be used as a behavioral modification tool.
(Fontana et al., 2015)	Estimate EI using individualized models based on Counts of Chews and Swallows (CCS).	EI was estimated by the CCS mathematical model and compared to the weighed food records, diet diaries and photographic food records methods.	Mathematical models based on the CCS could be potentially used to estimate EI.

(Liu, 2012)	Present an intelligent food-intake monitoring system that can automatically detect eating activities	The multi-sensor monitor detected chewing activity via its integrated ear-microphone, consequently the camera was activated, snapshots for food detection were taken.	The high correlation rates reported (*r* not shown) suggested the usefulness of the proposed method to provide with an overall understanding of eating behavior characteristics (speed, type and amount of food consumed).
(Ptomey et al., 2015)	To compare mean EI of overweight and obese young adults assessed by a Digital Photography + Recall method (DP + R), to the mean total daily energy expenditure assessed by $TDEE_{DLW}$.	Two digital still photographs (90° and 45° angle) were taken by a digital camera approximately 30 inches above the tray. Notes were placed on the tray to identify types of beverages and standard measures were included to guide the assessment of portion size. The type and amounts of food and beverages consumed and results from recalls were entered into the Nutrition Data System for Research to quantification for EI. $TDEE_{DLW}$ was assessed in all participants to compare mean daily EI.	The mean EI estimated by DP + R and $TDEE_{DLW}$ was not significantly different (p = 0.42). On average, DP+R overestimated EI compared to $TDEE_{DLW}$ by 6.8 ± 28%.
(Martin et al., 2014)	To validate the Remote Food Photography Method (RFPM)	Developed for automating dietary assessment. Participants include a reference card placed next to the food plate as well as labels of not easily recognizable foods for the portion size estimation to take place. A barcode reader phone app and a voice message option are innovations included to facilitate identification of foods. Participant received feedback about their food intake behavior and recommendations to achieve weight goals. To maximize and promote usage of RFPM in free-living conditions,	The RFPM and DLW did not differ significantly at estimating free-living EI (−152 ± 694 kcal/day, p = 0.16) nor did it differ when estimating energy and macronutrient intake.

		ecological momentary assessment (EMA) methods were adopted, which involves sending small reminders or prompts to the user via email or text message. EMA was tested by comparing two groups; the standard prompts (2 or 3 prompts a day send to their smartphones around meal time) versus customized prompts (3 to 4 personalized prompts, send at participants' specific meal time).	
(Kawano & Yanai, 2015)	To evaluate a mobile food recognition system which estimates calorie and nutritional components of food intake.	(1) User pointed the smartphone camera to the food (2) Drew bounding boxes to delimit food regions (3) Food item recognition started within the indicated bounding boxes. To recognize them more accurately each food item region is segmented by GrubCut. The recognition process results in a display of the top 5 food item candidates. The user selects the most accurate candidate and indicates the relative approximate volume of the food.	A 79.2% classification rate was achieved. The recognition processing time was only 0.065 s.
(Zhang et al., 2015)	To present Snap-n-Eat, a mobile food recognition system.	The user took a photo of the plate. The system detects the salient regions corresponding to the food items. Hierarchical segmentation was performed to segment the images into regions. The system estimated the portion size of the food and uses it to determine the EI and nutritional content.	The Snap-n-Eat application achieved a 85% accuracy when detecting 15 different categories of food items. Snap-n-eat recognized foods presented on a plate and estimated their caloric EI and nutrition content automatically without any user intervention.
(Rhyner et al., 2016)	To assess the accuracy of the GoCARB prototype when used	The user placed a reference card next to the dish and took two images using a mobile phone. A series of computer	GoCARB was more accurate at estimating carbohydrates content than individuals with

	by individuals with type 1 diabetes and to compare it to their own performance in carbohydrate counting.	vision modules detected the plate and automatically segmented and recognized the different food items, while their 3D shape was reconstructed. The carbohydrate content was calculated by combining the volume of each food item with the nutritional information provided by the USDA Food and Nutrient Database.	type 1 diabetes. The mean absolute estimation error while using GoCARB was reduced by more than 50% than without using GoCARB.
(Sanghvi et al., 2015)	To validate a mathematical method to measure long-term changes in free-living EI	DLW was used to assess Energy Expenditure (EE) at months 6, 12, 18, and 24. DXA and body weight measurements were taken twice at baseline, twice at month 6, and once at months 12, 18, and 24. Body weight measurements were taken at months 1, 3, 6, 9, 12, 18, and 24 in the CALERIE study. Then, they compared the ΔEI values calculated by using DLW/DXA with those obtained by using the mathematical model	The mean (95% CI) ΔEI values calculated by the model were within 40 kcal/day of the DLW/DXA method and were not significantly different throughout the 4 times segment (p = 0.14, p = 0.34, p = 0.32, p = 0.11). Most of the model-calculated ΔEI values were within 132 kcal/day of the DLW/DXA method.

Table 3.2. Summary of the reliability and validity of new methods for assessing food and energy intake.

Reference	Name of Tool	What is Measured	Reliability		Validity	
			Statistical Method Used	Result	Statistical Method Used	Result
(Dong et al., 2012)	Automated Wrist Motion Tracking	EI	Sensitivity (true detection rate) = (total true detection)/(total true detection + total undetected bites); Positive Predicted Value (PPV) = (total true detection)/(total true detection + total false detection); compared recorded bites with direct observation.	Control setting: Sensitivity = 94% PPV = 80% Semi-controlled setting: Sensitivity = 86% PPV = 81%	Pearson correlation of EI estimated by device vs. direct observation (*r*)	R = 0.6
(Salley et al., 2016)	The bite-based model of kilocalorie intake	EI	Pearson's correlation of device compared with direct observation; shrinkage value	R = 0.374 Shrinkage value (difference in R^2) = 0.014	Independent *t* test Paired sample *t* test	Mean estimation error kilocalorie information group: −185 ± 501 kcal; Mean estimation error no kilocalorie information group: −349 ± 748 kcal ($p < 0.05$); Best human-based estimation (kilocalorie information group) mean estimation error: −257 ± 790 kcal; Bite-based method (predicted formula) mean estimation error: 71 ± 562 kcal; ($p < 0.001$).
(Fontana et al., 2014)	Automatic Ingestion Monitor	EI	N/A	N/A	Accuracy = average between precision (P) and	Accuracy of food ingestion = 89.9%, range from 75.82–97.7%.

	(AIM)				recall (R).	
(Fontana et al., 2015)	Counts of Chews and Swallows Model	EI	A 3-fold cross validation technique, one sided Wilcoxon-Mann-Witney, Bland-Altman analysis and *t*-Test analysis.	Reporting error for the CCS model was lower than that of the diet diary ($p < 0.01$). The model underestimated EI. Energy intake estimation had the lowest bias.	A 3-fold cross validation technique, one-sided Wilcoxon-Mann-Witney, Bland-Altman analysis and *t*-Test analysis.	No statistical differences were found between the CCS model and either diet diary or photographic records.
(Liu, 2012)	Intelligent food-intake monitor	Food intake	Correlation: Proportion of food consumed from sound (auditory based) and image sequence (vision based) compared to the ground truth: proportion of food consumed.	Data not shown	N/A	N/A
(Ptomey et al., 2015)	DP + R	EI	Inter-rater reliability coefficients	Error rate ≤5%, Recall assessments ≥ 0.95	Dependent t-test comparing device to DLW method; Bland-Altman plots; Limits of agreement	Differences between methods in the total sample was not significantly different (DP+R = 2912 ± 661 kcal/day; $TDEE_{DLW}$ = 2849 ± 748 kcal/day, p = 0.42); DP + R was found to overestimate EI compared to $TDEE_{DLW}$ by 63 ± 750 kcal/day (6.8 ± 28%; limits of agreement: −1437, 1564 kcal/day). The Bland-Altman plot indicated no proportional bias variation as a function of the level of EI in the total sample (R = −0.13, p = 0.21).

(Martin et al., 2012)	RFPM	EI	Bland & Altman analysis	Significant difference: $p <$ 0.0001 between the RFPM and DLW in the standard prompt group. No significant difference in the customized group: $p =$ 0.22. The level of bias in both groups was not influenced by the amount of EI (Adj. $R^2 = -0.03$, $p =$ 0.55; Adj. $R^2 = -0.08$, $p =$ 0.78)	Independent sample *t*-test for error between methods = EI estimated with the RFPM - EI measured with DLW	Significant smaller underestimation in the customized group (270 ± 748 kcal/day or 8.8 ± 29.8%) when compared to the standard prompt group (895 ± 770 kcal/day or 34.3 ± 28.2%), t (33) = −2.35, $p < 0.05$ with RFPM.
(Kawano & Yanai, 2015)	Real-time Food Recognition System	EI	Test-retest reliability	79.2% classification rate	N/A	N/A
(Zhang et al., 2015)	Snap-n-Eat	Energy/dietary intake	Test-retest reliability	Classification accuracy (% of correctly classified images categories) = 85%	N/A	N/A
(Rhyner et al., 2016)	GoCARB	Carb EI	Comparison to actual foods/database	Automatic segmentation (portion size) = 75.4% (86/114); Food item recognition = 85.1% (291/342)	Mean absolute error; Relative error	Mean absolute error = 27.89 (SD 38.20) and 12.28 (SD 9.56) grams of carbohydrates; Mean relative error = 54.8% (SD 72.3%) and 26.2% (SD 18.7%). A significant error between estimations was found ($p =$ 0.001). In general, 60.5% (69/114) of the participants underestimated carbohydrate content.
(Sanghvi et al., 2015)	Mathematical method	Change in EI	Test-retest reliability; Mean difference	40 kcal/day of mean difference between the gold standard and the mathematical model; No	Paired, 2-sided t test; Pearson correlation (r) Spearman's	Change in EI values calculated by the mathematical method or the gold standard DLW/DXA weren't significantly different;

		significant difference between the methods for any of the time segments was found (weeks 0–26: $p = 0.14$; weeks 26–52: $p = 0.34$; weeks 52–78: $p = 0.32$; weeks 78–104: $p = 0.11$).	corrected (*rs*)	The mathematical model had an accuracy within 132kcal/day for predicting changes in EI; The magnitude of correlation of the change in EI values between models were correlated (weeks 0–26: $r = 0.57$ (95% confidence interval 0.45, 0.68); $p \leq 0.0001$; weeks 78–104: $r = 0.19$ (0, 0.36); $p = 0.05$).

Chapter 4: A Mixed Methods Evaluation of a Randomized Control Trial to Evaluate the Effectiveness of the Pure Prairie Living Program in Type 2 Diabetes Participants

4.1. Introduction

Obesity has been present since stone-age times and throughout the major eras of history (Haslam, 2016). Its social context has evolved from being associated with well-being and power to now being a health problem and an epidemic that threatens global welfare (Carpenter, 1941). Since the beginning of the 21st century, obesity has been regarded as a medical problem (Kopelman, 2000) because it is a significant risk factor for a number of cardiometabolic diseases (CMD) due to its link to chronic inflammation; disturbed cellular metabolism; increased insulin resistance; and overall metabolic dysfunction prompting metabolic syndrome (MetS), type 2 diabetes (T2D), hepatic steatosis, and cardiovascular disease (CVD) (Yang et al., 2009).

Alarming predictions suggest that in the USA, the national prevalence of adults with obesity (body mass index (BMI) 30 to 35) and severe obesity (BMI > 35), by 2030, will be three in four adults. Therefore, combined obesity and severe obesity should be the most common BMI category nationwide among women, black non-Hispanic, and low-income adults (Ward et al., 2019). In a similar manner, globally, the prevalence of T2D is predicted to increase from 8.8% in 2015 to 10% in 2030, accompanied by a corresponding 61% increase in economic burden to USD $2.1 trillion for diabetes and its complications (Bommer et al., 2018). Amelioration of the problem could be achieved by tackling suboptimal diet, which contributes an estimated annual CMD cost, in the USA, of USD $50.4 billion (Jardim et al., 2019). Although a wide variety of approaches to cure, treat, and prevent CMD are being investigated globally, a general consensus to prioritize the prevention and reduction of modifiable risk factors is difficult given the focus on associated comorbidities, which are major health and financial problems (Bommer et al., 2018; Ward et al., 2019).

Clinical practice guidelines have been developed to provide evidence-based care for people with CMD, in particular in the fields of CVD and T2D through specific diet, physical activity, and

pharmaceutical recommendations (Cheng, 2013; I.D.F, 2014; Guzmán et al., 2010; Handelsman et al., 2015). However, people tend not to meet dietary and physical activity recommendations, the main barrier being the complexity of translating the guidelines into actions, and in general, understanding what they mean (Berry, Anders, Chan, & Bell, 2012). Gaps in knowing how to address or overcome obstacles to behaviour change include "family influence, perception of healthy food being not tasty, lack of skills to prepare or choose healthy food, difficulty in finding healthier options when eating out, and healthy food being costly" (Lim et al., 2019).

Previously, our group has worked on bridging the guideline-practice gap through the development of a four-week menu plan focused on general dietary habits of people living in Alberta, Canada, translating the Diabetes Canada (DC) Nutrition Therapy Guidelines (Sievenpiper, Chan, Dworatzek, Freeze, & Williams, 2018) into a concrete menu plan and a recipe book based on the 4A framework, i.e., food availability, accessibility, acceptability, and adequacy (Chan & Bell, 2013). A pilot study was conducted to evaluate the feasibility and efficacy of menu planning combined with individual counselling on healthy eating for improving health outcomes and it yielded improved glycated haemoglobin (HbA1c) and dietary adherence score (Soria-Contreras, Bell, McCargar, & Chan, 2014), encouraging a larger trial. The Physical Activity and Nutrition for Diabetes in Alberta (PANDA) single-arm trial focused on group education sessions to help people incorporate DC Nutrition Therapy Guidelines into their daily lives through the use of menu planning and an educational program, with the primary objective of evaluating the effectiveness of the intervention on HbA1c and dietary adherence among patients with T2D (Asaad, Soria-Contreras, Bell, & Chan, 2016). Both studies demonstrated that the menu plan and recipe book could be a simple and practical resource, combined with education and behaviour change strategies, for improving adherence to nutritional recommendation guidelines (Asaad et al., 2016; Soria-Contreras et al., 2014).

The end goal of research findings is not complete until the knowledge acquired in research is fully applied in real-world settings (Garfield et al., 2003). Thus, we aimed to test our PANDA program in a primary health care setting to validate our previous results and further refine the programming to achieve real societal impact. Hence, the primary objective of this study was to evaluate the effectiveness of the Pure Prairie Living Program (PPLP), a lifestyle intervention

tailored to Albertans, in improving T2D management (HbA1c) and promoting better nutrition choices (dietary adherence to the guidelines, diabetes self-efficacy) in a primary care network (PCN) setting. To evaluate thoroughly the PPLP intervention beyond clinical parameters, a mixed-methods approach was undertaken to understand the perceived effectiveness and limitations of the PPLP contextualized by health care providers (HCP) and study participants.

4.2. Materials and Methods

4.2.1. Study design

The PPLP intervention (ClinicalTrials.gov ID: NCT03043859) was a 2-arm, parallel group, randomized controlled trial. Participants were blinded to group assignment through concealment of allocation until assignment occurred using a simple random table. Participants were randomized 1:1 to one of the groups (intervention (PPLP) or control (CON)). This educational program was originally designed to be implemented at 2 PCNs in Edmonton, AB, Canada, with the aim of recruiting 120 participants with 60 participants from each site (total 60 participants in each arm); however, after the implementation of the program at the first PCN, the study team came to a consensus to modify the original protocol to work with 1 PCN (total 60 participants, 30 per arm). The rationale behind this decision lies in the fact that the PPLP is part of a multistage study design that uses accumulating data. Thus, input from the first center directs modification of aspects of the PPLP.

4.2.2. Participants: Eligibility and recruitment

Eligible participants in the PPLP were adults (30–80 years) with T2D (self-identified) able to read and write in English, willing to commit to the study, and able to attend weekly meetings. Exclusion criteria were participants not able to read and write in English, pregnant or breastfeeding women, participants with type 1 diabetes or with medical comorbidities or severe diabetes complications requiring a highly specialized diet or living in long term care (LTC), and unable to provide consent (e.g., cognitive impairment). Two recruitment methods were followed. For the first method, a convenience sampling procedure was employed to recruit study participants through advertisement and posters at the PCN. Interested individuals contacted the study coordinator via phone and were recruited to the study if they met the inclusion criteria

described above. For the second method, the electronic medical record (EMR) was used to short-list participants with T2D in the target age range (n = 338) and their charts were screened for eligibility. Those who fulfilled the inclusion criteria were contacted via phone call. Those interested were recruited to the study.

4.2.3. Study setting

The study took place at Sherwood Park PCN, Edmonton, AB, from May to November 2017 (PPLP group) and January to February 2018 (CON). In Alberta, PCNs provide citizens with access to a multidisciplinary care team of clinicians, including dietitians. This study was conducted according to Canadian and International Standards of Good Clinical Practice for all studies. The University of Alberta Research Ethics Board approved the protocol for this study (Study ID Pro00070736).

4.2.4. Study intervention

The primary goal of this study was to evaluate the efficacy of the PPLP in improving HbA1c control and other risk factors for T2D. The intervention group participated in the PPLP group educational sessions. These sessions were conducted at the Sherwood Park PCN facilities and facilitated by two of the PCN registered dietitians (RDs). Site personnel were co-investigators in the research to facilitate maximal buy-in and integrated knowledge translation (KT). Prior to implementation of the study, the research personnel provided on-site training in the PPLP to the RD, reviewed materials and resources, and worked in conjunction with the PCN team to develop a site tailored PPLP intervention protocol (**Figure 4.1**). Modifications to the educational materials were made with consensus between researchers and practitioners in order to make some elements consistent with other programming offered by the PCN while maintaining the foci of the original PANDA trial (Asaad et al., 2016). The facilitators were provided with lesson plans for each education session to ensure standardized delivery of the education session across facilitators and to increase delivery fidelity. The intervention curriculum follows best practices in nutrition interventions for patients with T2D using the social cognitive theory as the overall theoretical model to guide behavioural change (Asaad et al., 2016).

Intervention study arm

Participants in the intervention study arm attended and participated in-group education sessions (~90 min each) during a six-week period. They received the PPLP resource package that consisted of the following:

Education sessions: Participants received a copy of the nutrition education presentations each week. The PPLP curriculum is based on the PANDA program which has been described elsewhere (Asaad et al., 2016). Briefly, the presentations included information to enhance knowledge of healthy eating based on practical information derived from Eating Well with Canada´s Food Guide (Health Canada, 2011) and Diabetes Canada Clinical Practice Guidelines for Nutrition Therapy (Sievenpiper et al., 2018). Participants learned to apply principles of menu planning, grocery shopping, portion control, label reading, and making healthy choices when eating out. A detailed summary of intervention activity content, presentations of group-based educational sessions, and support materials can be found at www.pureprairie.ca/resources, (Pure Prairie Eating Plan, 2020), or in **Appendix 4.1.**

PPLP workbook: Participants were provided with a workbook that guided them through the educational sessions. It provided support, positive reinforcement of concepts, and the opportunity for skill acquisition through the practice of goal setting, self-monitoring, and problem solving. This aligned with the principles of the social cognitive theory theoretical model.

Pure Prairie Eating Plan: Participants were provided with a copy of the Pure Prairie Eating Plan (PPEP). This four-week menu plan book meets the DC nutrition therapy guidelines (Sievenpiper et al., 2018) and is guided by the principles of the 4-A framework. Its overall goal is to facilitate solutions to some of the barriers that participants face when trying to adhere to the recommendations. Additional information on the PPEP is available at www.pureprairie.ca (Pure Prairie Eating Plan, 2020; Chan, C., 2013).

Wait-List Control Group

Participants in this group were required to attend three assessment sessions (baseline, 3-month, 6-month) after which they were offered the PPLP educational sessions delivered by the same

RDs as for the PPLP group. No further assessments were done. This procedure was chosen in order to guarantee equitable treatment for all participants enrolled in the study, thus all participants had access to the program.

4.2.5. Study outcomes

The primary outcome for this study was change in HbA1c. The secondary outcome was changes in the Perceived Dietary Adherence Questionnaire (PDAQ) and Diabetes Self Efficacy Scale (DSES) scores. Assessments were performed at three different time points (baseline, 3-month, 6-month) at the Sherwood Park PCN (**Figure 4.1**). All participants received a phone call to remind them of their upcoming appointment. The same instruments were used for all the measurements throughout the study.

4.2.6. Anthropometric measures

Body weight and height were measured to the nearest 0.1 kg and 0.1 cm, respectively, to calculate BMI. Waist circumference was measured to the neared 0.1 cm with the participant in a standing position, with a non-stretch tape placed midway between the lateral lower ribs and the iliac crest after a moderate expiration. Body composition was determined using a BIA scale (Tanita, Arlington Heights, IL, USA). Differences in weight, BMI and waist circumference (baseline to 3 months, baseline to 6 months, and 3 months to 6 months) were calculated.

4.2.7. Metabolic measures

Blood pressure was assessed with participant seated using an auto-inflated digital unit (BpTRU, Model BPM-100, Coquitlam, BC, Canada). Non-fasted finger prick blood samples were collected. Briefly, with the participant's hand and arm in a horizontal position, the middle or ring finger of the non-dominant hand was cleaned with an alcohol wipe. The end of a lancet was placed against the fingerstick site (top or bottom) and pushed firmly, then pressure was applied gently on the finger to collect two samples of blood. The point-of-care testing devices used 5 μL of blood for HbA1c (Bayer, Elkhart, IN, USA) and 20 μL for lipid profile (triglycerides (TG), total-cholesterol (TC), low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C)) (CardioCheck, Whitestown, IN, USA). Blood was collected using PTS

capillary tubes. The blood samples were applied to the analyzers within 30 s of collection. Differences in test outcomes pre- and post-intervention were calculated.

4.2.8. Demographic characteristics and additional self-reported data

All participants (CON and PPLP group) provided sociodemographic data at baseline and completed the following validated questionnaires at baseline and each follow up. The PDAQ (10 items) measured self-reported adherence to dietary recommendations by DC Nutrition Therapy Guidelines and Eating Well with Canada's Food Guide. Each item was scored 0–7 (0 = poor adherence and 7 = maximum adherence) with items 4, 9, and 10 scored using "reverse scoring". These results were averaged yielding a score of 0–7. The DSES (8 items) was used to measure self-reported changes in nutrition self-efficacy. Each item was scored 1–10 (1 = not confident and 10 = totally confident), then divided by 8, yielding a score of 0–8. 3. Quality of Life (EQ-VAS) recorded the patient´s self-rated health on a vertical visual analogue scale corresponding to a score 0–100 (0 = the worst health you can imagine and 100 = the best health you can imagine) reflecting participants' own judgment.

4.2.9. Qualitative assessment

During the three-month visit, two focus group discussions were conducted with PPLP participants and two semi-structured, individual interviews with HCP. The focus groups and interviews were conducted at Sherwood Park PCN and were 30 to 45 min long. The overall aim was to understand participants' experiences throughout the program including knowledge about managing T2D, barriers perceived, and suggestions with the aim of improving the overall program using a thematic analysis approach. Transcripts of focus groups and interviews were transcribed verbatim and analyzed using Nvivo software version 11.4. The transcripts were checked against the recordings for accuracy. When conducting the thematic analysis, Brauns' suggested step-by-step guide (Braun & Clarke, 2006) was used to ensure rigor. Morse's verification strategies were also acknowledged (Morse, Barrett, Mayan, Olson, & Spiers, 2002). Briefly, first, familiarization took place by reading the data in an active way and taking note of initial ideas. Second, the entire set of data was organized into meaningful groups and initial codes were created. In the third and later stages of coding, the initial codes were classified into

potential themes using an inductive approach followed by reviewing the initial themes to make sure they accurately reflected the whole dataset. The last phase involved defining and naming themes for the final analysis.

4.2.10. Sample size

Previous literature has indicated that nutrition therapy and lifestyle modifications could improve hyperglycemia in T2D patients by 1%–2% (Sievenpiper et al., 2018). Our research team's previous single-arm phase 2 trial with 73 participants with T2D demonstrated a 0.7% decrease in HbA1c (95% CI, 0.4% to 1.0%, $p < 0.05$) at three months after the intervention (Asaad et al. 2016). Because the primary objective of the present study was to evaluate the effectiveness of PPLP on HbA1c levels, the sample size was calculated with the aim of detecting a 0.5% change in HbA1c, which is clinically meaningful. Statistical power was considered as 0.80 and alpha = 0.05, thus sample size was estimated as 25 in each group with an estimated dropout rate of 20%.

4.2.11. Statistical method

The Statistical Package for the Social Sciences (SPSS) software version 24 (SPSS Inc., Chicago, IL, USA) was used for the following analyses: Kolmogorov–Smirnov and Shapiro–Wilk tests were used to determine distribution of variables; between groups, for continuous variables, independent t-test comparison of baseline, 3- and 6-month characteristics (demographic, anthropometric and metabolic) or, for categorical variables, Chi-square test; and paired t-test was conducted to analyze the changes over time within groups. Results are presented as mean group differences with 95% confidence intervals (CI). Statistically significance was set for two-tailed p values of <0.05. Significant differences in parameters are reported as * $p < 0.05$ and ** $p < 0.001$.

4.3. Results

All 62 respondents met the inclusion criteria and were randomized to either the wait-listed control (CON $n = 31$) or the intervention groups (PPLP $n = 31$) (**Figure 4.2**). Forty-nine participants attended the baseline meeting, provided signed consent, and received the allocated

intervention; 42 participants were assessed during the 3-month follow up; and 39 participants completed the 6-month follow up.

4.3.1. Quantitative outcomes

Baseline characteristics

The demographics characteristics of the study participants are presented in **Table 4.1.** At baseline, there were no between-group differences in gender, age, or duration of T2D. The majority of the participants (87.8%) used antidiabetic drugs, and/or insulin combined with diet and/or exercise to manage their T2D. Metformin was the medication most commonly used by the participants (76.7%). In addition to T2D, participants had a mean of two concurrent conditions with the highest prevalence being hypertension. Likewise, 79.1% and 60.5% reported taking medications to treat hypertension and hyperlipidemia, respectively. Baseline anthropometric and metabolic parameters of participants were analyzed separately by gender. As shown in **Table 4.2,** there were no statistically significant differences between PPLP and CON with the exception of systolic blood pressure (SBP) being higher in the control group (men) (**Table 4.2**).

Changes in HbA1c (Primary Outcome)

There were no significant within-group changes in HbA1c or lipids observed at either 3- or 6-month follow-ups, nor were between-group differences detected (Table 4.3).

Intervention effects on diet adherence and self-efficacy

Secondary Outcomes: The PDAQ and DSES scores for both CON and PPLP groups are presented in **Table 4.4.** At 3- and 6-month assessments, the PPLP participants improved their PDAQ ($p < 0.05$). These improvements were not different in the between-group comparison. No change in DSES score was detected (**Table 4.4**).

Intervention effects on anthropometric and metabolic parameters

Exploratory Outcomes: The analyses of mean change within groups from baseline to 3- and 6-month follow ups revealed a decline in BP for both groups (**Table 4.3**) that was not different

between groups. In the PPLP group, body weight decreased significantly at both 3- (** $p <$ 0.001) and 6-months follow ups (* $p < 0.05$), with the between-group difference trending to benefit the PPLP group at 6-months ($p = 0.069$). Conversely, the CON group experienced a decrease in waist circumference at 3-months that was not sustained at 6 months. Furthermore, a significant decrease in fat free mass (kg) was observed in the PPLP group at 3- and 6-month follow ups (* $p < 0.05$). This effect was further observed in the 6-month between group analyses (**Table 4.3**).

Intervention effects on quality of life

Exploratory Outcomes: Participants in both CON and PPLP groups showed an improvement in EQ-VAS score at three months. This improvement was maintained at six months by the CON group (* $p < 0.05$).

4.3.2. Qualitative outcomes

Two focus groups ($n = 17$) with participants and two one-on-one interviews ($n = 2$) with HCP were conducted to understand their experience throughout the program. For the focus groups, results were grouped into facilitators/barriers and experience evaluation. Facilitators are factors perceived by participants that influenced their decision-making process for applying what was learned throughout the program in their everyday lives. Barriers are factors preventing participants from applying what was learned in the program to their daily lives. Experience evaluation reports participants' satisfaction, limitations, and improvements (denoting tangible program modifications participants would like) after participating in the PPLP. Themes and representative quotes for these categories are presented in **Tables 4.5** and **4.6**.

Facilitators and barriers

Facilitators: Two themes reflected what facilitated participants' decision making about applying what was learned throughout the program: knowledge acquired and motivation. Knowledge acquired throughout the program, in particular healthy eating, label reading, and physical activity influenced participants' everyday life. Furthermore, health, family, and group support were the main motivators for participating in the program.

Barriers: The presence of complications that participants discussed were aligned with and supported what has previously been described as the "4 Ms framework" (Sharma, 2010). Mental, mechanical, metabolic, and monetary (including time) categories identify the issues participants faced throughout the program and in their everyday life **(Table 4.5**).

Experience evaluation

In order to improve the program, we asked participants what they liked, did not like, or how and what would they add/change to the program, with the aim of obtaining a better understanding of their needs and expectations.

Satisfaction: In general, participants reported an overall positive experience. They emphasized that the program was clear and easy to understand and, most importantly, realistic.

Limitations: A recurrent request was to modify or eliminate the workbook. Improvements*:* Potential improvements in areas including longer support from peer groups, more hands-on activities (cooking lessons), and active physical activity programs (exercise groups) were recommended (**Table 4.6**).

HCP perspective

Since these types of interventions were normally carried out by front-line HCP, obtaining their perspective on the overall program, logistics, delivery, satisfaction, and barriers was essential. Among the themes that could be distinguished, satisfaction, strengths, and effectiveness stood out and are presented in **Table 4.7**. The usefulness of the PPEP for helping to guide the overall intervention was emphasized as a strength of the program. The HCP stated that having the support of another peer and the research group was essential. Nonetheless, although the delivery of the program was described as enjoyable, the workload regarding the "back-stage" preparation was sensed as detrimental because it took a lot of their time, especially for participant recruitment, phone call follow ups, reminders and general administrative coordination. Furthermore, HCPs thought that the workbook needed to be simplified/modified so that participants would use it and benefit from it as a teaching tool. The importance of participant's active role was noted as crucial for them to get the most out of this or any program.

4.4. Discussion

Lifestyle interventions evaluated in research settings have frequently been shown to improve diabetes- and hepatic steatosis-related outcomes (Tuomilehto et al., 2001; Knowler et al., 2002; Lindström et al., 2006; Reginato et al., 2019;), and are effective for the prevention and treatment of obesity and T2D complications (Williamson, 2017). They have a positive effect on health and are capable of reducing the incidence of T2D among people with pre-diabetes (Lin et al., 2017) in a cost-effective manner, because delaying the onset of T2D for 10 years with lifestyle interventions could save USD $30,000 in lifetime medical spending per person (Zhuo et al., 2014). In Alberta, the PCNs' main goal is to increase the emphasis on health promotion, disease and injury prevention, and care of patients with complex problems or chronic diseases. Therefore, the PCN setting was ideal for implementation of the PPLP intervention because it provided a representative real-world setting.

Our data indicate that the PPLP offered in a real-world PCN as compared with usual care during a six-month follow up was not statistically significant or clinically relevant in relation to our primary outcome, HbA1c. A major factor, as reflected by the demographic characteristics and baseline HbA1c of the participants, was that our "real-life" participants were mostly middle class highly-motivated Caucasians who entered the study with overall good control of blood sugar (HbA1c = 6.9%) (Diabetes Canada, 2018). Previous evidence corroborates that patients who enrol in PCN-delivered interventions tend to be receptive, motivated (Chrvala, Sherr, & Lipman, 2016), and better managed (Manns et al., 2012). Our sample size calculation was based on the primary aim to detect a 0.5% change in HbA1c, however a 0.5% change in the difference between 11 and 10.5 is not the same as 8 and 7.5. In other words, achieving changes in glycemic control in patients with poorly controlled hyperglycemia can be feasible with intensive therapy and lifestyle changes versus improving glycemic control in patients with well managed tightly regulated glycemic control can be difficult to achieve and can include potential risk for hypoglycemia (Davies et al., 2018). Our results reflect, in part, what is known as "a ceiling effect", which occurs when baseline performance is nearly as good as it could be in both the treatment and control conditions. Furthermore, accordingly to systematic reviews, benefits are

more pronounced in individuals with poor blood glucose control (Chrvala et al., 2016; Tricco et al., 2012).

Regarding our secondary and exploratory outcomes, some improvements were observed, but not to the extent as observed in a study of T2D participants (n = 73) previously conducted by our team in a research setting (Asaad et al., 2016). This more modest efficacy has previously been reported as a limitation of lifestyle intervention program translation (Costa & Mestre, 2019; Kahn & Davidson, 2014). Indeed, weight loss in the present intervention group was 1.56 kg ($p < 0.001$) and 2.43 kg ($p < 0.05$) at three and six months. Benefits of weight control through caloric restriction (Sievenpiper et al., 2018) and intermittent fasting (Cho et al., 2019) have been reported to improve glucose metabolism through reduction of BMI, decreased circulating leptin, and increased adiponectin (Cho et al., 2019).

Qualitative analysis is an important part of behavioural intervention research (Brownson, Fielding, & Maylahn, 2009). Our findings contribute to public health prevention and management of CMD by providing essential participant perspectives. Thematic analysis was used to reflect reality (Braun & Clarke, 2006); it served our objective to understand participants' experiences throughout the program including what worked, what did not work for them, and how to improve the overall program. In general, participants reported enjoying taking part of the study, it helped them increase the amount of fruit and vegetables they consumed, changed the way they perceived and acknowledged the importance of menu planning, portion control, and the consciousness about what they bought and ate. Furthermore, the qualitative analysis provided useful insight to participants' barriers, which were consistent with previous frameworks (Sharma, 2010), echoing the vast evidence supporting the complexity of chronic diseases (Janke, Ramirez, Haltzman, Fritz, & Kozak, 2016). Participants' suggested improvements for future editions of the program included more hands-on activities such as cooking lessons and active exercise programs.

Results from the PPLP intervention provide important contributions. First, HCP and PCNs are effective in the overall management of T2D as evidenced by participants' HbA1c at baseline. Our data is corroborated by a cohort study showing that being enrolled in a PCN was associated

with a 19.4% relative reduction in admission to hospital or emergency departments, potentially as a result of receiving more guideline-recommended care as compared with individuals not attending a PCN (Manns et al., 2012). Participants who attend PCNs are prone to be more receptive and highly motivated, thereby maximizing the potential benefits they can obtain from this type of intervention (Chrvala et al., 2016). Thus, participants from, underrepresented and disadvantaged groups, and those who have just been diagnosed or have poor control of their T2D management need to be identified and encouraged to enrol in these types of programs (Cradock et al., 2017). This could help to refocus and prioritize resources to target patients with poor glycemic control (Murphy et al., 2017), who would greatly benefit from such programs (Hayward, 2015). Further research is needed to understand how to reach those most in need of such interventions, including those with a higher risk of developing T2D or T2D complications (Ward et al., 2019).

These results contribute to and further support what has previously been reported in the literature regarding outcomes of lifestyle interventions delivered in real-world settings. Transition from research into real-world settings can be less successful for a variety of reasons, particularly with regard to having less impact as compared with their research setting counterparts (Cardona-Morrell, Rychetnik, Morrell, Espinel, & Bauman, 2010; Linmans et al., 2011), and increased burden for HCP to deliver (Costa & Mestre, 2019), raising the question of how much of an effect a lifestyle intervention must have in a research setting in order to have a clinically relevant effect in a real-world setting.

This PPLP study had some limitations. First, statistical power for secondary outcomes was limited. Post-hoc power analysis indicated that with the exception of SBP (power = 90%) this study was low to moderately underpowered to estimate differences between the PPLP and the control group. Power to estimate weight, BMI was <10% while dietary adherence, diabetes self-efficacy, and quality of life had power ≤50% and DBP was 70%. Using the effect sizes and variances observed in the present study can help researchers plan adequately powered studies in the future to unravel the associations between the effects of lifestyle interventions on biomedical and behaviour outcomes. Furthermore, our sample was quite homogeneous; therefore, it was not representative of the general population and cannot be generalizable, although we predict an

enhanced response if individuals with poorer glycemic control were enrolled. The relatively short-term follow up (six months) limited our ability to report longer-term benefits. Thirdly, some methodological limitations merit mention. Although measures were taken to reduce observer bias (training to make assessment consistent, reduce conscious or unconscious prejudices) allocation concealment was not possible. In addition, given that the questionnaires used called for participants to accurately remember previous events or experiences, risk of recall bias cannot be discarded. Eligibility and recruitment log regarding screening, eligibility, and reasons for ineligibility or not enrolling were not conducted, which was a methodological limitation of the current study but did help to reduce the workload of the HCP involved with the program and was consistent with real-world practice.

This PPLP study has several strengths. By incorporating a variety of quality improvement strategies including working with site personnel to tailor the PPLP to their setting, providing resources relevant to the Albertan population, and a detailed curriculum guide to the healthcare provider team to enhance program delivery fidelity (Tricco et al., 2012), we attempted to overcome the identified limitation of general lack of replication of evidence from research to real-world settings (Kahn & Davidson, 2014). Secondly, the use of tools specifically developed for the needs of the local community is a novel approach aimed at contributing to the prevention and management of T2D and adoption of a healthier lifestyle. The DC Nutrition Therapy guidelines recommend the adoption of dietary patterns that have evidence for improving T2D outcomes. One of the dietary patterns recommended is the Mediterranean dietary pattern, which is known to have multiple health benefits (Sievenpiper et al., 2018). However, in places such as Alberta in Canada, following this dietary pattern is not always feasible given the extreme weather conditions that limit crop production, local food preferences, and other factors. Thus, the PPEP was developed to align with local reality through the use of the 4A framework, and therefore provided a dietary pattern that was acceptable to and nutritionally adequate for people in Alberta. The use of locally available and accessible food encourages the use of short supply chains, which have been linked to improved metabolic health (Santulli et al., 2019). Given the positive feedback received from participants and HCP in regard to the usefulness of the PPEP, the development of specific tools that facilitate adherence to the guidelines could be a novel approach to facilitate adherence to the guidelines and the long-term T2D management. These

tools can also reduce the workload of HCP, for example, by providing adaptable menu plans. Given that individuals are prone to engage in multiple unhealthy lifestyle behaviours (Pérez-Rodrigo et al., 2017), future interventions would benefit from using the same approach proposed in the present intervention and design tools to address other unhealthy lifestyle behaviours specific to individual participants' context. Lastly, weight loss was not a main outcome of the PPLP trial but it was considered to be a strength of the study. Given the multifactorial nature (sedentary behaviour, physical activity, sleep pattern, and stress levels) and complexity of weight management, we consider that weight loss does not necessary reflect improvement in pathophysiological mechanisms or metabolism. Rather, a focus on healthy eating can elicit more sustainable behaviour change (Sánchez-Sánchez et al., 2020; Willett et al., 2019). In order to provide new insights into the effect of lifestyle interventions on pathophysiological mechanisms in real-word settings, measuring surrogate markers of hepatic steatosis (Reginato et al., 2019) or adipose-derived secretory or inflammatory factors (Lee, Lee, & Oh, 2019) could provide more comprehensive insights.

4. 5. Conclusions

In conclusion, the modest positive effects of the PPLP intervention reflect the challenge of translating lifestyle interventions to real-world primary care settings. The development of specific tools was a novel approach to facilitate and improve participants' adherence to the guidelines and reduce HCP workload. Our results raised the important issue that the information provided in lifestyle interventions was absorbed and judged to be useful, but by itself was not enough support for participants to modify and sustain the behaviours and abilities for self-care. The PPLP allowed us to begin to understand some of the needs of participants in a general real-world setting but future research should address this gap in knowledge and investigate knowledge-to-action techniques that could improve T2D management and ease the health journey of persons with T2D. Further research is needed to conduct in-depth conversations with knowledge user to understand their needs in more detail, in order to develop contextually appropriate interventions that meets the dynamic needs of modern society. Designing tools to facilitate healthy behaviour change that is specific to individuals' context, as well as tools and techniques to alleviate HCP workload to facilitate long-term buy-in of such programming could benefit from additional research.

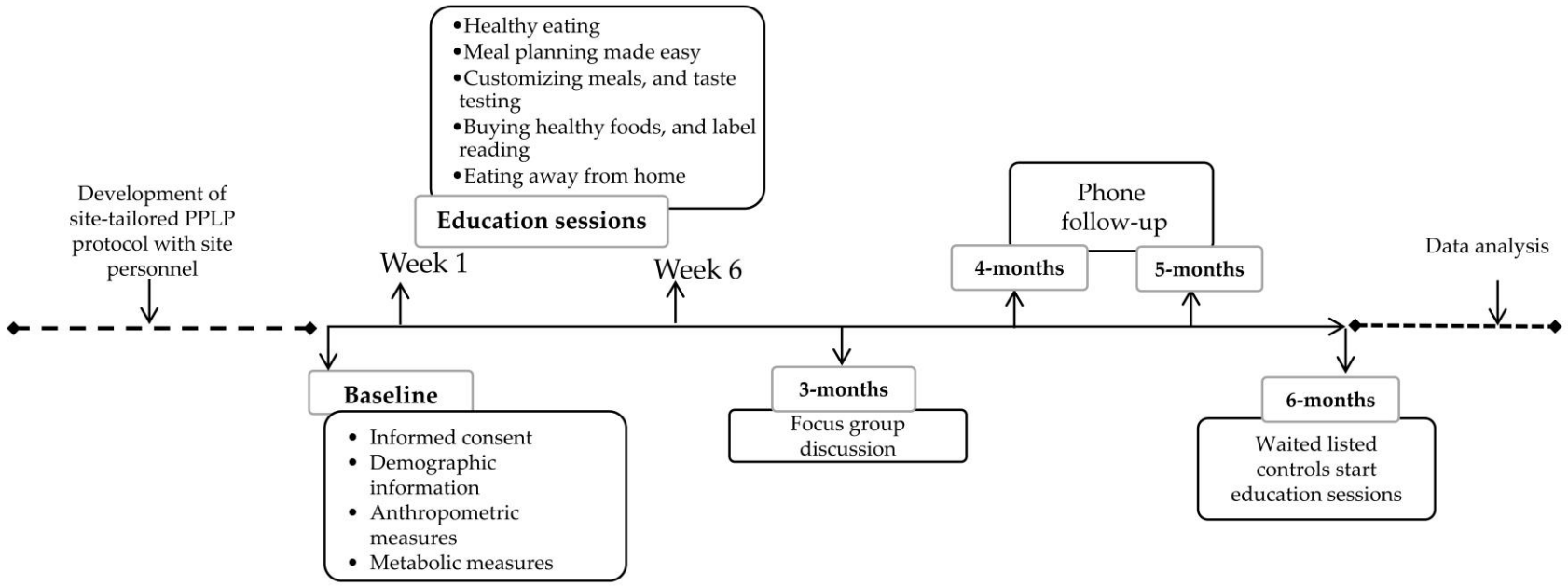

Figure 4.1. Intervention timeline

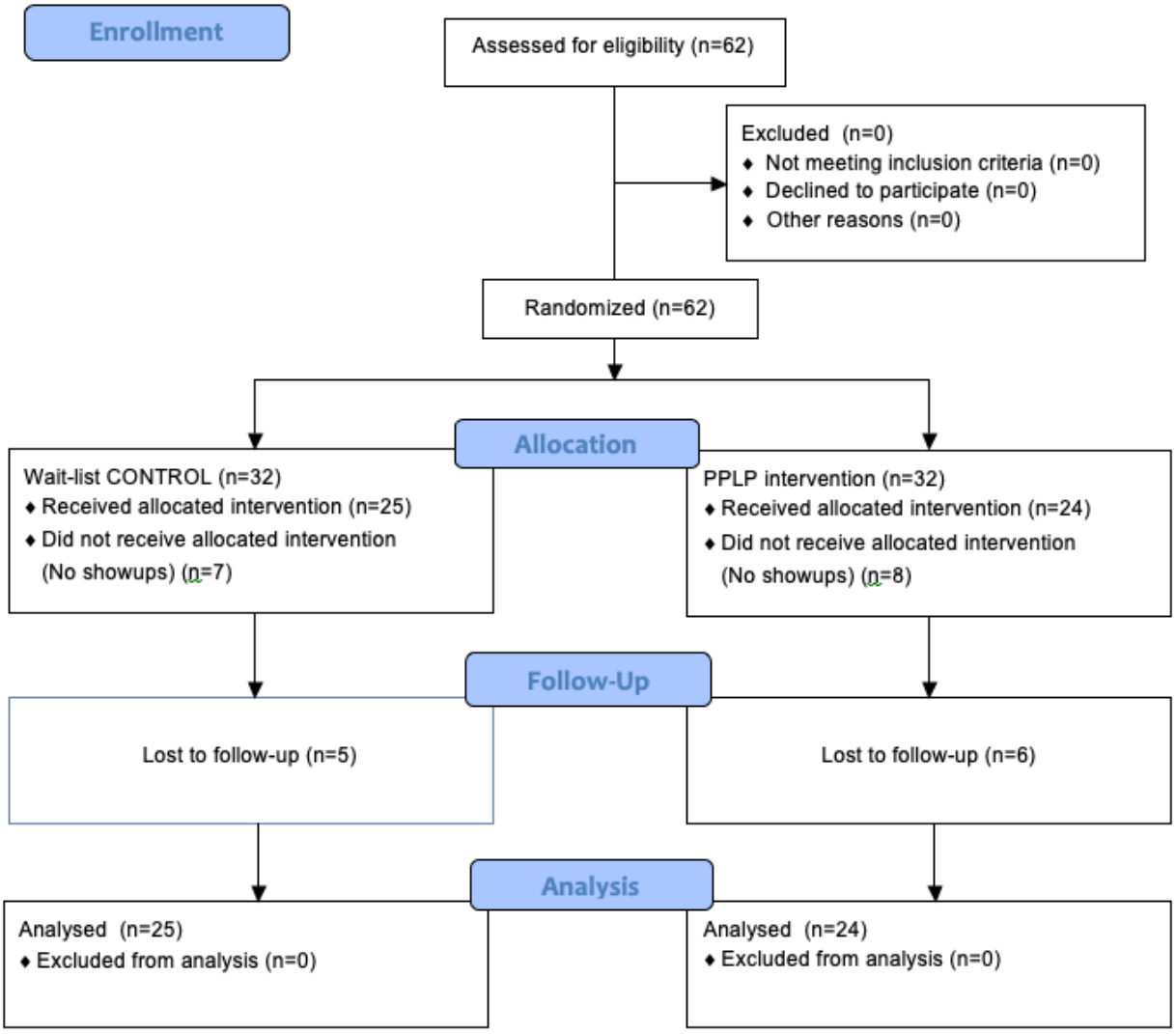

Figure 4.2. CONSORT flow diagram

Table 4.1. Demographic characteristics of participants

Demographic Variables	CON Mean (SD)	PPLP Mean (SD)	*t*	*df*	*p*
Age (years)	61.3 (9.4)	57.7 (11.8)	1.14	45	0.257
Diabetes diagnosis (years)	8.4 (7.1)	5.8 (5.7)	1.41	42	0.166
	***N* (%)**	***N* (%)**	X^2	*df*	***p* Value**
Gender			2.481	1	0.115
Male	15 (60)	9 (37.5)			
Female	10 (40)	15 (62.5)			
Ethnicity			0.327	1	0.568
White	23 (92)	20 (87)			
Other	2 (8)	3 (13)			
Education			0.10	1	0.921
High school or less	8 (32)	8 (33)			
More than high school	17 (68)	16 (67)			
Employment Status			0.10	1	0.921
Working	12 (48)	10 (42)			
Other	13 (52)	14 (58)			
Household annual income			0.016	1	0.900
< $59,999	10 (42)	10 (43.5)			
> $60,000	14 (58)	13 (56.5)			
Annual income					
< Meet needs	7 (28)	6 (25)	0.9	-	-
> Meet needs	18 (72)	18 (75)		-	-

Baseline characteristics were compared between groups (CON vs. PPLP) using t-test for continuous variables and X^2 test for categorical variables.

Table 4.2. Baseline metabolic characteristics.

Anthropometric Characteristics		**CON Mean (SD)**	**PPLP Mean (SD)**	***t***	***df***	***p***
Weight (kg)						
	Male	105.7 (16.4)	118.3 (46.7)	−0.96	22	0.345
	Female	90.1 (22.3)	92.7 (25.2)	−0.267	22	0.792
BMI (kg/m^2)						
	Male	33 (4)	37(11)		22	0.219
	Female	34 (5)	35 (8)	−0.502	22	0.621
Waist circumference (cm)						
	Male	114.3 (11.7)	121.3 (28)	−0.861	22	0.398
	Female	104.5 (17)	108.5 (13)	−0.659	23	0.516
SBP (mmHg)						
	Male	141 (12)	126 (13)	2.7	22	0.013*
	Female	142 (20)	138 (21)	0.417	23	0.680
DBP (mmHg)						
	Male	82 (10)	78 (10)	0.780	22	0.444
	Female	79 (9)	79 (8)	0.033	22	0.974
Fat mass (%)						
	Male	31.0 (4.8)	33.5 (11.7)	−0.710	21	0.486
	Female	39.4 (5.2)	40.7 (8.3)	−0.416	20	0.682
Fat mass (kg)						
	Male	32.8 (9.4)	36.9 (19.2)	−0.710	21	0.486
	Female	34.9 (10.4)	36.7 (15.9)	−0.305	20	0.763
Fat free mass (kg)						
	Male	70.9 (8.5)	65.9 (9.2)	1.3	21	0.206
	Female	52.9 (13.4)	49.9 (7.4)	0.673	20	0.509
Metabolic Characteristics		**Mean (SD)**	**Mean (SD)**	**t**	***df***	***p***
HbA1c (%)						
	Male	6.9 (0.9)	7.5 (1.1)	−1.40	22	0.175
	Female	7.3 (1.2)	6.7 (0.6)	1.38	22	0.179
Triglycerides (mmol/L)						
	Male	2.2 (1.2)	3.4 (1.6)	−1.84	22	0.078
	Female	3.0 (1.1)	2.8 (1.1)	0.435	23	0.667
Total Cholesterol (mmol/L)						
	Male	3.6 (0.7)	3.9 (1.2)	−0.759	22	0.456
	Female	4.4 (0.9)	4.3 (1.3)	0.163	23	0.872
LDL-C (mmol/L)						
	Male	1.7 (0.7)	1.6 (1.5)	0.172	13	0.866
	Female	2.0 (0.5)	1.7 (0.7)	0.865	18	0.399
HDL-C (mmol/L)						
	Male	1.0 (0.2)	0.9 (0.1)	0.997	22	0.330
	Female	1.3 (0.4)	1.1 (0.2)	0.965	23	0.345

Baseline characteristics were compared between groups (CON vs. PPLP) using independent *t* test. * Significant difference at $p < 0.05$.

Table 4.3. Anthropometric and metabolic changes from baseline to 3- and 6-month follow ups with differences within and between groups over time.

Anthropometric Characteristics	Control Group		PPLP Group		Mean Differences (95% CI) between Group × Time			
	Mean Change (95%) from Baseline		Mean Change (95%) from Baseline					
	3-month	6-month	3-month	6-month	3-month	*p* Value	6-month	*p* Value
Weight (kg)	−0.660 (−1.81 to 0.48)	−0.55 (−2.23 to 1.13)	−1.56 (−2.87 to −0.24) *	−2.43 (−3.63 to −1.23) **	−0.89 (−2.58 to 0.79)	0.290	−1.88 (−3.92 to 0.154)	0.069
BMI (kg/m^2)	−0.20 (−0.59 to 0.19)	−0.24 (−0.81 to 0.32)	−0.70 (−1.2 to −0.14) *	−0.90 (−1.41 to −0.39) *	−0.50 (−1.14 to 0.13)	0.118	−0.65 (−1.40 to 0.09)	0.084
WC (cm)	−1.05 (−3.42 to 1.32)	4.19 (1.9 to 6.4) **	3.39 (0.64 to 6.14) *	2.10 (−1.89 to 6.09)	4.44 (0.93 to 7.96)	0.015 *	−2.09 (−6.31 to 2.13)	0.322
SBP (mmHg)	−11.9 (−19.1 to −4.8) *	−9.5 (−16.5 to −2.4) *	−8.72 (−15.89 to 1.56) *	−5.80 (−13.75 to 2.15)	3.25 (−6.71 to 13.23)	0.512	3.70 (−6.49 to 13.90)	0.465
DBP (mmHg)	−5.0 (−9.2 to −0.8) *	−2.2 (−7.1 to 2.6)	−2.50 (−6.39 to 1.39)	−5.00 (−9.31 to −0.69) *	2.54 (−3.23 to 8.32)	0.378	−2.72 (−9.08 to 3.64)	0.390
Fat mass (%)	−0.24 (−1.36 to 0.87)	0.28 (−0.42 to 1.00)	0.51 (−1.14 to 2.17)	1.37 (−0.70 to 3.45)	0.75 (−1.09 to 2.61)	0.412	1.08 (−1.08 to 3.25)	0.308
Fat mass (kg)	−0.47 (−1.49 to 0.54)	0.14 (−0.92 to 1.20)	−0.30 (−1.76 to 1.16)	0.30 (−1.38 to 1.98)	0.17 (−1.48 to 1.83)	0.216	0.15 (−1.69 to 2.00)	0.863
Fat free mass (kg)	−0.13 (−1.49 to 1.21)	−0.45 (−1.63 to 0.71)	−1.59 (−2.81 to −0.37) *	−2.92 (−4.83 to −1.01) *	−1.45 (−3.32 to 0.41)	0.122	−2.46 (−4.54 to −0.38)	0.021 *

Metabolic Characteristics								
HbA1c (%)	−0.04 (−0.27 to 0.17)	−0.09 (−0.41 to 0.22)	−0.15 (−0.38 to 0.08)	0.06 (−0.26 to 0.38)	−0.10 (−0.41 to 0.21)	0.510	0.15 (−0.28 to 0.59)	0.474
Triglycerides (mmol/L)	−0.05 (−0.43 to 0.33)	−0.17 (−0.58 to 0.23)	−0.17 (−0.73 to 0.37)	−0.44 (−1.15 to 0.27)	−0.12 (−0.76 to 0.50)	0.686	−0.26 (−1.04 to 0.50)	0.484
Total Cholesterol (mmol/L)	0.02 (−0.30 to 0.34)	−0.10 (−0.42 to 0.27)	0.18 (−0.46 to 0.84)	−0.40 (−1.01 to 0.21)	0.16 (−0.49 to 0.83)	0.616	−0.29 (−0.92 to 0.33)	0.346
LDL-C (mmol/L)	−0.05 (−0.35 to 0.24)	0.07 (−0.11 to 0.26)	−0.01 (−0.48 to 0.46)	−0.16 (−0.57 to 0.24)	0.04 (−0.46 to 0.54)	0.862	−0.24 (−0.60 to 0.12)	0.183
HDL-C (mmol/L)	0.02 (−0.04 to 0.09)	0.04 (−0.04 to 0.12)	0.05 (−0.13 to 0.24)	−0.02 (−0.07 to 0.01)	0.0. (−0.14 to 0.21)	0.714	−0.06 (−0.16 to 0.02)	0.165

Mean differences within and between groups are presented as mean (95% confidence interval). A negative value indicates a decrease from baseline to 3 months and baseline to 6 months. Paired t-test was used to calculate the mean change within groups. Between groups, PPLP was subtracted from CON; thus, a negative value indicates a bigger change from baseline for the PPLP group. Independent t-test was used to calculate the mean difference between groups (CON vs. PPLP) at 3- and 6-month time points. * Significant difference at $p < 0.05$ and ** significant difference at $p < 0.001$.

Table 4.4. Diet quality, self-efficacy, and quality of life change from baseline to 3- and 6-month follow ups, with differences in within and between groups over time.

Diet Quality and Adherence Variables	Control Group			PPLP Group			Mean Differences (95% CI) between Group × Time			
	Mean (SD)	Mean Change (95%) from Baseline		Mean (SD)	Mean Change (95%) from Baseline					
	Baseline	3-month	6-month	Baseline	3-month	6-month	3-month	*p* Value	6-month	*p* Value
PDAQ (Score 7 max)	3.5 (0.9)	0.3 (−0.1 to 0.7)	0.3 (−0.03 to 0.8)	3.7 (0.9)	0.4 (0.1 to 0.8) *	0.5 (0.06 to 0.9) *	−0.3 (−0.9 to 0.2)	0.271	−0.1 (−0.9 to 0.5)	0.605
DSES (Score 8 max)	7.0 (1.8)	0.04 (-0.7 to 0.8)	0.68 (-0.3 to 1.6)	6.2 (1.7)	0.7 (-0.03 to 1.5)	0.3 (-0.5 to 1.2)	−0.03 (−1.09 to 1.01)	0.940	0.5 (−0.4 to 1.5)	0.277
EQ-VAS (Score 100 max)	68 (18.7)	7.3 (−0.1 to 14.8) *	7.5 (3.1 to 11.8) *	67.8 (15.2)	5.3 (0.4 to 10.2) *	3.9 (−2.5 to 10.4)	3.4 (−5.0 to 11.8)	0.416	5.3 (−5.4 to 16.2)	0.321

Mean differences within and between groups are presented in mean (95% confidence interval). Within group, a negative value indicates a decrease from baseline to 3 months and baseline to 6 months. Paired t-test was used to calculate the mean change within groups. Between groups, PPLP was subtracted from CON; thus, a negative value indicates a bigger change from baseline for the PPLP group. Independent t-test was used to calculate the mean difference between groups (CON vs. PPLP) at 3- and 6-month time points. * Significant difference at $p < 0.05$ and ** significant difference at $p < 0.001$.

Table 4.5. Qualitative analysis, representative quotes for key facilitators/barriers**.**

Facilitators and Barriers	
Themes	**Example Quotes**
1. Knowledge acquired	
Healthy eating	I spend a lot more time thinking about my menu for the week, versus just grabbing whatever out of the fridge. So when I go shopping, I do it with more intent, when I'm doing my cooking for the week, I do it with more intent [**PPLP-5B**].
Label reading	I had no idea, uh, one thing I really benefited from was reading labels. I, um, I had no idea how much salt was in processed foods, uh, and sugars, and that was a real benefit to me **[PPLP-1B**].
Physical Activity	I think awareness of activity level … is very beneficial because it, it did make you realize that you have days where you might walk fifteen hundred steps, which is barely enough to keep you alive [**PPLP-7B**].
2. Motivation	
Health	My biggest thing was to try and keep control on the diabetes with food and that because I don't want to go any further with medications. I'm scared of going on insulin [**PPLP-1A**].
	I'm getting older and I was afraid I was gonna get my legs cut off and I was gonna go blind and therefore I needed to find something to, to make sure I'm going down the right path [**PPLP-7B**].
Family	I just wanna be able to keep control so that I can stay healthy and that, because you know, like uh, I'm waiting…my son's getting married, hopefully within the next ten years I'll be a grandfather, I'd like to be pretty healthy to play with the grandkids and stuff like that [**PPLP-1A**].
Group support	I think what worked well for me was coming every week and being, like I said, accountable, and then hearing other people doing really well, and then feeling guilty that I didn't do really well and then the next week I felt…well I gotta…they're all doing it, I gotta step up and be accountable [**PPLP-2B**].
3. Barriers	
Mental	I've been able to go and buy the food and that, but it's uh, for me it's just a lot of laziness at times when I'll be driving home and thinking it's easier to stop and buy A&W and pick up a burger than trying to go through the hassle of making something at home and that. So, I still eat out way too much than I should and that [**PPLP-4A**].
	I find that you know, to cook it right before I have to eat it, I hahaha…I don't do that you know. Like, I just want it ready so I can just take it out

	and you know, don't spend the hour cooking … we do get lazy and guilt-ridden and uh you know whiny and that sort of thing [**PPLP-3A**].
	I've been really depressed and, so it's been hard to think of…to take care of myself [**PPLP-5A**].
Mechanical/ metabolic	Having MS [multiple sclerosis] and being immobile, I, my health really depends on what I eat, like I can't control my weight or anything with movement, so I can't exercise or burn calories that way [**PPLP-6A**].
	Sometimes you don't get home from work and you haven't had the time to plan so I, like I often felt like I need to take time to plan out the meals, to get the groceries, to…but if you don't have the time to get ahead of yourself like that, then the time is working against you [**PPLP-2B**].
Monetary	Financially, like I haven't really had much control over the food that's been coming into my home [**PPLP-3B**].
	Buying fresh produce and, and uh…and fresh, fresh ingredients is much more expensive [**PPLP-5B**].

Table 4.6. Qualitative analysis, representative quotes for key program evaluation experiences**.**

Experience Evaluation	
Themes	**Example Quotes**
1. Satisfaction	Practical and easy to understand and when you take a look at other, uh, books and programs, it becomes very complicated, but this one was, was laid out, I think in, um easy to understand and very practical terms [**PPLP2A**]. I find the best benefit is that…giving you the alternatives, like… saying don't eat this, don't do this…here is something you can…have instead…[**PPLP5B**] I just enjoyed all the sessions. I learned a lot, you know like I went for…to a dietitian, and it was one day, you know like what can you…learn all this stuff in one day so this is spread over time and you know with the group session, that's what I really like about it [**PPLP4A**]. This made me very conscious of my overall lifestyle [**PPLP-2A**].
2. Limitations	Honestly the paperwork. Like the recording of everything, I didn't do it. I, I do enough paperwork at work that when I, you know, spend…to come home and spend another twenty minutes, half an hour on that when I'm already doing lots of other work. This was a deterrent. If this was an app, it would be beneficial [**PPLP-5B**].
3. Improvements Support group	I think it would be nice that a core group has been established. If you're feeling like it's just, uh, overwhelming, or you're just, you're not doing as well as you anticipated, to be able to be a part of an evening group that does something, uh nutrition or whatever the program might be. And so that gives you that little bit of an extra boost [**PPLP-2A**].
Hands on activities	Active cooking classes for next [**PPLP-6B**].
Active PA	Set up an exercise program for you that would be sort of matched to um your goals, yeah, and your abilities [**PPLP-2B**].

Table 4.7. Qualitative analysis, representative quotes of health care providers (HCPs).

Examples of HCPs views of the intervention
I would rank it high, um I, I think…I was personally very pleased. I would rank it five. Like very high. Uh, I thought everything…I thought it was a…in my opinion, it was a quality um program [**PPLP-HCP1**].
I'd say probably about a four [**PPLP-HCP2**].
When we're talking to a lot of our patients regarding diabetes, we talk a lot about um either exchanging…like the carb choices or um grams of carbohydrate and um I know the Pure Prairie Eating Plan cookbook is based on Canada's Food Guide. That to me makes better sense in a lot of ways and it's easier, it's just wrapping our heads around thinking a little bit differently [**PPLP-HCP1**].
I think, because there was uh, like [RD] and I, there was two of us kind of working on implementing it, that was helpful cause we um tend to be on the same page with a lot of things. And she could take some tasks and I could take some tasks and we could kind of get it done together [**PPLP-HCP2**].
Uh well a lot of things went well, um I think just, [RD] and I were able to work together very well um with your help and [Research member´s] help…. It was a lot of work, but I think it really worked out well. That we really had, I think there was a lot of agreement, with how um things should look, how the presentation should, how the slides should look, how the presentation, how the slides um should be presented. And I think it was nice to have the support from the team, uh the U of A, um our, our girls out front received everybody here [**PPLP-HCP1**].
Examples of HCPs challenges of the intervention
The calls were a lot of work haha. A lot more work than we anticipated… For the recruitment and for the follow-ups, yeah… it was a lot of administrative time on our part, and it took away from the rest of our patient time [**PPLP-HCP2**].
Definitely trying to schedule the boardrooms, cause we're in competition with all of our regular classes plus our mental health classes plus there's board meetings, there's um, Alberta Health Services uses our board rooms for some of their programming too, so there's…it's a challenge… to, to find it, and especially 'cause it…when you need the same board room consistently at the same time for several weeks in a row…that was the big challenge. We could, you know, here and there you can always find an empty boardroom, but um the multiple weeks in a row was very challenging to get the space [**PPLP-HCP2**].

Chapter 5: From research to real-world settings: A systematic review on the scale-up penalty of lifestyle interventions for type 2 diabetes management

5.1. Introduction

Type 2 diabetes (T2D) guidelines are designed to support practice and patterns of care, promote self-management, enhance prevention and reduce complications of T2D, thus improving quality of life (Diabetes Canada Clinical Practice Guidelines Expert Committee & Houlden, 2018). The presence of hyperglycemia due to impairment of insulin secretion and/or defective insulin action (Goldenberg & Punthakee, 2013) is the underlying cause of micro and macrovascular complications, including neuropathy and cardiovascular diseases (Fowler, 2008). Thus, optimal glycemic control (glycated hemoglobin (HbA1c) levels < 7%) is crucial for the disease management and to prevent its complications (ADVANCE Collaborative Group, 2008; Diabetes Control Complications Trial Research Group, 1995). According to the Diabetes Canada Clinical Practice Guidelines, incorporating components from the Chronic Care Model (CCM) framework associates with overall improved quality of care for people with T2D (Stellefson, Dipnarine, & Stopka, 2013). These components include a multidisciplinary and interprofessional team with specific T2D training, and the provision of self-management support (SMS) enabling people to be more active in self-managing their chronic disease (Diabetes Canada Clinical Practice Guidelines Expert Committe et al., 2018). Furthermore, it is stated that a multidisciplinary strategy should be used to manage T2D including self-management education (SME) and SMS, nutrition therapy, physical activity, pharmacological and/or complementary and alternative medicine for diabetes.

Despite these strategies being considered the cornerstones of T2D management, discrepancies between the guidelines and day-to-day practices exist (Diabetes Canada Clinical Practice Guidelines Expert Committee & Houlden, 2018). Given the complexity of complying with the guidelines, structured lifestyle interventions (LI) with defined curricula have been developed to integrate the recommendations into feasible programs to prevent progression and promote sustained management of T2D. LI programs have validated feasibility and efficacy to prevent

progression to T2D with up to 58% reduction in the incidence of T2D as a result of changes in lifestyle (Knowler et al., 2002; Tuomilehto et al., 2001) and up to 31% with the use of metformin (Knowler et al., 2002). Similar results were found in prevention trials conducted in Finland (Tuomilehto et al., 2001) and China (X.-R. Pan et al., 1997). Regarding improvements in glucose control and CVD risk factors in people diagnosed with T2D, results show a short-term improvement in blood glucose control and body weight (American Diabetes Association, 2007; Hamdy & Carver, 2008) yet their long-term benefits attenuated and do not decrease the occurrence of cardiovascular events (Look AHEAD Research Group, 2013).

Thus, the viability of implementing these LI in real-world settings is often questioned. On one hand, feasibility has been undermined by a lack of health care provider (HCP) buy-in, inability to integrate complex LI into daily work routines or on a larger scale (Blonstein et al., 2013; Costa & Mestre, 2019; Kahn & Davidson, 2014). Conversely, LI benefits in real-world settings have been questioned due to the decreased efficacy compared to their research counterparts (Kahn & Davidson, 2014), a concept coined "scale-up penalty" referring to the reduced effects when moving through a program's scale-up process (efficacy, effectiveness, dissemination) (Welsh, Sullivan, & Olds, 2010). It is plausible that many of these programs have limited impact, in part because not all programs include the main pillars of T2D guidelines (SME, SMS, nutrition therapy, physical activity and pharmacological therapy*),* hindering their overall efficacy and effectiveness.

As such, uncertainty remains regarding the effectiveness of LI for T2D management. Thus, the aim of the present systematic review is to compare the effect size when moving through the scale-up process (efficacy to effectiveness trials) in LI that align with the cornerstones of T2D management. Throughout this review the following questions will be answered:

I. Do LI developed for people with T2D include the four pillars for T2D management recommended by the Diabetes Canada Clinical Practice Guidelines?
II. When comparing LI programs efficacy vs effectiveness in research setting and real-world setting, what is the scale up penalty of HbA1c reduction in adults with T2D?

III. For the studies included, what are the barriers and facilitators encounter by the participants or research group to implement LI in each of these settings?

5.2. Methods

5.2.1. Study inclusion and exclusion criteria

This review adhered to the Preferred Reported Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement (Moher et al. 2009) (**Appendix 5.0**).

Inclusion criteria: Studies addressing i) T2D LI programs, reporting on at least two of the main pillars of T2D care in accordance with the Canadian guidelines (SME and SMS, nutrition therapy, physical activity, pharmacological therapy, or others) (intervention, I); ii) studies that have gone through scale-up process (efficacy to effectiveness) (comparison, C); iii) studies reporting HbA1c (outcome, O).

Study design: Studies in this review were included based on their ability to provide evidence from both a research setting trial aimed to validate its efficacy and a transferability counterpart that translated the research setting results into real-world settings/practice aimed to evaluate its effectiveness. Given the explanatory-pragmatic spectrum of RCTs, their low risk of bias, and the grand evidence they provide to test and evaluate an intervention (Neta & Johnson, 2018; Patsopoulos, 2011), RCTs studies carried out in a real-world setting were included in this review. The RCTs' explanatory counterpart study (efficacy trial) was included regardless of the study design, since in efficacy studies a pre-post assessment is used as study design followed by RCTs in real-world setting (study design, S).

Participants: Studies conducted in male and female adults (≥18 years) diagnosed with T2D were included. Studies including people diagnosed with overweight or obesity, hypertension, or metabolic syndrome (MetS) were included provided participants with T2D were also included (participants, P). Exclusion criteria: studies reporting i) only one pillar of diabetes care (specific nutrition therapy, pharmaceutical or physical activity approach) instead of multiple, integrated interventions; ii) studies without research or real-world counterpart (not scaling from efficacy

trials to effectiveness trials); iii) studies not reporting HbA1c; iv) studies with comorbidities outside of the MetS cluster, even if T2D was present, were excluded. Cross-sectional studies, case series, retrospective studies, case reports, surveys result and non-randomized studies were excluded. Studies with non-English language or publication date before 2000 were excluded.

5.2.2. Search and selection of literature

Literature search strategy: Ovid MEDLINE interface, EMBASE (OVID interface) and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases were searched. The literature search strategy was developed by MCAH and SCCZ with input from the research team using terms related to a) T2D management such as nutrition, pharmaceutical and/or physical activity; b) programs such as lifestyle intervention and/or RCTs in research or real world settings. The search terms were applied to title and abstract search. English language, human subjects (≥18 years), and a publication date (2000 – 2020) were imposed on the search. The complete search strategy can be found in **Appendix 5.1**. The search results were imported into EndNote X7.8 and duplicates were removed. The resultant retrieved search results were uploaded to Rayyan QCRI Systematic Review online software program for the screening process.

Selection and classification of the literature: Titles and abstracts of the retrieved search results were reviewed based on the pre-determined inclusion and exclusion criteria by two independent reviewers (MCAH and SCCZ) blinded to the others response. Potential identified studies were retrieved, full text reviewed, and hand searched for additional relevant available studies. If they meet the inclusion criteria, their pairs were sought by hand search and they were retrieved. In this iterative process, disagreements were solved via discussion and if agreement was not attained, a third party (CBC) was involved. The reasons for excluding full text screened articles can be found in **Appendix 5.2**. Included publications were classified into research or real-world settings.

5.2.3. Data extraction, outcomes and data synthesis

Data extraction: MCAH and SCCZ independently retrieved data from the same sample of 2 pairs of publications (4 articles) to check for consistency and accuracy. Thereafter, MCAH and SCCZ

independently extracted data from the remaining papers. Discrepancies were solved by discussion and third party (CBC) consensus. The following information was extracted from the studies: general study and participant characteristics, ethnicity, average age (by group) and gender (%). The interventions that comprised each study were extracted and categorised into the main pillars for T2D management (SME + SMS, nutrition therapy, physical activity, pharmacological therapy and others). Where available, details regarding each specific pillar were extracted (group session frequency, education topics, nutritional approach/distribution, dose/frequency of PA and pharmacological approach, other). From each study, main outcomes and conclusions were extracted with the major focus on primary and secondary outcomes. Given that each study had different follow-up periods, HbA1c and BW measurements were extracted at baseline and at the time interval(s) each study reported. Facilitators and barriers reported by the end users (participants) or the research group were also extracted.

Primary outcome: Because HbA1c reductions is the main goal of T2D management proposed by the guidelines (Lipscombe et al., 2018), the primary outcome of this review was to compare changes in HbA1c within and between research setting vs. real world counterparts.

Secondary outcomes: The secondary outcomes were: i) changes in BW within and between research setting vs. real world studies; ii) intervention components; iii) facilitators and barriers of the study reported by the end users (participants) (if available) or the research group.

Risk of bias: We considered the risk of bias components independently without attributing any overall score to the studies and used the template for RCTs (Joanna Briggs Institute, 2017) and quasi-experimental studies (Joanna Briggs Institute, 2017[a]) available from Joanna Briggs Institute. Risk of bias **(Appendix 5.3)** was assessed independently by MCAH and SCCZ and any disagreement was solved by discussion and third party (CBC) consultation if necessary.

Data synthesis: A narrative systematic review was conducted to compare the research and real-world setting studies including the following information: in **Table 5.1**, the intervention components used were included. In **Table 5.2**, the absolute change at follow-up relative to

baseline in HbA1c levels was reported. HbA1c absolute change was calculated by the authors of this review considering follow up value minus baseline values. When various time points were reported, the time point included was the one established in the objectives for each study. The same calculation was made for BW. In **Table 5.3**, the barriers and facilitators of each study are presented. The tables facilitate comparison between the studies and present the data in an organized way. The general characteristics, control group description, main results and conclusions of each included study can be found in supplementary material **Table S.5.1**. The text will follow the same order, summarising the findings and providing an overall conclusion.

5.3. Results

5.3.1. Search outcomes

The systematic search identified 2057 records published between Jan 2000 and May 2020 (**Figure 5.1**). After duplicates were removed, title and abstract of 1315 records were screened. Of those, 1277 did not meet the inclusion criteria leaving 38 that were full text assessed for eligibility. Detail on reasons for excluding full text screening can be found in **Appendix 5.2**. A total of six studies were included in this review with five additional studies included after hand searching of references from the included studies.

5.3.2. Characteristics of included studies

In total, 11 studies (5 research setting, 5 real-world, 1 additional follow up time) were included in this review. Reported ethnicity was >80% white in 2 studies (Brown et al., 2015; Lean et al., 2018), 2 had a ≈ 50:40:10 black:white:mixed ratio (G. Foster et al., 2013; G. D. Foster et al., 2009), 1 included only Middle East and North African participants (Taheri et al., 2020) with the remaining studies not reporting participants' ethnicity. Participants mean BMI ranged from 25 kg/m^2 to more than 50 kg/m^2. The age of participants varied from early forties to late sixties with all interventions including males and females. The studies were conducted in different settings including university settings, medical centers and primary care. The total number of participants in the studies varied between 20 and 298. The follow up time for research setting varied between 2 and 12 months. In real-world setting studies, the follow up time was between 6 and 36 months.

Risk of bias assessment showed that all of the quasi-experimental studies reported unclear information related to the power of the statistical analysis (Appendix 5.3A). In addition, two out of three had unclear information about outcome assessments. In terms of RCTs, most of the unclear information was regarding treatment allocation concealment (43% of trials), blinding of outcome assessors (57%) and reliability of outcomes measurements (57%) (**Appendix 5.3B**).

5.3.3. Program component alignment with cornerstones of T2D treatment

All of the studies in our analysis reported SME+SMS in both settings, 4 (80%) reported some kind of nutrition therapy in both settings (Al Asmary et al., 2013; Brown et al., 2015; G. Foster et al., 2013; G. D. Foster et al., 2009; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020; Tourkmani et al., 2018), 3 (60%) reported physical activity in both settings (Brown et al., 2015; G. Foster et al., 2013; G. D. Foster et al., 2009; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020) and an additional 1 reported only on a real-world setting (García de la Torre et al., 2013), pharmacological therapy was reported in 3 (60%) of the research setting studies (Al Asmary et al., 2013; Brown et al., 2015; Durán et al., 2010) and in 4 (80%) of the real world setting studies (G. Foster et al., 2013; García de la Torre et al., 2013; Lean et al., 2018; Tourkmani et al., 2018).

SME + SMS: Diabetes SME + SMS was the only cornerstone included in all of the studies. All studies approached this cornerstone differently, varying also within each setting. SME and SMS were delivered using both group sessions and individual one-on-one approach with increased (Brown et al., 2015; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020), decreased (G. Foster et al., 2013; G. D. Foster et al., 2009) or similar intensity (Al Asmary et al., 2013; Durán et al., 2010; García de la Torre et al., 2013; Tourkmani et al., 2018). Sessions were delivered by certified diabetes educators (G. Foster et al., 2013; G. D. Foster et al., 2009), multidisciplinary teams including physicians, nurses, clinical pharmacist specialist, dietitians, diabetic educators, health educators and social workers (Al Asmary et al., 2013; Tuomilehto et al., 2001). Self-education included a wide variety of topics such as goal setting, self-monitoring, healthy eating, relapse management, problem solving, and self-esteem (Al Asmary et al., 2013; Brown et al., 2015; Durán et al., 2010; G. Foster et al., 2013; G. D. Foster et al., 2009; García de la Torre et al., 2013; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020; Tourkmani et al., 2018).

Follow-up phone calls were made to provide support and encouragement in 3 studies (Al Asmary et al., 2013; Lim et al., 2011; Tourkmani et al., 2018).

Nutrition therapy: Three of the studies focused on reduction of calories through total diet replacement (TDR) using commercially available formulas (G. Foster et al., 2013; G. D. Foster et al., 2009; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020), restricting calorie intake to 600 kcal/day for 8 weeks (G. D. Foster et al., 2009) or ≈ 800 - 850 kcal/day for 12 weeks (Lean et al., 2018; Taheri et al., 2020), 2 studies used a mixed method providing 690 kcal/day via nutritional liquid formula with the remainder of the calories (560 kcal for women and 890 kcal for men) being provided through conventional foods (G. Foster et al., 2013; G. D. Foster et al., 2009). Additional guidance was provided after the initial TDR phase in order to achieve weight loss maintenance through a structured food reintroduction phase (Brown et al., 2015; Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020). Diet composition for the nutritional liquid formula varied with an overall distribution of 47-59% carbohydrates, 20-33% proteins, 13-25% lipids. Soluble fibre supplement was included as part of the nutrition therapy (Lean et al., 2018; Lim et al., 2011; Taheri et al., 2020) along with water intake recommendations. RD guidance was provided based on American Diabetes Association (ADA) guidelines (Al Asmary et al., 2013; Tourkmani et al., 2018) or UK's eat well plate (Brown et al., 2015; Taheri et al., 2020). The remaining studies did not include any nutritional intervention (Durán et al., 2010; García de la Torre et al., 2013).

Physical activity: A couple of studies in the research setting included PA recommendations (G. D. Foster et al., 2009); (Brown et al., 2015)). In contrast, 4 of the real-world setting included this pillar in their program, making PA the cornerstone that changed the most across settings. Recommendations included >200 min/week of walking (G. Foster et al., 2013), increase number of steps (Lean et al., 2018), aerobic and resistance training 200 min/week (García de la Torre et al., 2013) and a walking phase followed by 150 min/week of aerobic and resistance exercise (Taheri et al., 2020). Step counter (Lean et al., 2018), supervised training sessions (García de la Torre et al., 2013) and individual program design (Taheri et al., 2020) were resources provided.

Pharmacological therapy: Of the 10 studies, 3 reported adjustments in medications. This was the approach most commonly used, including withdrawal and reintroduction of medications if

needed (Brown et al., 2015; G. Foster et al., 2013; Lean et al., 2018), 2 developed a specific algorithm for the initiation and follow up adjustment of medications (Durán et al., 2010; García de la Torre et al., 2013). Medication adherence, side effects, and dose adjustment were managed by pharmacist in collaboration with physicians in 2 studies (Brown et al., 2015; Taheri et al., 2020).

5.3.4. Effectiveness of research setting vs. real world programs: HbA1c (primary outcome)

Table 5.2 describes the values for the main outcomes considered in this review, HbA1c (primary outcome) and BW. In the research setting, 2 out of 5 studies included a control group and expressed HbA1c values at baseline and follow up (Durán et al., 2010; G. D. Foster et al., 2009) while all expressed baseline and follow up values for the intervention group. All the studies in the research setting reported improvement in HbA1c after LI compared to baseline values, although one of them did not report the statistical support for this measurement (G. D. Foster et al., 2009). HbA1c absolute reduction varied from -0.4% to -1.9% in the intervention groups. When compared to control, the two studies that had a control group (Durán et al., 2010; G. D. Foster et al., 2009) reported lower HbA1c for the intervention group at follow up (**Table 5.2**).

All six studies in real-world setting reported baseline and follow up HbA1c values for control and intervention group, and all the groups that received the LI achieved lower HbA1c compared to controls during follow up measurements (**Table 5.2**). Compared with their respective control, all the studies in the intervention group reported an absolute decrease in HbA1c values (-0.4% to -3.2%). When compared with baseline values, all the studies reported lower HbA1c at follow up for intervention groups, although most of them did not report statistical analysis for this measurement (G. Foster et al., 2013; Lean et al., 2018, 2019; Taheri et al., 2020). While for control groups, the values remained similar or higher compared with baseline (-0.36% to +1.6%).

When we used the reported data from paired studies to analyse the magnitude of absolute change across study settings (research setting vs real world), the intervention group showed less reduction in 3 studies (Foster et al., 2013; Lean et al., 2018; Lean et al., 2019), 1 study reported an overall similar reduction (De la torre et al., 2013) and 2 studies reported a higher reduction

(Taheri et al., 2020; Al Asmary et al., 2018) in HbA1c values in the real world compared with the research setting (**Table 5.2**).

In terms of goal achievement, the percentage of participants who achieved HbA1c <7% in research setting was reported by only one study, in which 79% of the participants in the intervention group achieved this goal after 3 months of LI compared to 47% of control participants ($p<0.0001$), (G. D. Foster et al., 2009) (**Table 5.2**). This result was comparable with the real-world setting counterpart, which reported that 72% of participants in the intervention group achieved the target for HbA1c, while in the control group only 44% of participants achieved the goal ($p<0.01$) (G. Foster et al., 2013). All the studies reported an increase in the percentage of participants achieving HbA1c <7% after LI in a real-world. The percentage of participants achieving this goal varied from 32% to 72%. In the control groups, the percentage of participants achieving this goal varied from 0% to 44%.

It is interesting to note that Lean et al. 2018 and 2019 refers to the same study but in different follow up times. While at 12 months the measurements show -0.9% of absolute decrease in HbA1c, after 24 months this decrease is about -0.5%. They also reported a lower number of participants below the 7% HbA1c target compared to 12 months measurements. Nevertheless, after 24 months HbA1c values and the percentage of participants with HbA1c <7% after LI remained improved compared to the control group (Lean et al., 2018, 2019).

BW was a secondary outcome considered in this review. Of the 5 studies conducted in a research setting, 4 reported BW measurements but only 2 studies reported baseline and follow up values for control groups (Durán et al., 2010; G. D. Foster et al., 2009), and found that the intervention group achieved greater BW loss compared to control group, although the final BW was not different between the groups in 1 of the studies (Durán et al., 2010) (**Table 5.2**). Compared to baseline values, 1 out of 4 studies reported no statistically significant change in BW (Al Asmary et al., 2013) whereas 3 studies reported a decrease in BW varying from -3.5 Kg to -15.3 Kg. One study reported only the BW change for patients with T2D (Brown et al., 2015) and another study did not report statistical analysis for this measurement, because their calculation was based on the difference of the changes in BW achieved between control and intervention group (G. D. Foster et al., 2009).

In the real-world setting, 5 out of 6 studies reported baseline and follow up BW measurements for both control and intervention groups (**Table 5.2**). Compared to control, 4 of the studies reported greater BW loss in the intervention group, while 1 of the studies reported increased BW in the intervention group (Tourkmani et al., 2018), which was suggested to be due to insulin usage by the participants. A similar trend was found when comparing baseline and follow up values for BW measurements. The percentage of participants who achieved the goal of 5% of BW lost was reported by 4 out of 6 studies (G. Foster et al., 2013; Lean et al., 2018, 2019; Taheri et al., 2020), and in all of them the intervention group presented a greater percentage of participants achieving the goal, varying from 11% to 60% of participants in each study.

When we analyzed BW measurements between settings using the data reported, 3 studies showed a smaller reduction in BW (G. Foster et al., 2013; Lean et al., 2018, 2019), 1 study reported a greater reduction in BW (Taheri et al., 2020) and 1 study reported weigh gain (Tourkmani et al., 2018) in real-world setting compared to research setting. It was not possible to compare one of the pairs due to the lack of BW measurements in real world setting (García de la Torre et al., 2013).

5.3.5. Program barriers and facilitators in each setting

While barriers and facilitators reported by participants were not explicitly identified by research teams, they were extracted from the text (**Table 5.3**). Facilitators were found in 9 studies while barriers only in 2. Important facilitators included provision of food, which facilitated adherence and enhance weight loss (G. Foster et al., 2013; G. D. Foster et al., 2009; Lean et al., 2018; Lim et al., 2011), flexibility in the duration of the program phases (Lean et al., 2018), the structured approach of the educations sessions and the knowledge obtained from them (Al Asmary et al., 2013; Durán et al., 2010; G. Foster et al., 2013; G. D. Foster et al., 2009; Tourkmani et al., 2018). These characteristics, when combined with self-monitoring of blood glucose (SMBG) (Durán et al., 2010; García de la Torre et al., 2013), empowered participants to better manage their T2D. Furthermore, the use of multidisciplinary teams including clinical pharmacists and physiotherapists as well as quick referrals to HCP or resources as needed were viewed as facilitators (Al Asmary et al., 2013; Brown et al., 2015; Taheri et al., 2020; Tourkmani et al., 2018). On the other hand, constant blood sugar monitoring and side effects associated with TDR

were reported to negatively impact quality of life (Durán et al., 2010; Taheri et al., 2020). The duration of T2D considered by the studies is relatively of short duration, which can be seen as a facilitator. For the studies that reported this information (60%), all of them included participants with disease duration less than 6 years; 1 study included participants with disease duration up to 6 years (mean = 3 years) (Lean et al., 2018, 2019), 1 study up to 4 years (Lim et al., 2011), 1 study up to 3 years (Taheri et al., 2020), 2 studies around 1 year (Durán et al., 2010; Tourkmani et al., 2018) and 1 study included participants with disease duration less than 6 months (García de la Torre et al., 2013).

5.4. Discussion

While there are many studies that aim to demonstrate the benefits of lifestyle intervention to prevent or improve overall T2D management, only a handful were identified that included at least two of the cornerstones of DM management and had gone through a program scale-up process. In general, we did find evidence for a scale-up penalty ranging from 0 to 35%, with most real-world interventions achieving somewhat less HbA1c reduction than their clinical counterparts. Achieved HbA1c values either close to or below target (HbA1c <7%) presented by the studies in this review confirm that multiple approaches in T2D management can decrease HbA1c levels. Some of the studies achieved a considerable absolute reduction in HbA1c values. The study pair of Tourkmani et al., (Tourkmani et al., 2018) and Al Asmary et al. (Al Asmary et al., 2013), which presented the greatest real-world and research setting HbA1c reductions, respectively. Although the final HbA1c values were higher than the target recommended, it should be noted that these studies had the highest HbA1c baseline values, >10% for both control and intervention groups. This is consistent with observations that higher baseline HbA1c values predict a greater reduction post-intervention (Chrvala, Sherr, & Lipman, 2016). Furthermore, the results of this study are also confounded by higher insulin use in the intervention group. The remainder of the studies reported baseline HbA1c values closer to the target of 7%, accounting for their lower absolute reduction after intervention. Here, the reductions range from -0.4 to -1.4 in the intervention groups compared to -0.36 to +1.6 increase in the control groups. Additionally, some real-world studies showed sustained lower HbA1c even after 24 and 36 months following the LI protocol implementation (García de la Torre et al., 2013; Lean et al., 2019). T2D duration and poor management influence the extent of T2D complications and increases the risk of all

cause mortality (Ghouse et al., 2020), thus this range of improvement in HbA1c seen in the interventions is clinically important given its association with reduced microvascular complications, diabetes-related mortality and all-cause mortality (UK Prospective Diabetes Study Group, 1998).

The studies in this review mainly included participants with a short duration of T2D. Managing participants well at this early stage has several benefits. A recent observational study reported that for individuals with short duration of diabetes (< 5 years) the hazard of death increases with higher levels of HbA1c (Ghouse et al., 2020). In addition, given the progressive deterioration of T2D, as time passes the need for multiple therapies to maintain the same HbA1c target increases (Turner, Cull, Frighi, Holman, & Group, 1999).

Clinically meaningful improvements in HbA1c are associated with the use of diabetes SME, which provides benefits independent of HbA1c baseline levels (Chrvala et al., 2016) because it involves enabling knowledge, attitudes and self-efficacy to self-manage diabetes by means of educational and support programs that teach basic knowledge and skill training. In addition SMS provides frequent follow-ups and incorporates shared decision-making (Sherifali, Berard, Gucciardi, MacDonald, & MacNeill, 2018), resulting in overall improved glycemic control. This was reflected in all of the studies in this review given their use of SME + SMS approaches.

Nutritional approaches used in the studies included in this review aimed for weight loss through strategies that aligned with Diabetes Canada Clinical Practice Guidelines, which include counselling provided by a RD with expertise in T2D management with frequent follow-up (3 months) and weight loss of 5%-10% of initial BW for overweight individuals, (Sievenpiper, Chan, Dworatzek, Freeze, & Williams, 2018). BW loss was exhibited in all of the studies, except the study pair of Tourkmani et al. and Al Asmary et al., which reported higher final BW in the intervention group (Al Asmary et al., 2013; Tourkmani et al., 2018). The higher final BW reported in the in these studies was suggested to be due to higher insulin dosage in the intervention group (Tourkmani et al., 2018). Insulin is an anabolic hormone known to increase BW (Lau & Teoh, 2015). Despite that, even though several studies didn't report the percentage of participants achieving the goal of $\geq$5% BW loss, a rough calculation shows that all of them achieved a decrease of 5% or more of initial body weight, both in research and real world

settings. This suggests that the LI proposed are beneficial in achieving statistically significant and clinically relevant BW loss. Long-term weight management programs have been reported as effective for T2D treatment, reducing medications and cardiovascular risk and improving quality of life (Hamdy & Carver, 2008). Provision of food (pre-packed or liquid formula) was a strategy used to facilitate adherence and achieved weight reduction, leaving to question the long-term effectiveness given the importance and necessity of food skills (selecting, planning and preparing meals and snacks), to halt the progression of diabetes complications (Sievenpiper et al., 2018). Even though relapse management plans for weight regain were in place (Lean et al., 2018), they were based on food provision and medication to aid weight loss rather than development of food skills.

Physical activity provides extended physiological beneficial effects and is a crucial cornerstone to glycemic control through multiple complex mechanisms by decreasing insulin resistance, reducing visceral adipose tissue, and enhancing pancreatic ß-cell function (Wake, 2020). PA of 150 minutes per week of aerobic exercise and 2 sessions of resistance exercise are recommended to improve glycemic control (Sigal et al., 2018) and are associated with HbA1c reduction in patients with T2D (Umpierre et al., 2011). Combined aerobic and resistance exercise results in more pronounced improvements (B. Pan et al., 2018). Despite its well-established beneficial effects, PA is the cornerstone with least attention paid to it, with only two studies providing general recommendations in the research setting (Brown et al., 2015; G. D. Foster et al., 2009). Nevertheless, through the scale-up process, 2 recommended increasing the level of PA (G. Foster et al., 2013; Lean et al., 2018) and two aligned with the guidelines using a combined approach (García de la Torre et al., 2013; Taheri et al., 2020). PA is a powerful tool that tends to be underutilized where an individualized approach is recommended (Wake, 2020); provision of step counters (Lean et al., 2018), gradual rate of progression (Taheri et al., 2020), or PA programs designed for each individual by a physiotherapist (García de la Torre et al., 2013), are strategies with the potential to encourage PA in T2D patients.

Guidelines recommend that pharmacological therapy be mainly managed and adjusted by general practitioners; in particular, if HbA1c is more than 1.5% above target, drug therapy should be initiated at diagnosis, together with lifestyle changes, with metformin indicated as the first line therapy (Lipscombe et al., 2018). A combination of drug therapies may be necessary in

severe cases, and may include the use of dipeptidyl peptidase 4 (DPP-IV), sodium glucose cotransporters 2 (SLGT2) inhibitors, and glucagon like peptide-1 (GLP-1) receptor agonists. In pre-existing T2D, a more intensive approach is usually necessary. In this case, dose adjustment should be conducted, and poly-therapy evaluated (Lipscombe et al., 2018). Bringing a pharmacist to provide additional support to verify adherence, manage adverse effects, request additional tests (Al Asmary et al., 2013; Tourkmani et al., 2018), as well as incorporating SMBG use (Durán et al., 2010; García de la Torre et al., 2013) led to better glycemic management in the reviewed studies.

In summary, with regard to the primary and secondary outcomes of this review, the studies show clear effectiveness of lifestyle intervention for T2D management accomplished by incorporating the majority of the four cornerstones, each playing an essential role in a broad range of health benefits. This approach is supported by previous research, which highlights that given the deterioration of diabetes control with time, serial introduction of multiple therapies is necessary for glycemic control (Turner et al., 1999). This systematic review demonstrates the extent of the scale-up penalty of moving from efficacy to effectiveness. In that sense, this penalty ranged from a low of 22% to a high of 35% with two cases of no-penalty being observed. However, clinically relevant improvements in both HbA1c and BW were achieved in both settings and some evidence for longer term sustainability in the real world was presented. While it is true that none of the studies reported in this review have been broadly disseminated and established in routine T2D management, they are good examples of the steps future programs should go through before getting to that stage, thus providing strong foundations on which conclusions can be drawn. Furthermore, research studies should plan strategies to ensure success at the dissemination stage, where a greater scale-up penalty is expected as a result of moving away from tightly control settings (Welsh et al., 2010). These programs should be used as a guide, that can be adapted to individual patient characteristics and aptitudes. Implementing strategies to assess if participants are receptive, motivated and ready to engage would allow the greatest engagement, resulting in better glycemic control (Chrvala et al., 2016).

5.4.1. Limitations

The main methodological limitation in this review was the difficulty in comparing the study outcomes because of differences in the way data were reported and analyzed. For example, some studies reported outcomes as a comparison between final vs. baseline measurements (Al Asmary et al., 2013; Brown et al., 2015; Durán et al., 2010; Lim et al., 2011; Tourkmani et al., 2018), while others focused on changes after the intervention (G. Foster et al., 2013; G. D. Foster et al., 2009; Lean et al., 2018, 2019; Taheri et al., 2020). These differences were not only within the study setting but also between research and real-world setting pairs, which made it difficult to compare the intervention effect accurately between the studies. Additionally, not all studies reported using intention to treat analysis. Likewise, the lack of standardized statistical analysis between baseline and follow up times, or lack of control group, made difficult the assessment of their intervention effect. The differences in follow up time limited between-study comparison of efficacy. These limitations suggest that more attention to consistent practices and analysis among T2D management interventions would facilitate the translation to daily practice. Special attention should be paid when reporting intervention characteristics. Access to all of the program materials and detailed description of intervention characteristics should be accessible in order to allow effective detailed knowledge translation (Reis, McDonald, & Byers, 2008). It would be beneficial to have standardized data reports to facilitate the understanding of the magnitude of the translation within and between settings reported. In addition, a broader range of health benefits should be considered when evaluating the effect of these programs including the effect on hepatic fatty acid metabolism (Parry, Turner, & Hodson, 2020), intestinal microbiota and mitochondrial function (Vezza, Abad-Jiménez, Marti-Cabrera, Rocha, & Víctor, 2020). The risk of bias assessment highlighted that interpretation of the results should be done carefully and the lack of information reported should be taken in consideration. Furthermore, the unclarity of methodological information could account for difficulties in reproducing the same effects in different trials.

5.5. Conclusion

In conclusion, comprehensive LI that incorporate most of the cornerstones of T2D management have benefit on HbA1c in research settings and generally sustain those benefits in real-world

setting, albeit with a scale-up penalty under some circumstances. The finding of a modest scale-up penalty does not negate that real-world application of lifestyle interventions can result in clinically relevant improvements in diabetes outcomes.

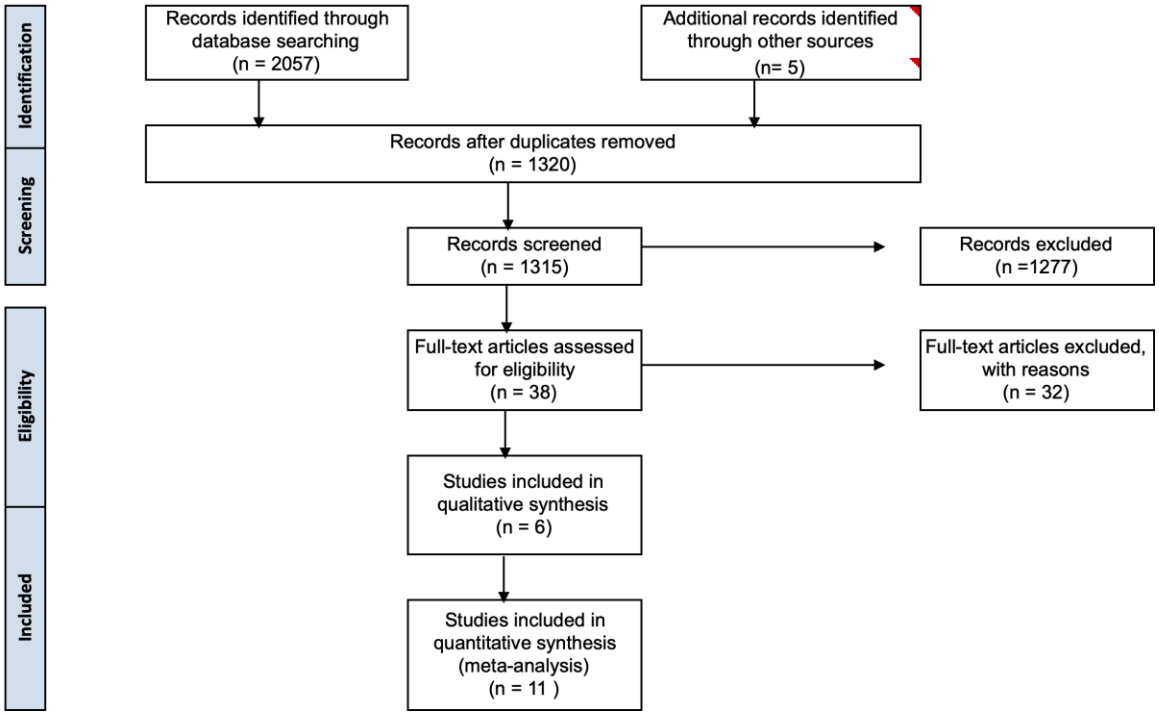

Figure 5.1: Flow diagram of the literature search

Table 5.1. Program intervention used by research and real-world setting studies.

Pillars for diabetes management according to Diabetes Canada Clinical Practice Guidelines				
Research setting				
Reference	**SME +SMS**	**Nutrition therapy**	**Physical Activity**	**Pharmacological therapy**
Foster et al., 2009	**Portion Control Diet (PCD)** **Group session:** These group attended 18 group session (weekly = week 1 - 12; biweekly = week 13 - 24) led by a HCP with expertise in behavioural weight control. **SME** **Self education topics:** Self-monitoring, stimulus control, goal setting and relapse managemen. Additional support material was provided by NutriSystem® D™	**Nutrition approach:** NutriSystem® D™. **Nutrient distribution:** 47% carbohydrate, 30% protein, and 23% fat. **Diet instructions:** Women 1250 cal/day - Men 1550 cal/day, 690 kcal/day were provided by NutriSystem® D™ (3 meals and 1 snack per day). The rest of the calories were added by conventional foods (2 additional sources of dairy, fruit, lean protein, and fat, and 4 sources of vegetables).	**PA:** primarily walking - beginning at week 4 with 4, 20 minute sessions/week and progressing to 5, 40 minute sessions by week 24.	N/A
Real world setting				
Foster et al., 2013	**Portion control diet (PCD)** **Group sessions**: (90min) led by experienced lifestyle and diabetes educators at weeks 0, 1, 2, 4, 8, 12, 16, 20 and 24. **SME** **Self education topics:** self-monitoring food intake and physical activity, stimulus control, goal setting, problem solving, cognitive restructuring and relapse prevention.	**Nutrition approach:** NutriSystem® D™ **Diet instructions:** PCD (three entrees and one snack daily) supplemented with conventional foods Goal: achieve ≈1250 kcal per day (women) or 1550 kcal per day (men) with the help of a calorie-counting guide. **Diet composition:** ≈55% of total energy from the packaged foods and 45% conventional food. (≈50–55% of energy from carbohydrate, 20–25% fat and 20–25% protein + ≈2300mg per day of sodium. Diet glycemic index: ≈34 (glucose scale).	**PA:** increase walking / aerobic activity) to >200 minutes/ week	Adjustment managed by respective providers. Self blood glucose recordings at least 2/day starting one week prior the intervention. If repetitive episodes of hyper- (three or more episodes >300mgdl-1) or hypoglycaemia (three or more episodes <60mgdl 1) were recorded, lifestyle strategies and medication adherence counselling was given.

Research setting				
Lim et al., 2011	**SMS:** Regular telephone calls were made to provide support and encouragement. **SME**: Portion size and healthy eating information was provided after the 8 week intervention.	**Nutrition approach:** Optifast, Nestlé Nutrition liquid formula.**Nutrient distribution:** 46.4% carbohydrate, 32.5% protein and 20.1% fat; vitamins, minerals and trace elements.**Diet instructions:** The liquid formula provided 600 kcal/day from which 510 kcal/day came from the liquid formula. The additional 90 kcal were provided with three portions of non-starchy vegetables. Recepies were provided to increase adherence. Participants were encouraged to drink 2L of water. At the end of the 8 weeks reintroduction of normal eating patterns was provided.**Dietary adherence:** Capillary ketone levels were used to assessed adherence.	**PA:** Participants were instructed to make no changes in their physical activity level.	N/A
Real world setting				
Lean et al., 2018	**Treatment group:** Usual guideline-based care **SMS:** Participants attended 35 appointment over 2 years. **SME:** Support printed materials for each phase of the intervention was provided to all participants in this group. **TDR phase**: Review visits were schedule 1 week after initiation of TDR and at 2 weekly intervals there after. **FR phase:** Participants monitor their weight weekly and review visits were schedule every 2 weeks. **Weight loss maintenance phase:** Monthly review appointment.	**Nutritional approach:** Counterweight Plus. **Diet instructions:** This program includes three phases: 1. Total diet replacement (TDR); 2. Structured food reintroduction (FR); 3. Structured support program for long term weight loss maintenance. **Diet Composition:** **TDR phase (0-12wks):** Liquid formula diet in the form of soups and shakes were provided for a period of 12 weeks. 823 - 853 kcal/day (59% carbohydrates, 13% fat, 26% protein, 2% fibre). A soluble fibre supplement (Fybogel 2 x 3.5 g/day) and 2.25L of water were prescribed to reduce constipation. **FR phase (weeks 12- 18):** Based on Eat well guidelines and with a caloric distribution of about 50% carbohydrates, 35% fat and 15% protein, food based diet was reintroduce while reducing TDR. **Weight loss maintenance phase (weeks 19 - 104):** Participants provided with an individually tailored energy diet for weight stabilisation and to prevent weight regain. **Relapse management for weight regain or re-emergence of diabetes**: Rescue plans during the 18-month maintenance stage were offered. 1. Weight regain >2 kg: One or two meals per day were replaced by liquid formula for a period of 4 weeks. Additionally orlistat (120 mg) was prescribed with each meal. 2. Weight regain between 4 - 15 kg: Liquid formula was reintroduce for a 4 week period with nurse/dietitian follow up every two weeks. Subsequent FR phase of 2-4 weeks with individualised dietary advised and physical activity reinforcement was provided.	**PA:** Step-counter and advice provided to increase daily PA to a maximum of 15,000 steps/day.	**TDR phase (0-12wks)**: Previous to the initiation of this phase, oral hypoglycaemic agents, antihypertensive and diuretic drugs were withdrawn and reintroduce if necessary. Beta-blockers and aspirin were continued if related to previous MI or angina management. Orlistat treatment with each meal was prescribed during relapse mangement phase.

Research setting				
Durán et al., 2010	**Lifestyle intervention**: Patient specific intervention were developed for each participant. **SME:** 1-h session were held to teach participant how to perform and collect SMBG test and data. **SMS:** At each follow up visit reinforcement of SMBG methodology was performed. Participants were followed every 2 weeks (first 3-months) and once every 3 months. **SMBG**: Six-point profiles every 3 days (before and 2 hrs. after breakfast, lunch, and dinner). If pharmacological therapy changes were done, profiles were also carried out. **SMBG stabilizatio**n: Five complete SMBG profiles within target in two consecutive visits reflected participant stabilization transitioning towards one profile every 2 weeks if they were on metformin or every week if they were in another treatment other than metformin and/or pioglitazone.	N/A	N/A	**Pharmacological therapy**: 850 mg of metformin. **FBG:** Fasting SMBG levels outside target (FBG >110 mg/dL) metformin was titrated if tolerated. If needed, pioglitazone was included. Basal insulin was added if target was not achieved. **PPBG:** If postprandial SMBG levels were outside target (PPBG between 145 and 160 mg/dL) glinide, a DPP-4 inhibitor, or sulphonlyurea was considered. Bolus insulin was added if target was not achieved.
Real world setting				
De la Torre et al., 2013	Similar to Research setting	N/A	**PA:** Aerobic and resistance training: 50 min x 4 days/week (2 supervised; 2 unsupervised) for 20 weeks. **Aerobic:** 75% MaxHR **Resistance:** 3 sets x 8-10 repetition each. **Time:** warm up - 20min of aerobic - 20 min resistance - cool down Program was designed for each individual participant by a physiotherapist.	**Pharmacological therapy**: 850 mg of metformin. **FBG:** Fasting SMBG levels outside target (FBG >110 mg/dL) metformin was titrated if tolerated. If needed, pioglitazone was included. Basal insulin was added if target was not achieved. **PPBG:** If postprandial SMBG levels were outside target (PPBG between 145 and 160 mg/dL) glinide, a DPP-4 inhibitor, or sulphonlyurea was considered. Bolus insulin was added if target was not achieved.

Research setting				
Brown et al., 2015	Monthly group approach program during 6 months delivered by a trained facilitator. **SME** **Group session:** Weekly (60-90 min) **SME** **Self education topics**: Self-monitoring, goal setting, stimulus control, cognitive restructuring, eating behaviour, maintenance, all of nothing beliefs, reward and support, problem solving and self-stem. Homework between sessions.	Recommendations based on guidance for healthy eating designed by the UK Department of Health using the eat well plate. Encouragement of regular meal intake and techniques to reduce portions and identify satiation, and instructions about portions and serving control. **Diet instructions:** based on starchy foods, 5 servings of fruit and vegetables, reduce fat intake and replace them with unsaturated fat sources, and high-quality sources of protein and dairy foods.	**PA:** at least 30 min/day, 5 days/week.	Adjustments made by physicians.
Real world setting				
Taheri et al., 2020 **Taheri et al., 2018**	Intervention protocol delivery by dietitians, personal trainers, and physicians. **SME** A dietitian helped the participants to identify appropriate food and portion sizes. Recipes and meal plans were provided. **Self education Topics:** similar to reserach setting **Physician visits:** baseline and after every 3 months. Dietitian and personal trainer visits every 2 weeks during diet replacement. **Clinic visits:** once a month after diet replacement.	**Diet approach:** Cambridge Weight Plan, Northants, UK. **Diet instructions**: total diet replacement followed by 12-week partial replacement and structured food reintroduction plan until achieve 3 meal/day pattern for 6 months guided by dietitian. **Diet composition:** low-energy formula provided 800–820 kcal/day with a caloric distribution of 57% carbohydrate, 14% fat, 26% protein, and 3% fibre. Raw vegetables and salad were allowed. After food reintroduction phase, a similar macronutrients distribution and consumption of low glycemic index foods were recommended. For constipation a fibre supplement (psyllium/inulin) was prescribed. **Diet replacement:** low-energy formula followed by own participants management of their food intake and lifestyle changes for 6 months. During the diet replacement and food reintroduction period, participants visited dietitians every 2 weeks.	**PA:** initially walking (minimum 10,000 steps/day) followed by at least 150 min/week of exercise (moderate intensity). Aerobic exercise (3 days/week) and resistance exercise (at least 2 days/week) - gradual rate of progression.	N/A

Research setting				
Al Asmary et al., 2013	Followed ADA guideline. **Multidisciplinary team:** senior family physician, nurse, clinical pharmacist specialist, dietitian, diabetic educator, health educator and social worker. **Intervention focus:** enhance clinic visits, monitoring of outcomes, improving interdisciplinary communication and coordination, evaluating the need of insulin titration, efficacy of the treatment. **SMS:** reminders, telephone calls and social worker support. **SME** **Self-education topics:** diabetes education, diets, medication adherence and self-management. **Clinic visits:** mean was 13 (range 6-26)	Dietitian appointments	N/A	The pharmacist was the case manager and met the participants once a week to check adherence to the intervention, manage hypoglycaemia, medication side-effects, request renal and liver function tests and refer participants to another team member. Medications adjustment was done in collaboration with the physicians.
Real world setting				
Tourkmani et al., 2018	Similar to reserach setting Followed ADA guidelines but intensified for clinical and social factors.	Similar to reserach setting	N/A	Similar to research setting

Table 5.2. Main outcomes (HbA1c and body weight) values reported by the research setting and real-world setting studies.

Research Setting						Real World Setting					
Author	**Follow up**	**Baseline**	**Follow up**	**Absolute Change**	**% goal achievement**	**Author**	**Follow up**	**Baseline**	**Follow up**	**Absolute Change**	**% goal achievemen**
Control HbA1c (%)											
Foster et al., 2009	3	7.5 ± 1.7	7.5 ± 1.8	0	47	Foster et al., 2013	6	7.9 ± 1.3	7.5 ± 1.3	-0.4	44
Lim et al., 2011	2	5.7 ± 0.1	N/A	N/A	N/A	Lean et al., 2018	12	7.5 ± 1.1	7.6 ± 1.1	+0.1	4
						Lean et al., 2019	24	7.5 ± 1.1	7.5 ± 1.3	0	3
Durán et al., 2010	12	6.6 (6.4 - 7.1)	6.6 (6.2 - 7.3)	0	N/A	De la Torre et al., 2013	36	6.7 ± 0.5	6.8 ± 0.6	+0.1	9.2
Brown et al., 2015	6	N/A	N/A	N/A	N/A	Taheri et al., 2020	12	6.95 ± 1.22	6.59 ± 0.92	-0.36	12
Al Asmary et al., 2013	6	N/A	N/A	N/A	N/A	Tourkmani et al., 2018	9	10.1 ± 1.6	11.7 ± 11.3	+1.6	0
Intervention HbA1c (%)											
Foster et al., 2009	3	7.6 ± 1.6	6.7 ± 1.3$$	-0.9	79***	Foster et al., 2013	6	7.6 ± 1.3	6.9 ± 1.2$	-0.7	72*
Lim et al., 2011	2	7.4 ± 0.3**	6.0 ± 0.2##	-1.4	N/A	Lean et al., 2018	12	7.7 ± 1.2	6.8 ± 1.2$$$	-0.9	46
						Lean et al., 2019	24	7.7 ± 1.2	7.1 ± 1.5$	-0.5	36
Durán et al., 2010	12	6.6 (5.8 - 7)	6.1 (5.8 - 6-5)#*	-0.5	N/A	De la Torre et al., 2013	36	Ia = 6.6 ± 0.3 Ib = 6.7 ± 0.5	Ia = 6.2 ± 0.6**# Ib = 6.1 ± 0.6 **#	Ia= -0.4 Ib= -0.6	Ia = 32.3 Ib =44.6
Brown et al., 2015	6	8 ± 3.8	7.6 ± 3.6#	-0.4	N/A	Taheri et al., 2020	12	6.95% ± 1.40	5.96 ± 0.84$	-0.99	61***
Al Asmary et al., 2013	6	10.5 ± 2.7	8.6 ± 1.9##	-1.9	32	Tourkmani et al., 2018	9	11.2 ± 1.4**	8.0 ± 1.2**##	-3.2	18.5

Control BW (kg)											
Foster et al., 2009	3	110.9 ± 23.5	110.4 ± 23.0	-0.6	N/A	Foster et al., 2013	6	104.0 ± 20.1	101.8 ± 19.4	-2.2	14
Lim et al., 2011	2	101.5 ± 3.4	N/A	N/A	N/A	Lean et al., 2018	12	98.7 ± 16.1	97.7 ± 16.4	-1	0
						Lean et al., 2019	24	98.8 ± 16.1	96.4 ± 16.3	-2.4	2
Durán et al., 2010	12	76 (67 - 89)	76.5 (64 - 91.7)	+0.5	N/A	De la Torre et al., 2013	36	N/A	N/A	N/A	N/A
Brown et al., 2015	6	N/A	N/A	N/A	N/A	Taheri et al., 2020	12	101.7 ± 19.3	96.85 ± 17.13	-4.85	29
Al Asmary et al., 2013	6	N/A	N/A	N/A	N/A	Tourkmani et al., 2018	9	74.8 ± 14.3	74.9 ± 14.8	-0.1	N/A
Intervention BW (kg)											
Foster et al., 2009	3	111.5 ± 19.3	103.9 ± 17.6 $$$	-8.2	N/A	Foster et al., 2013	6	101.8 ± 16.7	93.9 ± 14.7$$$	-7.3	54***
Lim et al., 2011	2	103.7 ± 4.5	88.4 ± 4.3*#	-15.3	N/A	Lean et al., 2018	12	100.4 ± 16.5	90.4 ± 16.4$$$	-10	24
						Lean et al., 2019	24	101 ± 16.7	93.2 ± 17.2$$$	-7.6	11
Durán et al., 2010	12	80.5(69 - 87)	76 (68.8 - 85.7)#	-3.5	N/A	De la Torre et al., 2013	36	N/A	N/A	N/A	N/A
Brown et al., 2015	6	N/A	N/A	-5.7##	30	Taheri et al., 2020	12	100.6 ± 19.5	90.30 ± 16.85$$$	-10.3	60***
Al Asmary et al., 2013	6	81.7 ± 13.3	82.9 ± 15.5	+1.2	N/A	Tourkmani et al., 2018	9	82.9 ± 17.6**	85.7 ± 17.8**##	+2.8	N/A

Note 1: Absolute change was calculated by the authors by subtracting the follow up value from the baseline value.
Note 2: Goal achievement expresses the percentage of participants who achieved the recommended goal of losing at least 5% of BW and HbA1c <7%. Goal achievement in % was calculated by the authors when reported in number of participants.
Note 3: ( ) refers to the first and third quartile reported in the study.
Note 4: For Brown et al. 2015 only the subgroup of participants with T2D were included in our review.
Note 5: p value expressed when provided by the studies included in the review. * expresses significant difference between intervention vs. control group regarding final means obtained by each group and # express statistical difference vs. baseline values. */# $p<0.05$, **/## $p<0.001$, ***/### $p<0.0001$.
Note 6: Shadowed squares means that the study did not report a statistical calculation for baseline vs follow up time. Instead, the statistical value for the difference between the changes obtained by control and intervention groups was reported. \$ $p<0.05$, \$\$ $p< 0.001$ and \$\$\$ $p<0.0001$.
Abbreviations: PCD, portion controlled diet; SMBG, self-monitoring blood glucose

Table 5.3. Barriers and facilitators in research and real world setting studies.

Research setting			Real world setting		
Author	**Facilitator**	**Barriers**	**Author**	**Facilitator**	**Barriers**
Foster et al., 2009	**1.** The structured approach (prepackaged, portion-controlled) of the meal plan facilitated adherence and enhanced weight loss. **2.** Commercially available program.	N/A	**Foster et al., 2013**	**1.** PCDs provide pre-measured amount of food and energy intake that facilitate weight management. **2.** Fewer sessions than a traditional program, which facilitates patient adherence and reduce costs.	N/A
Lim et al., 2011	**1.** Diabetes duration: < 4 years	N/A	**Lean et al., 2018**	**1.** Flexibility of the program (duration of the different phases) was important to achieve results. **2.** Relapse management support for those that needed a "rescue plan". **3.** Diabetes duration: Mean 3 years (0-6 years)	N/A
Durán et al., 2010	**1.** SMBG helps participants and HCP to adjust medication, diet (food type, quantity, timing, preparation) and exercise for optimal glucose levels. **2**. Provides real-time information enabling timely and appropriate treatment adjustments. **3.** SMBG training/education empowers patients to know how to interpret the results and more importantly know what to do with that data. **4.** Diabetes duration: < 1 year	**1.** SMBG impact on quality of life.	**De la Torre et al., 2013**	**1.** Adherence to lifestyle recommendations can be achieve and enhanced through the use of the SMBG tool. **2.** SMBG provides blood glucose information which combined with education provides participants with a powerful motivator to measure directly the impact of their eating and PA behaviour. **3.** Diabetes duration: < 6 months	N/A
Brown et al., 2015	**1.** Care provided by specialist during 24 week period (longer than usual). **2.** Structured approach, use of standard presentations and coverage of core topics in each session. **3.** Participants adherence shown to be important for greater weight loss.	N/A	**Taheri et al., 2020**	**1.** Young participants with recent diagnosed T2D. **2.** Emphasis on physical activity with the help of personal trainers to maintain weight loss. **3.** Only one trained multidisciplinary team to apply the intervention. **4.** Diabetes duration: < 3 years	**1.** Side effects in the intervention group, associated with the TDR phase.

Al Asmary et al., 2013	**1.** Multidisciplinary team **2.** Clinical pharmacist - focus on insulin intensification. **3.** Integrated care focusing on more clinic visits, glycemic management, quick referral to specialists, adherence and participants education.	N/A		**Tourkmani et al., 2018**	**1.** Multidisciplinary team. **2.** Short diabetes duration. **3.** Clinical pharmacist - focus on insulin intensification and quick referral to specialists. **4.** Focus on multiple interventions, including self education and specialist advice to improve glycemic control, adherence. **5.** Diabetes duration: approx. 1 year	N/A

Abbreviations: PCD, portion controlled diet; SMBG, self-monitoring blood glucose; T2D, type 2 diabetes.

Chapter 6: Identification of contextually appropriate tools and solutions designed to facilitate healthy eating in people with T2D

6.1. Introduction

Type 2 diabetes (T2D) is a complex, multifaceted disease driven by multiple pathophysiological processes (Pearson, 2019). Thus, a multidisciplinary approach that integrates the four main pillars of T2D management is needed to achieve optimal glycemic control, thereby minimizing health complications (Diabetes Canada Clinical Practice Guidelines Expert Committee, 2018). However, incorporating these recommendations into daily life represents a heavy burden on patients, who need to incorporate multiple treatment strategies into daily life including adherence to medications, changes in eating habits and physical activity.

Multifaceted lifestyle interventions (LI) that include change in diet, exercise as well as education help guide participants through this overwhelming process, resulting in significant improvement in cardiovascular disease risk factors in patients with T2D (Chen et al., 2015). Through a process of self-management education and support (SME and SMS) people with T2D can acquire the motivation, knowledge and skills necessary for a lifetime of well-controlled blood glucose (Sherifali, Berard, Gucciardi, MacDonald, & MacNeill, 2018). As presented in Chapter 5, strategies to maintain and enhance LI programs should integrate and provide the same importance to each pillar of T2D management and increase or maintain its intensity over the long term. However, as reflected by these studies and our previous results, there is still a gap between what people learn in the programs and what they do over the long run. (Archundia-Herrera, Subhan, Sakowsky, Watkins, & Chan, 2020). This is especially true for nutrition therapy. Since healthy eating involves a wide range of behaviour modifications and skill acquisition this behaviour is especially hard to achieve and sustain in the long run (Forouhi, Misra, Mohan, Taylor, & Yancy, 2018). Even though some studies have focused on identifying the barriers and facilitators to follow the recommendations (Booth, Lowis, Dean, Hunter, & McKinley, 2013; Mohd Suan, Asli, Abdullah, Shafie, & Johari, 2019), there is an unequivocal imbalance with a lack of focus on enablers when developing the interview guides (Armstrong and Fettig, 2020), thus little is known about how to facilitate improvements in nutrition behaviour, especially from

the participants' perspective (Armstrong and Fettig, 2020). Thus the aim of this study is to work with participants to understand their perceptions and lived experiences regarding healthy eating behaviour change, enabling us to identify and incorporate relevant intervention components to the PPLP and other LI programs.

6.2. Methodology

6.2.1. Design

An explorative qualitative study was undertaken to understand the lived experience of people with T2D, what healthy eating habits means to them, and how they solve some of the barriers they encounter when implementing healthy eating behaviours, purposeful sampling was used. This method allowed for the selection of information-rich cases from which we could learn, yielding insights and in-depth understanding (Patton, 2014). Additionally, participants were recruited from different age groups, gender identifications, socio-economic backgrounds, and cultural affiliations to maximize variations of participant context as much as possible. The COREQ checklist was used as a guide when reporting the study methods (**Appendix 6.0**) (Tong, Sainsbury, & Craig, 2007).

6.2.2. Participants

The study took place in the Human Nutrition Research Unit at the University of Alberta, Edmonton, AB, Canada and online using secure, encrypted videoconferencing software. Adults (+18 years), diagnosed with T2D (self-identified) who had participated in LI programs, had past experience in consultations with a registered dietitian (RD), and/or any other HCP regarding their T2D, and who were able to speak/write English were included in this study. Individuals were not eligible to participate if they met any of the following criteria: i) not able to read or write English, ii) type 1 diabetes, iii) pregnant or with medical comorbidities requiring highly specialised diet.

Participants were recruited from the 5AsT cohort (Campbell-Scherer et al., 2014) and the Alberta Diabetes Institute Research Contact Registry. In both cases, the original databases were searched to identify possible participants. Once identified, those from the ADI Research Contact Registry were sent information about the study and asked if they were interested in participating. The list

of possible participants was then provided to MCAH who approached participants via telephone, as were individuals from the 5AsT cohort (**Appendix 6.1**). In this first contact, MCAH explained the purpose of the study in more detail, as well as the procedure, time requirement; she then answered questions and invited participants to participate. Those interested were provided with an information letter containing all the details of the study and researchers contact information (**Appendix 6.2**). A total of 82 participants were obtained from the two databases; 68 participants were phoned; 29 did not answer and a voice messege was left; 39 were invited to participate, 10 declined due to lack of time mainly; 14 said yes but later declined to participate due to COVID or difficulties connecting to the video-conference interview: 15 consented to participate[1]. The study was approved by the ethics board of the University of Alberta (Study ID: Pro00092713). All participants provided written informed consent either in person or via a Google form provided via an email link prior to their interview.

6.2.3. Procedure

One-on-one, semi-structured, open-ended, in-depth interviews were conducted. Patton´s guide (Patton, 2014) was used to develop the interview guide. A total of ten questions were asked in order to understand participants' experiences in relation to healthy eating habits. The interview was divided into three sections. The first section aimed to understand their overall knowledge and the importance healthy eating played in their lives; for example, "*How important is healthy eating to you when you think about your diabetes?"* The second section aimed to understand past experiences in relation to healthy eating; *"Describe to me any strategies you have use to help you eat healthy in the past?"* The last section aimed to understand how to facilitate people's adherence to the Diabetes Canada Nutrition Therapy guidelines, particularly focusing on behaviours that were potential targets for PPLP intervention; *"What type of activities could we offer to help people make these changes?"* Furthermore, since the Pure Prairie Living Program (PPLP) aimed at helping people adhere better to the Canadian guidelines (Archundia-Herrera et al., 2020), participants were presented with a summary of the following key messages from the

[1] The number of participants that were contacted and declined to participate was considered to be higher than normal. Considering that COVID-19 pandemic escalated during the conduct of this study, the study team considered it was understandable for participants to be apprehensive about participating.

Diabetes Canada Nutrition Guidelines to better understand the behavior and identify possible intervention options.

- Select whole and less refined foods instead of processed foods, such as sugar-sweetened beverages, fast foods and refined grains
- Reduce caloric intake to achieve and maintain a healthier body weight
- Pay attention to both carbohydrate quality and quantity
- Select unsaturated oils and nuts as the preferred dietary fats
- Choose lean animal proteins. Select more vegetable protein

Cues and probes were used to clarify and obtain additional data. Journal notes were taken during and after each interview to record the researcher's reflections, feelings and interpretations (Patton, 2014).

Interviews were conducted by a female author (MCAH - RD, MSc, PhD candidate) with previous research experience with this population and in conducting focus groups. The reason for conducting the study and professional background of the interviewer were presented to the interviewees before the start of the session. Interviews were audio recorded (with participants' consent). Interviews were conducted between March 2020 and September 2020, either face-to-face or via videoconference. Three pilot interviews were carried out to ensure coherence and flow of questions, after which adjustments were made to the interview guide (**Appendix 6.3**). Participants were asked to complete a basic demographic questionnaire (**Appendix 6.4)**.

6.2.4. Data analysis

Data were collected and analysed concurrently. All interviews were transcribed *verbatim* by an outsourced transcription service (Consentia Inc., Edmonton, Canada) and subsequently checked against the audio recording for accuracy by MCAH. Each transcription page contained a header with the participant code (name removed and replaced with a number), the number of the interview, the location and date of the interview and the page number. The data collected during the interviews was managed, analysed and coded using NVivo 12.6.

Thematic analysis was used for identifying, analysing and reporting patterns within the data (Braun & Clarke, 2006). An essentialist paradigm was adopted in order to report experiences, meanings and the reality of participants (Braun & Clarke, 2006; Vaismoradi, Turunen, & Bondas, 2013). Inductive approach was used, thus, no predefined outcomes were established, and instead, the coded categories were derived directly from the data. The process of data analysis was guided by Vaismoradi (2013) and Braun & Clarke (2006) (Braun & Clarke, 2006; Tong et al., 2007; Vaismoradi et al., 2013). To ensure rigor, two independent coders (MCAH, CBC) coded four interviews using open coding, enabling the creation of initial codes from which two independent coding manuals were created. MCAH and CBC compared and discussed the similarities to create a final coding manual. The rest of the interviews were coded by MCAH, providing full and equal attention to each transcript and refining codes as needed. MCAH defined categories and subsequently checked for convergence and divergence with CBC to create the final categories.

6.3. Results

The results of this study are organized in 5 sections. The first section describes the participants' characteristics, background and health. The second section describes participants' experience in regards to feelings, motivators and personal attributes when dealing with being diagnosed and living with T2D. The third section describes the impact external forces have had on their T2D management. The fourth section refers to participants' health behaviour cycles and current knowledge regarding T2D management and healthy eating. The fifth section reviews what participants would like to have included in a program.

A total of 15 participants aged 30 – 79 years were interviewed (mean age 61 years). Participants had on average 12.6 years of T2D diagnosis varying from 5 to 25 years. Participants also varied in gender, ethnicity, education and socioeconomic status (**Table 6.1**). Most participants were from the greater Edmonton area, but had moved around during their education years or as a result of work. A wide variety of professions, from taxi drivers, librarians, and full time parents, to labour workers, healthcare professionals and bureaucrats participated in the study. The majority of the participants reported having concomitant health issues: "*I broke my back in '08 so I have challenges with that - PT153", "I've gone through, I've gone through prostate cancer*

– PT132", "I got arthritis in my knees – PT98". Several participants shared having mental health issues: *"I was d-diagnosed with severe depression – PT178", "my GP called it anxiety depression. Later on it was diagnosed as PTSD – PT97".* Some identified having obesity from an early age as a health issue, *"as a child… [Smacks lips] I was, uh, I was always overweight – PT97";* others linked obesity to childbirth *"I gained a lot with the first child - PT38"*, *"after you have a baby, … I had gained a tremendous amount of weight with that pregnancy – PT623";* others linked it to pharmaceutical therapy, especially with the use of insulin: *"I've been gaining more weight – just diabetes and medication I'm taking. [Interviewer: Mhmm.] Insulin and all [stammers] the pills. I'm just, like, exploding – PT153".*

6.3.1. Theme 1: Dealing with being diagnosed and living with T2D

The analysis revealed a pattern of participants reporting being scared, confused, overwhelmed and terrified when diagnosed with T2D; many also experienced the process of living with T2D as overwhelming, where they felt anxious, trapped and ashamed, thus making it an everyday struggle. Those patterns identified dealing with T2D as a major theme of this analysis (**Table 6.2**).

Feeling accountable and engaged influenced and impacted how participants dealt with being diagnosed and living with T2D. Some participants were motivated and felt accountable to deal with T2D so they wouldn't be a burden to others and to avoid developing further health issues. Achieving a good quality of life was a reason for dealing with T2D, as were life goals and future consequences. Participants noted that making an effort to be mindful, practicing self-control, and taking ownership of ones' health were ways to deal with T2D (**Table 6.2)**.

6.3.2. Theme 2: Impact external forces have on T2D management

Participants' individual context influenced the way they were able to manage their disease, making this a theme that reflected the impact external forces and their context had on their T2D management. Health care providers (HCPs) played a major role in providing patients with adequate guidance and tools to enable successful management. Participants reported being granted access to programs, updated information and ideas, and felt encouraged to adhere to their guidance when their HCP were encouraging, enthusiastic, practically-oriented, positive, and supportive (**Table 6.3**). In contrast, for those who had difficulties accessing a HCP, or who

encountered a HCP who did not provide enough time, attention or clear information, as well as those who did not support different treatment strategies and in general did not listen to them, the negative experiences had a direct detrimental impact on the participants' T2D self-management (**Table 6.3**).

Family also had a big influence on how participants managed their T2D. Having a family member that had gone through the same process encouraged a hands-on approach to avoid "going down that road". Household members that provided encouragement, guidance and support motivated and enabled a positive attitude towards T2D management (**Table 6.3**). On the contrary, loss of a family member and family strains had a direct negative effect and led to discouragement and a surge in apathetic feelings. Participants also acknowledged that they compromised their own desire to eating healthy in order to harmonize meals with their family members. Becoming parents also hindered T2D management as a result of lack of time and picky eating of children, which required preparing different meals (**Table 6.3**).

Several major factors that affect participants' T2D management were directly influenced by their everyday context including time, personal resources and competing priorities. Time and type of work impacted the quality and type of food they consumed and several expressed views of healthy food being expensive, not affordable for everyone, and laborious to prepare whereas "junk food" was seen as easy, cheap and available. Changes in living arrangements, such as moving from their parents' home to living by themselves, or having children move out and becoming an empty nester, or having ones' partner pass away also affected the way participants managed their T2D. On one hand, having someone at home who took care of the planning, shopping, and cooking could lead to a lack of these skills when that person moved out, resulting in increased consumption of fast foods. On the other hand, cooking for just one after being used to cooking for more people was described as too much work and not worth the effort. The food environment, exemplified as widespread availability of fast food and processed food, coupons, TV advertisements and promotions/discounts explained in part lack of adherence to T2D management (**Table 6.3**).

The current, unprecedented COVID-19 situation had a negative impact on T2D management. Having gyms, recreation centers and pools closed down triggered reductions in physical activity

despite available classes being offered online. Participants expressed strain in going out for walks. Isolation from family, friends and work has been hard and stressful to adapt to (**Table 6.3**).

6.3.3. Theme 3. Health behavior cycle

While knowledge related to T2D varied between participants, there was a common awareness that feeling unwell related to blood glucose levels. Reasons as to why blood glucose was elevated were linked to early morning obligations such as work, food choices and stress levels. Interestingly, while acknowledging that medication adherence, diet, and controlling levels of stress helped to control blood glucose levels, uncertainty about which type of physical activity, what specific diet they should be consuming and impact of ethnic background were noted. Furthermore, T2D was recognized as multifactorial disease, where routine medical check-ups are necessary (**Table 6.4)**.

Part of the aim of the interview was to obtain an understanding of what people perceive by "healthy eating habits". Participants in the study expressed their understanding of healthy eating habits in a variety of terms. They talked about healthy eating in terms of type of foods (fruit and vegetables, fish, poultry, red meet, white flour, whole wheat flour, pasta, sugar), nutrients (proteins, carbs, fats, fiber), state (natural, organic, processed food, artificial ingredients, junk food), perceived value (nutritious foods, empty calories, good food, bad food) and in terms of how to eat healthy (follow Canada Food Guide, use the plate method, limit calorie intake, portion size, less process food, meal planning) (**Table 6.4).** Some participants described eating healthy with antagonism, referring to it as something they have to do, but do not enjoy. Uncertainty about healthy eating was mentioned in terms of knowing what they should not be eating but unsure of what they should be eating, how much, and when (time of day) (**Table 6.4)**.

When looking at the specific knowledge and understanding of the key messages from the Diabetes Canada Nutrition Guidelines presented to participants, a notable gap in knowledge emerged, in that people understood the guidelines, but were uncertain and hesitant as to how to perform them. This was accentuated in the key messages that used technical language such as

"unsaturated oils, glycemic index, dietary patterns" (**Table 6.4)**. Furthermore, the thematic analysis revealed a pattern of participants reporting that they knew what they should do but doing something different; many also reported going through cycles of "good behavior" and "bad behavior". Those patterns make health behavior cycle a major theme of the study (**Table 6.4)**.

6.3.4. Theme 4. Understanding participants' needs and identifying intervention components

As expected, the majority of the participants had received a variety of T2D management advice from HCP (general practitioners, specialized MDs, registered nurses, registered dietitians, pharmacist, etc.), had attended various educational programs at different health facilities (Hospitals, Primary Care Networks, University Research Centers) and commercially available programs (Jenny Craig, Weight Watchers) that focused on different pillar of T2D management (**Table 6.5 and 6.5.1, Figure 6.1**).

Inquiry of intervention components revealed the **program content** as informed by participants. The requirements espoused by participants included training in a wide variety of components comprising the different pillars of T2D management. Knowledge in programs should be "explicitly clear". Information related to the severity of T2D consequences, how to pack an emergency kit, blood glucose monitoring, nutrition, diet on a budget and/or household diet, foot care, blood glucose monitoring and medication effects were requested (**Table 6.6)**. Access to a multidisciplinary team through the program including registered nurses, registered dietitians, kinesiologists, pharmacist and **mental health** therapy and counselling, was considered an asset. Providing exercise programs that are **individualized,** and understanding and **knowing** who is in the program (what their needs are) were considered essential. Furthermore, they described wanting to be held accountable if they didn't comply with the program. The content provided should be **applicability, practical and realistic** to address the participants' desires. Some mentioned learning how to order something healthy from a fast food chain, or what to look for at a drive-through window that is healthier. Application of a variety of nutrition skills was sought including cooking classes for T2D. Participants explained knowing what they should not consume but required knowledge of alternatives of what they should/could consume, thus questions related to what to eat, how much to eat, when to eat should be answered. Participants

desired learning how to go from big portions to smaller portions, or wean off sugar and processed foods; they felt that learning this would actually have an impact on their health. In addition, learning how to use a glucometer and the importance and relationship it has with food consumption and exercise was an active learning approach they desired. Some participants explained that doing the measurements but not really understanding why or what they could do about it made it essentially useless (**Table 6.6)**. A continuingly expressed requirement from participants was to **make eating healthy easy** by means of, for example, providing a line of T2D fast food, having someone else provide the food and takes care of the cooking, an option where no shopping for food, no looking at food, no guessing is required; it has to be as *"simple as opening a bag of potato chips"* – ***PT115.*** **Individualized attention, follow-up** and **ongoing group supports** were also identified as critical components of a program. Participants explained that having one-on-one sessions with HCP who could answer questions, set goals and track their progress could provide them with a plan that works for them and a sense of purpose. Likewise, participants desired a program that was ongoing, provides a refresher every couple of years, sends reminders via text message, e-mail, phone calls or provides a coach as an incentive to keep going. **Group support systems** were a concurring request, given the value participants saw in being able to be part of a group of people that understood them, were going through the same process and could relate to their experience. Having a group that was ongoing, meets on a regular basis, and provides some type of buddy or mentor system were described (**Table 6.6**).

Lastly, some recommendations on a **policy change** level were made. A request for clearly-marked with the healthy options spaces in convenience stores should be put in place. If participants had learned more about health and nutrition at early stage and incorporated healthy eating habits within their school curricula, they felt it would have improved their chances of maintaining health eating through their adult years (**Table 6.6**).

From participating in different programs, receiving advice and guidance from different sources, and through their own personal experience, participants are valuable sources of experience and knowledge, able to provide advice to help people manage T2D. **Table 6.7** shows an overview of the subthemes pertaining to advice from people with diabetes to people with diabetes. Tracking food consumption (limiting, measuring, monitoring and logging), being mindful of food choices (don't add salt, no pop, don't eat what you don't love, eat seasonally, consume vegetables),

taking ownership of one's health (have a plan, have a support system, think of the long term) and having a good team support (with health care team and friends and family) were advice and recommendations suggested to help manage T2D.

6.4. Discussion

The present study was designed to understand participants' perceptions and lived experiences regarding healthy eating behaviour change, enabling us to identify and incorporate relevant intervention components into the PPLP and to guide the development of future LI programs. When moving through the phase of evaluating the PPLP in a Primary Care Network, we identified the need to provide more guidance for participants to be able to incorporate healthy eating behaviour in their everyday lives (Archundia-Herrera et al., 2020). In that study (Chapter 5), some initial themes regarding gaps in the PPLP programming were revealed, which provided the rationale for the present study.

Findings from the present study reflect the participant perspective that living with and managing T2D is an overwhelming process that mirrors the intricate process of providing effective T2D care. Others have identified that dealing with being diagnosed and living with T2D or other health issues is an overwhelming process associated with negative feelings an anxiety. Crossley, through the use of focus groups, illustrated how health is connected to morality (Crossley, 2003), which was reflected in this study in that part of participants' motivation thrive was to avoid being a burden to others and to maintain their independence. The latter is a highly valued function that has been reported previously in older women (Gustafsson, Andersson, Andersson, Fjellström, & Sidenvall, 2003). Age also seems to be a factor that hinders motivation in older adults, as reported previously (Chambers, Lobb, Butler, & Traill, 2008).

As noted by Atkins & Michie (Atkins & Michie, 2015), our results reflect that healthy eating behaviours are influenced by and form part of a complex, evolving system. Participants indicated that their behaviour was influenced by their personal health background, history, and their external environment where work, family and HCP promote changes in their behaviour towards more positive or negative outcomes.

Participants had a good understanding of the relationship between T2D and eating habits. When participants were asked what healthy eating habits were, a wide variety of accurate information was described, referring to types of foods, nutrients, degree of processing, perceived nutritional value and in terms of guidance. These findings are consistent with a previous study exploring healthy eating (Povey, Conner, Sparks, James, & Shepherd, 1998). Not surprisingly and in line with previous results (Lake et al., 2007; Paquette, 2005), a health behaviour cycle was described consistently throughout the interviews, where participants reported going through cycles of "good behavior" and "bad behavior". Qualitative studies have provided insight towards understanding this gap, for example, participants' identity, social factors, resources, environment and competing priorities influence their eating behaviour. A deeper description of these factors is beyond the scope of the present study, but further detail can be found in the review of Bisogni (Bisogni, Jastran, Seligson, & Thompson, 2012).

Interesting, even though the interview guide was developed to focus on healthy eating and how to facilitate adherence to the guidance, requirements outside this scope were mentioned. The "ideal" program content as informed by participants should involve care that covers the major cornerstones of T2D care including, SME + SMS, nutrition therapy, physical activity, pharmaceutical recommendations, foot, eye and dental care as well as mental health (**Figure 6.2**) reflecting on the complexity of T2D (Pearson, 2019). In addition, several additional programming characteristics were sought. First, an active learning, hands-on approach were desired for all of the knowledge being taught. For example, instead of just recommending or teaching what not to eat, participants would like to learn what they can eat, how to prepare it (cooking classes) and what it looks like in a real-life situation (e.g. drive through at a fast food restaurant). Another example is when teaching the relationship between food, physical activity and blood glucose levels, the lesson should incorporate active real-life demonstrations.

The second characteristic is that the program should incorporate close follow-up of participants and provide individualized attention. Interviewed participants emphasized the importance of researcher and HCP learning who is in the program – **know your audience** – because through this understanding they can provide individualized advice that will be effective for each individual context. Research in this area has recently been developed by the 5A's Team, whose research shows that patients with obesity want personalized, evidence-based care (Torti et al.,

2017)(Asselin, Osunlana, Ogunleye, Sharma, & Campbell-Scherer, 2016). The HCP delivering programs needs to convey compassion and listening; try to make sense of root causes and contextual factors, focus on whole-person health and action planning, foster reflection and experimentation within others ; these are key processes for a personalized approach to support and manage health improvements (Luig, Anderson, Sharma, & Campbell-Scherer, 2018) and mirror the expressed needs of people with T2D. This approach has been recently incorporated into the Canadian Obesity Guidelines, which foster a patient-centred health outcome approach (Wharton et al., 2020). Increasing skills, abilities and confidence of HCP in this area could be achieved, in part, by training in "healthy conversation skills", which allow the development of competencies for identifying and creating opportunities to hold healthy conversations, using open-ended questions, reflecting on practice, listening more than talking, and supporting SMARTER goal setting (Black et al., 2014). Such competencies would address participants' needs as shown in the themes developed from the participants' interviews.

Third, a group or peer support system should be incorporated into the program. The importance of belonging to an ongoing, group support system that continues beyond the end of formal programming was underlined throughout the analysis. Such support groups were believed to provide a safe space where empathy, acceptance and understanding can be sought. Mohr et al., show that these groups are more effective when moderators are integrated to the team (Mohr, Burns, Schueller, Clarke, & Klinkman, 2013) and recently, such groups have moved to (or added) online interfaces though social media such as WhatsApp, Twitter and Facebook (Rains, Peterson, & Wright, 2015) thus enabling interactions even when face-to-face meetings are not possible. This could be important for uptake, given the priority-juggling challenges voiced by our participants.

Lastly, changes at the policy level were requested, including clearly-marked "healthy options" spaces in convenience stores to facilitate healthy eating. Recently, Mexico implemented front-of-pack warning labels on food and beverages products deemed unhealthy to help people make healthier choices; however it is too early to evaluate the effectiveness of these approach (White & Barquera, 2020).

A recent research study aimed at understanding how to facilitate healthful behaviour change in a culturally-sensitive self-management support program for T2D in the United Kingdom was developed (Moore, Rivas, Stanton-Fay, Harding, and Goff (2019). Their approach consisted of applying the Behaviour Change Wheel (BCW) in the design and identification of potential targets for intervention through conduct of focus groups and using a pre-conceived deductive analysis based on the BCW (Moore et al., 2019). Interestingly, key concepts of social support, credible sources and demonstration were identified by their participants as techniques helpful to behaviour change. These themes were also voiced by our participants and suggest that information can be applied across situations where behaviour change is desired.

While the use of theory and framework is encouraged when designing health care interventions (Atkins & Michie, 2015), and could be seen as a limitation of the current study, our essentialist paradigm and inductive approach precluded us from using predefined codes and thus allowed the perspectives of participants to be captured faithfully. Codes and categories were derived directly from the data, attaining methodological coherence. Another limitation of the present study refers to our sample. Even though efforts were made to include participants from different cultural backgrounds, most participants were from a white ethnicity and medium-high socioeconomic background, hindering the generalizability of the results.

6.5. Conclusion

In conclusion, T2D management is influenced by complex evolving factors in people's lives. The voice and needs of people with T2D need to be incorporated into LI programs. The results of this study indicate that people living with T2D request a more extensive and comprehensive treatment. Shifting of program content, delivery methods and provision for long-term support is required to address participants' needs and the multifaceted aetiology of T2D. Taking these actions would address the knowledge–action gap and help people with T2D manage their disease over the long run.

Table 6.1. Demographic characteristics of participants.

Demographic Variables		
		Mean (min - max)
Age (years)		61.4 (33 - 79)
Diabetes diagnosis (years)		12.6 (5 - 25)
		n (%)
Sex	Female	8 (53%)
	Male	7 (47%)
Ethnicity		
	Aboriginal	3 (20)
	Black	1 (7)
	White	11 (73)
Education		
	High school or less	1 (7)
	More than high school	14 (93)
Employment Status		
	Working	4 (27)
	Retirement	7 (47)
	Other	3 (20)
	Not reported	1 (7)
Household annual income		
	<$59,999	4 (27)
	>$60,000	9 (60)
	Not reported	2 (13)
Annual income		
	<Meet needs	1 (7)
	>Meet needs	13 (87)
	Not reported	1 (7)

Demographic characteristics. Data presented as mean (min – max) or (%).

Table 6.2. Dealing with being diagnosed and living with T2D

	Example quotes
DM feel	
	We're whole people... I almost had to stop being a whole person and become this machine that was focused totally on diet and exercise. But I'm not, that's not all that I am.… because I mean what we're talking about is quality of life, and if your quality of life is "I can't eat this. I got to go here. I've got to do 6 laps of the track. Have a nice day." For some people that's not quality of life at all - **PT132**
	I'm just, I'm thinking, what can I do to make this work. And yet you still need those treats and indulgences. Or else life just isn't worth living - **PT115**
	Because we have so much [smacks lips] sweetness and sugar in our systems that that's all we know that is right. That's what we feel we need to feel better. [Interviewer: Mhmm.] But in actually, it's actually harming us - **PT149**
	I can tell you right away, for 75% [chuckle] of the people you're talking to, even if they don't tell you that right. And you [unclear] like I have – am telling it right now, they probably feel that, um, that - they have this issue with food. When you're, like, as heavy as I am, whenever you go for restaurant, you go to a party, people are just watching your plate. [Chuckles] Watching what you're going to choose to eat - **PT153**
	I was really overwhelmed with this. It was really, really difficult - **PT153**
	If you're emotionally not down that day, it's hard - **PT159**
	Doing a whole change like [DM management] that would be… it's overwhelming - **PT300**
	Sometimes you can feel very alone - **PT364**
	But I really think there has to be more support. Maybe just for fatness in general.
	It's looked at as a weakness ... Like if you've got cancer, people, you know, they "oh you poor thing", and "good, I hope you get over it" and "I'll help you get over it". Or if you have anything else I guess, uh, plus my husband's got, uh myasthenia gravis. And so he gets notes from BC and the university wants to keep track of him and everybody's caring about him. Um, they don't do that for people that are obese. And, I just find I need, I guess I want more attention - **PT623**
	At first, it was really difficult because you just… It's a whole mind shift - **PT623**
	When I first got diagnosed it was completely overwhelming - **PT623**
	it's a constant battle between a recognition or admission of a disease and how you're going to, uh, how that reflects of what your choices are - **PT87**
	I take insulin every day and… I know I'm not very steady at it because I should take it three times a day. [Interviewer: Uhuh.] But I don't bring my monitor with me, like, I forget about ... but if I'm in a restaurant, I don't… If I'm in public, I don't like to take a needle... And sometimes the washrooms don't have a counter. [Interviewer: Mhmm.] And uh, it's hard to put my stuff on a – you know, I – I have to put it on the floor or something and – and, um… It's awkward. [Interviewer: Yeah.] - **PT98**

Accountable

I mean death doesn't terrify me at all. But I see people with, um, medical issues, and the one that comes to mind, rightfully, is dementia. And, and, I know that some of these things you can't help but some of these diet and exercise can definitely help. And, and, and, uh the idea of leaving my wife with me as a dementia person terrifies me. I've had a relative that's done that. And, that is something that absolutely terrifies me is that, that… I would do anything to make sure that I don't inflict that on my children and my grandchildren if that makes sense to you - **PT132**

People who have a reason to live take better care of their bodies than people who don't have a reason to live. The fact that I have, uh, a grandson now that I adore and I'm more open to going back to the diet and exercise than I was 6 months ago or 6 years ago, that's not coincidental. That's just the way life goes

He [Medical Doctor] was a specialist, first of all, and he was, like, following me really closely and we talked a little bit about things I could do, and he was giving me a purpose. 'In six months, I want you to come back with lower numbers!' I was like 'okay. I'm terrified.' But six months, I try whatever I can - **PT153**

I can go without having that junk food or without having a craving for the stuff and people'll look at me like 'how do you do it? How do you do it? How do avoid all these foods?' [Interviewer: Mhmm.] It's a difference between my health and living longer, or being sick and losing a limb, or dying earlier something – or something, right? - **PT178**

I didn't really like... fruits – or, uh, vegetables, really that much, before and now I just… consider it a… a requirement that I don't exactly overly enjoy but it's – it's something that… I need to do, basically, right? - **PT300**

Not everybody has a lot self-control. [Interviewer: Mhmm.] So if you're asking them to – to make a change, whether it's exercise or diet or medication or whatever… there's usually some reluctance to – to actually do it - **PT364**

Looking at the people around me, my wife is the same as I am and I'm noticing that her health is becoming – is beginning to, uh… uh, get worse. She has a-arthritis and such. So just looking at that and – and understanding that 'no, you've got to be conscience of your health.' So you have to actually do some things to makes that you… work to mitigate your health long-term - **PT555**

And we're talking about being healthy. And we're talking about being mindful. And we're talking about, uh, you know, feeling good in your life. If like you would refer to, you know, what are your like kind of life goals? Like you've got diabetes, where do you want to go next? Like what is – where is your life gonna take you and do you see any barriers? So when we talk in that kind way and say 'well, you know, I want to do this and that' and say 'okay, so let's start here, let's eat healthy and you're going to have more energy to take those online classes to become a phlebotomist or whatever.' Like, [chuckles] you know, kind of put it in perspective of a whole life mentality versus you have to lose weight - **PT623**

It's very, uh, it's a fear kind of based regulation and honestly that was great way to learn about food at that time because I didn't want to kill my baby so I was very adherent to the – the guidelines - **PT623**

Reasons to engage
I think if people – if I hadn't had that experience of, you know, how – how truly uncontrolled behaviour can result in really, really bad results, [Interviewer: Mhmm.] um, I – I might not have had the same kind of reaction - **PT70**
I start to feel lousy again. I start – low-energy and – and, uh, lethargic. And then I know that something is on, I do a – I test my blood and then I find out that 'oh, yeah, I'm not in control - **PT97**
I have a family history of diabetes. My father was diagnosed at approximately the same age that I was. Uh, he did not particularly look after himself that well, as a result of which he died at age 70 from diabetes complications. And I am determined that I am not gonna go the same way. I will do what I need to do to maintain my health as best as I can - **PT364**
I've seen people who have died or lost limbs because of diabetes and that's a big motivator. I don't think the dietitians and the people emphasize that enough - **PT178**
But they [people in general] need to know severity, the seriousness of what can happen if these people don't take care of their lives. They're – they're not gonna have – they won't be able to be – uh, interact with their family 'cause they're gonna be trapped at home. They're gonna become overweight. They're gonna have heart disease, they're gonna get heart attacks, they're gonna have… uh, diabetic episodes. They could lose limbs. They could be trapped in a wheelchair, or they could be on oxygen which is gonna restrict their lifestyle. They may not enjoy their grandchildren growing up or see their kids growing up because they're sick. They're gonna be a drain on their family, they're gonna be a drain monetarily on the health system. They're just – they're gonna be sick all time. They… need to know that, to see that, to hopefully [smacks lips] help motivate them to start following and training themselves to do the proper diet, the proper exercise, the proper reading and everything else - **PT178**
Probably fear. Probably fear. I don't know. Like the first time I went to weight watchers was, I was embarrassed because someone asked me if I had had my baby and I just had him - **PT38**
I'm now getting to the point where I have grandchildren. So, all of a sudden being healthy enough to keep up with the grandkids weighs it back on the plus side, rather than the minus side - **PT132**
The support is really important. [Interviewer: [unclear]] Oh, and lately I also had a friend, she also have diabetes, and this was amazing. Because we were talking and I was like 'oh you go for this too?' [Laughs] So the support of your people with diabetes - **PT153**
And I think you really have to like it, like… I – you know, when you do Zumba or something that's fun, I… even though it doesn't have the benefits of strength training, like, I just – it's such a mood booster so I also like those kinds of things - **PT623**

Table 6.3. Impact external forces have on T2D managment

External forces
Health Care Providers
That first dietitian at [doctor's name]'s office, she was a knockout. She was just an absolutely fantastic human being.... but she was just top of the line. She was fun to come to. She was a person first and we could laugh together and we could joke together. Uh, she took her work seriously enough in the sense of, of, um, doing it and doing it well, but not so serious that she couldn't have a laugh. I kid you not, you, you knew that if you were 5 pounds overweight, you, she would have liked... that you weren't in huge trouble, it was just life, you know. But she was wonderful. She was absolutely wonderful - **PT132**
My doctor just sent me to diabetes classes. Okay? And, uh, he had me meet with a nurse as well, every 3 months I believe, to go over, you know, like the – the health issues with the blood pressure, the feet. Stuff like that. So, uh… you know, he's maintained this… you know, over the last 10 years. Like I go every year for this assistance with the nurse and he… [Interviewer: Okay.] you know, validates my blood work and stuff. So, like, I've had the help - **PT149.**
She connected me to the, uh, primary healthcare network which, uh, let me to some fitness programs through them. There, I was coming in once a month, uh, once a week. Uh, and, walking around their offices and doing squats and all sorts of things like that with them, working on some of their machines - **PT132**
Having access to the nurse, from time to time, with this program, it was really good, because now I – I had someone I could actually ask questions from time to time. So that did make the experience a little bit easier to go through - **PT153**
He was a specialist, first of all, and he was, like, following me really closely and we talked a little bit about things I could do, and he was giving me a purpose. 'In six months, I want you to come back with lower numbers!' I was like 'okay. I'm terrified.' But six months, I try whatever I can - **PT153**
What I liked about her is she never told – like, 'cause there's things I don't wanna eat..., she would like 'okay, so try it', so I would try it and then she's say 'okay, so you still don't like that, why don't we go for [example..] You know, she would make real suggestions that worked for me - **PT623**
We were going to see the dietitian, but, you know, last time she just spent half an hour basically lecturing me on everything I was allowing him to do. If you got a behavior problem, then it's also food-related. It's kind of like, yeah we know, to stop it. But it's kind of like, I can't tolerate being lectured as a parent. Well you have choices to make. You're not making the right choices and okay, yeah I know that. Would you like to try to deal with him when he's having a meltdown on the kitchen floor screaming at you? And threatening you with a knife? Easier said than done, right? - **PT87**

One day I went back again because, thank god, my mom was like 'I wanna know what your number.' And I didn't have any idea what the number was. So I went to the doctor and had a nurse actually took my blood sugar. I just [unclear] to do that because I don't have the – the meter. And she did and she was like 'uh, can you stay? Because the doctor wants to see you.' She asked, uh, how long you have been [unclear] since I had my – my lunch. [Unclear] Afternoon. I thought it was like maybe a couple hours or more. She said 'okay, the doctor wants to see you.' It was the first doctor I saw that – when I got here. And he was like 'okay, we have problem.' And I'm like 'what?' He told me 'okay. You –your sugars is just way too high! Not good. I told you to try to lose weight.' And I was like 'I –I don't even know how to do it, first, and last time I came here you – another doctor told me that I don't have diabetes.' So I went back home, because I don't have diabetes [Interviewer: [exhales]] and I was like sure, happy. So that's when we started [Interviewer: Okay.] everything. I was put on metformin and everyone. And, uh, they tried to pick me a little bit of medication but it wasn't as much at the time. I think it because he didn't have, um, a lot of patients - **PT153**

The way the doctor put it is – was that I was 'borderline diabetic', so in my eyes… I thought, well, I'm not diabetic, so I'm not gonna… concern myself with it, right? [Interviewer: Okay.] But… if I had honestly…. [smacks lips] looked at it, I would probably would have been diabetic, yeah, way, way, way back, uh, and if I'd started taking care of it then, maybe it wouldn't have been such a problem now? - **PT300**

So I never went back because she "This is what you can do. Solve your lunch problem and everything will be fine". So I thought well how could I go back to tell her I don't like the plan? It wasn't working. I don't know sometimes I just get mad at myself for that. Because I... it's like, um… I know that she's right. Um, and it probably would work. I did have almonds in my car for a while. I did have almonds - **PT38**

Completely demeaning.. It was painful and awful. And then you walk in to some guy's office and he look at – I have a log book of everyday, 5 times a day when I was stabbing myself with insulin, every unit – and he looks at me – he says 'well, these aren't the right numbers. I think you've got too many zeros on these.' And I was like 'I can recall every single stab. Every single time I had fluid pockets under my skin from injecting that much subcutaneous – like you can't tell me that I'm lying or that I don't know what I'm talking about.' So it's – it was pretty bad... And he sends me back with metformin which, you know, my other – my – my specialist had counselled me was not a good option for breastfeeding. So it was – it was a terrible time - **PT623**

One of the doctors sent me to, uh, a kind of a one day, um, what AHS was currently offering – that would be about 8 or maybe 10 years ago - **PT70**

Family

I'm lucky that my wife still likes to cook and that she's a really good cook and she likes [Interviewer: Mhmm.] flavourful food, which I do. - **PT70**

My granddaughter, because she's overweight as well and she's 12, we're doing 30 minutes on the treadmill at night together so, you know, [Interviewer: Okay.] She's in another house, I'm in this house so we just kind of FaceTime and we just do our 30 minutes together. So even though I'm tired, she said 'let's go grandma', you know, so we're doing it together but she struggle too - **PT149.**

I remember- remember when I was younger, my father had kicked a table in the dark with his foot and – his toe. And he didn't go to the doctors right away 'cause he was stubborn and cranky and he almost lost his foot because of the diabetes. Blood circulation in the feet and everything wasn't working properly. Luckily they were able to filter his blood and screen it out and get it cleaned up again. But he almost… he came very, very close to losing his foot to the diabetes because of poor circulation and that – just – I remembered that and I didn't want to end up that way

My wife still doesn't understand what I should be eating. I – our diets are separate. I cook my own food. I… buy my own groceries. I eat separately. 'Cause my wife – I don't think really has an understanding of what I should or shouldn't be eating and also it then becomes restrictive on what she can eat - **PT555**

Life makes it tough, like it – like just finding the time, especially with – when you have little kids, so you wrestle with that - **PT623**

I think that's what a lot of people… that I've talked to are missing is that they've, you know, they've got the diabetes. They're trying to make the changes. But you're not eat – you're not getting the support from your family. [Interviewer: Mhmm.] And if you're the one that's doing the cooking and providing the food and your family's not willing to change to allow you to have a better diet then… it's – it's hard for you to do it - **PT364**

Once I'm done, I'm like 'no more eating.' So I had to learn to do that because I grew up in a Ukrainian family. So you eat until you're really full - **PT178**

Context

I work in the oil field. And… I guess… something that can probably contribute to… the – the fluctuations I see is I don't, um… I'm away from home a lot so I have to eat, um… restaurant food. And… it's not that I would probably get a… a decent meal at 6 o'clock, it might be 8 or 9 o'clock- **PT300**

In my career I also travelled a lot and I think that was probably one of the onsets of diabetes was that I was travelling… in hotels, eating in restaurants continuously… eating very, very badly. Limited activity and bad food - **PT555**

Three months after I got, uh, let go from [company name], I was in bankruptcy and, um, that bankruptcy didn't help my health at all - **PT97**

I was working [company name]… for 40 years, … And at that point, you're very… involved in life. [Interviewer: Okay.] So you're working, you're busy and a lot of things… like diet and all the rest of the stuff, are not sort of front and center - **PT555**

Adopting the changes – I mean it gets harder as your kids are little and you keep having more children, I mean, life gets crazy - **PT623**

It's great if you've got the time and you've the money and you're, you know, you're somewhat unemployed or whatever to be able to spend those hours and get the weight down and everything else. But, in a real world, it, it sometimes just doesn't work - **PT132**

Eating well does cost more money. It is very difficult to eat well. Uh, it's easier to buy macaroni and cheese, you know? - **PT97**

I'll buy groceries, I'll buy this, I'll buy the cauliflower, I'll buy the – I like the stuff. And yet, I guess because what I use as an excuse there is I'm driving my husband places. I'm driving my granddaughter places. I'm going out to [grandson's name]. I'm going out to look after [grandson's name] a couple times a week. And I get home at 5 or 6 and I don't feel like cooking much. So I mean it's a lot easier to have, um… What do I usually… well order a pizza or something - **PT38**

I can't afford this organic stuff. I've got it. Yes, it does taste lovely. Yes, it's wonderful, blah blah blah. But ultimately I can't afford it - **PT115**

I went to, er, an appointment to, uh, um, diagnostic or something ... But it was expensive. [Interviewer: Hmm.] It was REALLY expensive. That's the thing that [stammers] I couldn't go through this. It was too expensive and I was like 'okay… I can manage that much' and [stammers] ... That – that I had and I told him that 'this is too expensive!' And he was like, he – he just told me 'well, if you want to lose weight, if you want to be healthy, you have to make sacrifices.' And I was like 'that's it! See ya!' [Chuckles] I just left - **PT153**

And, there's also the fact that back home I wasn't really the one cooking...here, I had to cook for myself, which was a new experience [stammers] a – a really new experience for me, coupled with the fact that I had to use ingredients I wasn't really familiar with - **PT153**

In[name of store] last night they had 10 different baked items. We could have chosen any of those for half price. You know - **PT87**

Accessible and also it's advertised continuously. And you know they are not advertising eat a bag of vegetables. I haven't seen any ads for eat a bag of vegetables - **PT115**

Television in Scotland was they have less fast food advertising on the TV… All the same fast food restaurants. But you don't see as much promotion of it there - **PT555**

You get the coupons all the time too. And yes we go to the A&W and etcetera, etcetera - **PT115**

The transition from that… [Interviewer: Mhmm.] sort of those diet choices to - better diet choices, that – it was not easy to make that transition. Those temptations were always there. [Interviewer: Mhmm.] Uh, they always are there - **PT70**

When you're kind of home alone, especially now with this Covid, I seem to just kind of eat something throughout the day, you know what I mean? And it might be some good choices but some – quite a few bad I think, you know? - **PT149**

I find doing it at home is harder than going out to do it. And that is one thing I found during the Covid-19, that what I started again – so you get re-motivated, you get ready to go and then the Covid-19 hit. [Interviewer: [chuckles]] I know there was lots of stuff offered online – yoga and that but [chuckles] it wasn't as easy - **PT159**

Like some people don't wanna go to the gym. They don't wanna go for a walk and now with Covid, everybody's scared to go outside - **PT178**

Tend to have my A1c's measured every three months, although it's been a while now with the – the Covid thing that I haven't had it done - **PT364**

A lot of people are feeling a strain of not being able to get out and about with all their friends and relatives and that, and that's making everything more difficult for them - **PT364**

Table 6.4. Health behaviour cycle

Example quotes
DM Knowledge
If I get a day for whatever reason I get up and I don't take much of anything, I know enough that I have to eat something on a regular basis to keep my blood sugar somewhere - **PT132**
As soon as I feel different, if I feel something that does not – like, normal, I check my blood - **PT178**
My meds and my insulin are sort of the – the first thing, you know? [Interviewer: Mhmm.] I try to ensure that I regularly take it, that, you know, that – that I use that medication. Um, and then the next most important thing is, you know, what I eat, and when I eat, and how I eat -**PT70**
It's important to always look after your feet, make sure that you don't – when you put your shoes, that you shake your shoes out. You – you wipe the bottom of your foot off before you put your foot into the shoe.… you can, you know, if you're stepping on a stone or something in your shoe that, you know, and you don't feel it - as the diabetes progresses and you don't feel it, you can get like a sore and sometimes that sore doesn't heal - **PT149**
I start to feel lousy again. I start – low-energy and – and, uh, lethargic. And then I know that something is on, I do a – I test my blood and then I find out that 'oh, yeah, I'm not in control - **PT97**
The stress, I don't know what it does exactly, and I'm still trying to find that out. But the more I got stressed, the higher my numbers were - **PT178**
Do the medical things, have your eye exam and your… you know… Uh, exam for your… [Interviewer: A1c.] your kidney – your kidney levels and all that sort of stuff and, you know, if they recommend doing it once a year, then try and do it once a year so that if you are gonna start developing problems, you're – you're getting ahead of the game and maybe you can prevent them from getting really bad - **PT364**
Understanding, like, that it's a… as an endocrine disorder it's something that – there's like 20 different hormones that regulate your diabetes. It's not just insulin. It's not – you know, it's not just this one thing that you do. It is – there are so many factors that actually contribute to your overall health and it – I think that's also a really important… to understand - **PT623**
Rudimentary understanding of activity, you know, that you should be more active when you're diabetic - **PT555**
Indigenous people, that would more – more of, uh… I don't know, I was gonna say receptive but that's not the right word. But more impacted by – by diabetes. W-why is that? And – and what is the impact relative to diet? As an Indigenous person, you know, it should be like 'don't hang around McDonald's. It's really bad for you'- **PT555**
Healthy eating knowledge
Healthy eating is lots of veggies. Uh, healthy eating is, not only not white flour, but I'd say, uh, to a certain degree we minimize the pasta intake. Very little macaroni and cheese. We do some spaghetti and we try to go for whole wheat but that's not always 100%. But, lots of veggies and a thoughtful dessert. Uh, possibly um fruit. Possibly yogurt. But you try

to go for something a little bit more nutritional - **PT132**

Basically following Canada's food guide. You know, that's basically how you should do it - **PT149**

Healthy eating' would be, um, an equal – you, know, making sure that you put your proteins in. You're, um, making sure that most of your plate is vegetables and fruit as compared to carbs and proteins - **PT159**

It's a balance of things, you gotta do your whole grains, you have to do your fruits, you have to do your vegetables. Um, naturally occurring… I guess sugars if you're going to consume sugars like from fruit, from watermelons, the things that your body can digest, staying away from the manufactured to the man-made or the artificial stuff. So that's where I think of… not – healthy eating. Rather than dealing with process, anything that's natural - **PT178**

The plate method .... Eating a balanced diet, um… with… uh – not with – nutritious foods, not a lot of junk food. Not eating out a lot. Um, when I do eat out, making sure it's healthy choice that I'm making. Um… Tend to eat a lot of vegetables, fruits, uh… fish, poultry. Limited amount of red meat. Um… Tend to drink just water with maybe one glass of fruit juice a day but don't drink coffee or tea or alcohol - **PT364**

To me that would mean, um, sort of a mix of foods and – and kind of a balanced mix. So, uh, right amount of vegetables and fruits. Um, uh – um – the – the correct amounts or – or balanced amount of protein, carbohydrates, vegetables, fruits, um, combined with, you know, enough liquids to keep it all working - **PT70**

Some of the wine is good for you, yes, in moderation, but it has a lot of calories because of the sugars and the processing and the way – and the fermenting and everything else. Beer has a lot of calories in it. Where your vodkas, your clear – like, your clear liqueurs, your gins, your rums… not your dark rums or your gold rums or anything else because they all have more sugar in them. They got more caramel, they got more cane sugar. The clear liqueurs are… I noticed they're less spikes in my numbers as well when I drink those - **PT178**

Less prepared foods, I suppose - **PT87**

Like on your plates, supposed to be half vegetable, uh, quarter starch and quarter protein - **PT98**

Now I use turmeric [Unclear] all the time. And it blocks a lot of the sugars and helps you balance and control, it reduces cholesterol, it reduces, uh, heart disease and everything else - **PT178**

If you're… gonna follow that recommendation you have to be willing to… perhaps make more of your own meals. Make, you know, start reading labels. Learn what's in things and for the most part fast foods and prepared foods are not really that healthy when you look them - **PT364**

You have to basically make a meal plan to try to follow some of this. Planning meals helps. Like pre-planning for the week or whatever - **PT87**

To me it's so general, like, in every definition of healthy that I heard from my friend just becomes like, whatever 'healthy' is… but mostly eating right portions, lots of fibre, lots of

veggies, yup… Something you don't like - **PT153**

I didn't really like... fruits – or, uh, vegetables, really that much, before and now I just… consider it a… a requirement that I don't exactly overly enjoy but it's – it's something that… I need to do, basically, right? - **PT300**

I have a sense of some things I shouldn't be eating but what should I be eating? - **PT555**

I eat at nighttime is, like, I don't know if – if eating at nighttime puts more weight on or not, um… If I eat before I go to bed, and, um… Are you supposed to sleep – or sleep with a… a full stomach or – or after you eat? Or will it cause problems in sleeping? If you eat before you go to bed..? - **PT98**

Key messages from Diabetes Canada Clinical Practice Guidelines – Nutrition Therapy

1. Select whole and less refined foods instead of processed foods, such as sugar-sweetened beverages, fast foods and refined grains

I think that's a big thing that people really need to know, that that's the bad item, is the carbo – the wrong carbohydrate. Like, you know, the – the refrying stuff, like you have to figure donuts and white bread and stuff, [Interviewer: Mhmm.] even though it may be delicious and everything, it's just that that's the worst that you can do for your body - **PT149**

Initially, 25 years ago, um, I – I – I loved sweets. I eat – ate sweets, you know? Cookies, donuts, ice-cream… Whatever. I drank high-test Coke. Um, I don't do very much of any of that anymore - **PT70**

Less pop. You know, well, no pop actually, I shouldn't say less pop. No pop. Carbonated water instead - **PT159**

The ketchup, that ketchup has sugar in it for crying out loud. I mean everything, everything, has sugar in it - **PT87**

I mean I've made some changes so… you know, no – no soda pop. Trying to restrict the amount of, um, you know, junk food that I eat. That sort of thing. So I pretty cut all of that out as much as I could - **PT364**

It talks about 'sugar-sweetened beverages', I understand that very clearly. Don't – don't eat those, you know, don't – but is – is diet – is, uh, diet Pepsi okay or diet… you know, the diet drinks – are they good? Or should- should it say specifically 'don't drink sugary drinks, don't drink… don't drink, uh, pops and such. Drink waters, juices or these things much…' you know, much clearer recommendations. That's really where I struggle. I just don't understand what I should be and shouldn't be – what's within those groups and without those groups - **PT555**

What about… Diet Coke? Like… Can it harm you eventually or like a – aspartame and – and, uh, like… What's the better choice for me if – if I don't want to drink diet coke - **PT98**

2. Reduce caloric intake to achieve and maintain a healthier body weight

Monitor how much you're eating. [Interviewer: Okay.] No matter what type of food it is, you've gotta… understand the calories that are in there, um… and really understand the amount of food you're taking in and I think most people probably don't realize how much they actually eat - **PT364**

I honestly think… I'm overweight, for the most part of – because of the… size of portions I was having. [Interviewer: Okay.] Um… so I… watched the… quantity I'm actually eating. And… I… I had a bad habit of having soda for super. [Interviewer: Okay.] Um… so I don't have that anymore and I have – try having water. Um… and yeah. Um… I try to… instead of just having meat and – and pasta and that kind of stuff I try to have a side of salad or vegetables or something like that to go along with the meal - **PT300**

Like 'yeah, I know I need to reduce my calories.' And calories, to be honest, they're not… like, calories in, calories out, yes. And the end of the day, it comes down to that equation. But all calories aren't created equally, right? And before people can come to understand that, they really need to understand the food first. Because a – like a blueberry is going – like the calories of a blueberry are going to digest and be used in your body in a very different way than say 10 calories of a chocolate bar - **PT623**

You would need to be made aware about what your calorie intake should be, for your – and – well, first of all, you'd have to be aware of – of – for your body size and your, um, frame? [Interviewer: Mhmm.] What weight you want to achieve. And then what amount of calories you need to get there - **PT159**

Planning your carb intake. You – if you're gonna eat any kind of food, say you're out on the road and you have to eat, uh, at McDonald's or you have to eat at a restaurant just because of where you are or you don't have access to healthy foods 'cause you're out on the road, you should try to plan your day so that you're consuming the most of your calories or your worst food at your highest energy output. Or when you're gonna – when you're gonna be working the hardest. When you're putting out the most energy. And you eat the least amount of calories when you're not working as hard - **PT178**

Not buying it. We don't have it in the house, it's not there, I can't eat it. So we changed what we buy so we don't buy much junk food anymore - **PT178**

3. Pay attention to both carbohydrate quality and quantity

I guess, I've kept some basic things in my thinking. Is that, for the most part, and this isn't 100%, I stay away from white sugar. I stay away from white flour. And I stay away from salt, in the sense that I, 99% of the things I get, I force myself not to put any additional salt on it. Whatever it is - **PT132**

I eat oatmeal every morning, partially because of my cholesterol levels, um, I eat that with nuts and fruit, which I would not have done in the past - **PT70**

White is always going to bring you up higher than brown - **PT87**

You don't realize things like, the difference between watermelon or bananas, which are supposedly a good fruit but they're actually sugar bombs, right? They're actually high in carbohydrate, high sugar content. I mean for years, I ate lots of those, but I've given them up now because they are literally sugar bombs. They'll spike you 3 points on your readings. Just for having a banana just like a banana sandwich. So, things like that where it's that applied information - **PT87**

Trial and error was a big thing. Try this – oh, no, can't do this. Try that. Like, uh, one of the things we really noticed, I – well, me and my wife notice – white pasta or white flour, white - white bread versus whole wheat… the whole wheat, the body took it better, even though there's more energy and good food in it, the body processed it better than it did the white pasta or the white flour - **PT178**.

I'm not gonna start counting carbohydrates… just not something I'm willing to do **-PT300**

4. Select unsaturated oils and nuts as the preferred dietary fats

I always read labels on processed foods so if I find they're really, really high in saturated fats, [Interviewer: Mhmm.] well I'm not even gonna go there, you know? And if it's high in sodium, I'm gonna watch that as well - **PT149**

Unsaturated oils.' [Clears throat] Um, so by 'unsaturated oils', are we talking, like, olive oil and that kind of thing? - **PT300**

Okay, unsaturated oils and nuts. What's an, oh, is nuts, do they have saturated oils? - **PT115**

5. Choose lean animal proteins. Select more vegetable protein

When you say 'choose lean animal proteins', you're – that – I mean that to mean would mean chicken and fish and turkey. Um, I'm not sure I'm – controversially still over where the pork stands. [Interviewer: Mhmm.] Um, because at one point, you know, just like before you shouldn't eat more than two eggs a week, now the – all – those things have changed. [Chuckles] You can eat more eggs, you can, you know, pork is also one of those things that you didn't eat often. Um, cheese, yeah, you're not supposed to eat more than a – [chuckles] that – that – that's bad fats - **PT159**

Lean proteins', I understand that. That's probably, uh, like chicken and pork. So you don't eat red meats. 'Select, uh, more vegetable protein…' What is vegetable protein? And – and I assume that's lentil and beans, but I'm not sure if that's true. Don't understand what these categories are. And I will… profess my ignorance in that - **PT555**

Vegetable protein? Well what is that?

For most things. [Smacks lips] Uh… 'lean animal protein…' Um… the only problem with lean animal protein is it has no taste.

Health behaviour cycle

She was also recommending some exercise strategies which I initially followed for while but then I fell off - **PT115**

I love candy. [Interviewer: Mhmm.] [Chuckles] And I like sweets. And – which is – and – and cakes and stuff and that's probably my downfall. [Interviewer: Okay.] That's the biggest thing. Okay, and that's very difficult to… stop that. And I don't know why. I, um… I know it's not right. I know I should be eating more, you know, like – like fruits and vegetables and you know – and – and I'm not a high protein eater. [Interviewer: Okay.] I'm more of a carbohydrate eater so I think that's my second downfall… is – that's why I have to, um… my abdomen's quite a bit large, right? - **PT149**

It wasn't difficult to learn, at the time, when they taught me it. But it – it became difficult afterwards to maintain it and follow it. Because they could show you something simple in the course that you would do [Interviewer: Mhmm.] but then to go home and convert different things… well… um, that weren't introduced in the program was where, I think, I believe I failed on - **PT159**

Staying on track, staying committed. You know the – you – you want to cheat. Oh there's time I – even now – I – I wanna cheat, I wanna go eat that junk food, I wanna go eat that – I want to eat something that's bad for me. And what I've done [Interviewer: Mhmm.] to kind of curb it is once/twice a week, depending how busy I'm working and everything, I allow myself a cheat - **PT178**

I've just in to the habit of doing what I think I need to do and, [Interviewer: Mhmm.] you know, if I… feel that I'm not getting enough exercise, maybe I'll just go out and do a little

bit more or… you know… Yeah, occasionally I'll eat probably what I shouldn't eat but then [smacks lips] realizing I've done, I try to make the rest of the day or the next day that I'm eating more sensibly and I'm watching what I'm doing to kind of counter balance when I do sort of fall of the wagon - **PT364**

At some points in my life, I've been very well behaved and I've watched my diet more carefully. Uh, or I've exercised more purposefully and, um… So I – I cut – I think I kind of go through cycles where I begin to get a little bit lazy and sloppy - **PT70**

I've got lists of things you're supposed to eat and all the good things you're supposed to have. And you go there. Do I shop with that list? I think about it. We try and do it, but not necessarily - **PT87**

I think as I'm older I – I know that I can't eat as much. I know years ago, growing up as a child, I could eat 2 big plates of spaghetti. Well, I can't do that now, you know? [Interviewer: Hmm.] So, I think as we get older, your body just can't do that - **PT149**

Table 6.5. Type 2 Diabetes programs

Example quotes
Diabetes programs
Alberta Health used to have… um, seminar series that they'd go around to local communities and – and present things on – on diabetes and that. I took some of them - **PT364**
I talked about the pharmacy… uh, oh, at London Drugs, that was one of the best sessions because it was a very – it was one to one. It was open. And as the pharmacist said 'ask any question. There's no dumb questions here.' So I really began to ask, you know… a lot of questions and he had a much more, uh, layman explanation for things – simple things - **PT555**
Bernstein's. I was on that. And I lost some weight there. I was losing fast. And I think that's very disciplined too- **PT38**
Diabetes classes - **PT149**
Diabetes clinic which included, you know… all kind of information including health eating habits - **PT70**
Weight Watchers - **PT149**
Fitness programs - **PT132**
Jenny Craig diet - **PT98**
Grey Nun's Hospital. It was only, I think, one session. It was on a – I think a Saturday or Sunday. It was probably maybe… I'm gonna say close to a full day session 'cause we had a morning – afternoon - **PT555**
Healthy eating program through the church - **PT87**
I decided to go for a personal trainer and he was really good - **PT153**
I didn't realize that until one of those sessions. You know, and it's through those – through those Primary Care sessions that they said 'always have a protein when you're eating something so that – 'cause the carbohydrate will go – will – will be used in your body quicker than the protein will.' The protein will keep you more satisfied - **PT149**
I had a – a very specific, uh, uh, menu that was set out for me [research study at Univeristy]. And, you know, how many calories I supposed to be eat and such – eating and such. And of course, then they were taking my blood sugars and like and such. So yeah, had an opportunity to look at that and I began to understand that… from that – looking at my blood sugar's… that were taken with the, uh, with the monitor that, uh, I tend to spike in the morning. About, uh, probably an hour goes when – when my spike – when my blood sugars would go up in my rhythm in my day - **PT555**
I see a dietitian - **PT98**
I took away from that conference was, uh, understanding – was I… Was the impact on the eye - **PT555**
I volunteered for a number of years through, uh, the institute and – so I was involved in that Panda program - **PT70**
I was put right through into the pregnancy, uh, diabetes program - **PT555**
I would have to meet, you know, kind of reg- regularly with a nurse dietitian. I'd take classes. Um, and the doctor as well - **PT555**
I've been in 2 diabetic studies with the University of Alberta - **PT178**

I've been to the nurses through the, uh, care system - **PT87**

I've done webinars and that through, um, Diabetes Canada. When they used to have - **PT364**

I've gone to, through the Primary Care Network, I've gone through quite a few classes on, you know, healthy eating, moving for health… uh, Canada's food guide. I've gone to – to a lot of those classes - **PT149**

Moving for Health, I think I went to that 2 or 3 times - **PT149**

But you go in [Bernstein diet] and you get the 1-on-1. Like it serves my needs a little bit and it gives me this injection which probably makes me feel like "oh boy, medicine" and, uh, and then I didn't feel hungry. And the thing with this injection, I don't know if it's a B12 or what, but I didn't crave sweets. Like I could come home at 4 and not want to eat the muffin. Yeah that worked then. But I don't know I was losing weight too fast. And, uh of course it all comes back like really quick. - **PT38**

My wife and I attended that. It was five days. All day long [….] it was intended for, um, primarily for recently diagnosed diabetics - **PT70**

Nutrisystem or whatever they, what do they do, they ship you food with exact amounts and that's how it works, but you can't eat out of those amounts. You're not supposed to be eating other things, right? So they have controlled situations with controlled amounts - **PT87**

One of the doctors sent me to, uh, a kind of a one day, um, what AHS was currently offering – that would be about 8 or maybe 10 years ago - **PT70**

Prescription to get active program - **PT132**

That program, um, fed us – so we arrive in time and had a – a breakfast which was then explained to us about, you know, what was in the breakfast and why those components. We stayed [coughs] through lectures and then would have lunch and we didn't have dinner there, we – but we ended the day. But there was instruction about, um, you know, there were dietitians providing instructions about, um, [smacks lips] you know, the – the food guide and – and then also the impact on blood sugar levels of certain kinds of food. So, [Interviewer: Mhmm.] sort of, not glycemic index per say, but, you know, what will happen because you eat an orange versus eating a – an apple. Or eating a cookie. Or a donut, or whatever. [Interviewer: Okay.] So, um, so there were dietitians, there were kinesiologists, so there was a – a portion of it that was about exercise and walking and after every meal that we had there, there was time provided for us to go for a brief walk for 10-15 minutes. And then, because we were measuring blood sugars pretty constantly through the day, you could see the impact of the exercise after a meal… and then see the impact of, you know, not exercising after a meal. Of just being sedentary. So – so that was, you know, [Interviewer: Okay.] after five days of that, that was sort of a big introduction that my wife and I had to, you know, what living in a diabetic world would be like - **PT70**

The kinesiologist in that five day program talked about all of the possibilities, right? [Interviewer: Okay.] But did basically encourage people to seek out the things that were, um… [Inhales] easiest and most comfortable for them – for – for anyone to do, right? So – so that's where I went. I – I did not join a hockey league or anything like that - **PT70**

Then I went back for a retraining course and that was, uh, one day long and that was less than helpful than that week long thing, 'cause I wanted that week long thing but they didn't do it anymore 'cause, uh… I think Ralph Klein been cutting the strings to – to healthcare by then already - **PT97**

they had this program, it was a week long, and it was, uh, learning about how diabetes works and how you can help yourself. And it was conducted at the U of A. [Interviewer: Hmm.] And, uh, you would go in there in the morning and you'd have your breakfast, what they would show you how to eat right – they – they provide you breakfast and a lunch and… And, um, you'd be responsible for what you eat when you got home but then it would go through everything to do with diabetes and – and the soups they made and stuff like that there at the time, that – that week long program was beautiful! I really, really helped put things in perspective for me - **PT97**

We walk every Wednesday with my current family doctor who is part of the Southside PCN network and so once a month we also walk with the registered nurse, the dietitians, and the kinesiologist. And if we have any questions, um, or they have any new information, uh, that gets shared - **PT70**

Table 6.5.1. List of programs participants have attended

SME + SMS	Nutrition therapy	Phisical Activity	Pharmacological Theraphy
AHS	Healthy eating program through the church	Moving for health program	Meetin with pharmacist
Alberta Health	Dietitian	Personal trainer	Doctor medication adjustments
Conference	Weight Watchers	Prescription to get active program	
Diabetes classes	Bernstein diet	YMCA	
Diabetes clinic	Jenny Craig diet	Fitness program	
Diabetic studies with the University of Alberta	Nutrisystem		
Educational program for recently diagnosed diabetics at the University hospital			
Grey Nun's Hospital diabetes classes			
Pregnancy diabetes program			
Nurses - Care system.			
Primary Care sessions			
The PANDA program			

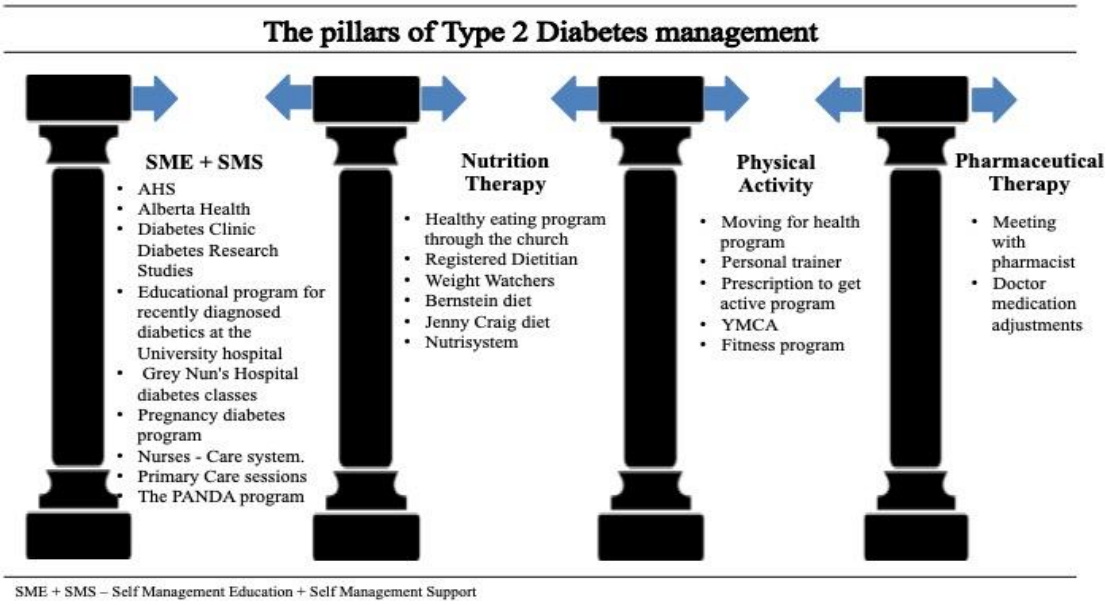

Figure 6.1. List of programs participants have attended

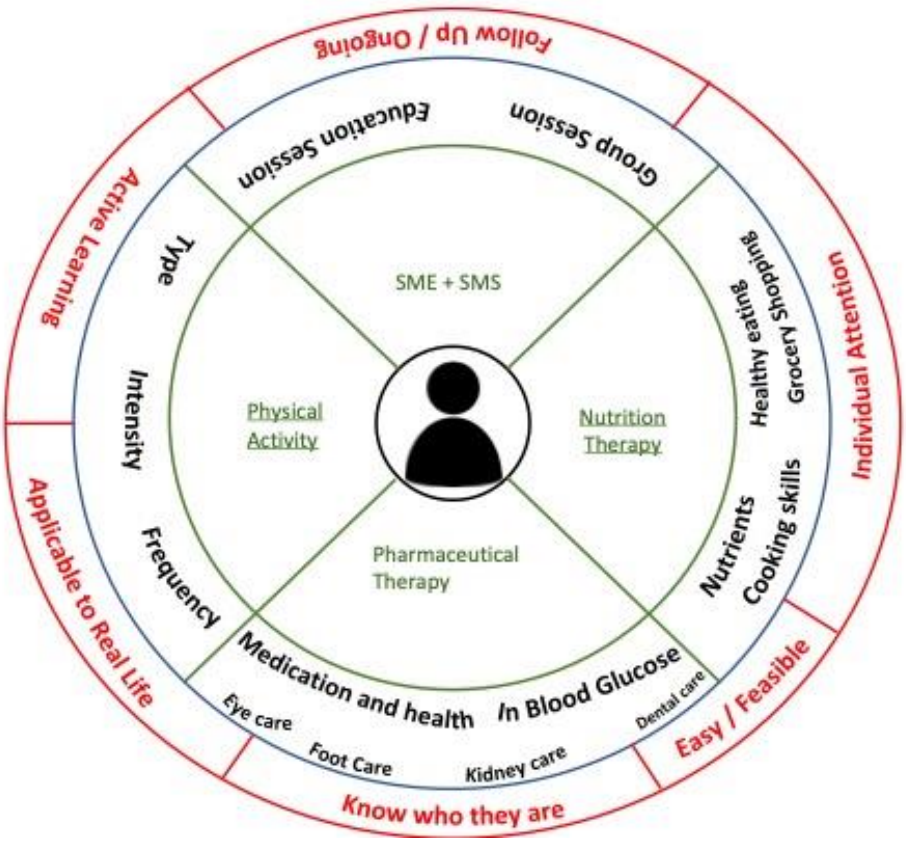

Figure 6.2. "Ideal" program content and delivery for DM management as reflected by participants with T2D

Table 6. 6. Identifying intervention options as required by participants

Example quotes
Program Attributes – Content/delivery/focus a program should have as requested from the participants
It has to be explicitly clear - **PT115**
Packing an emergency kit and what does that look like - **PT132**
Foot care - **PT149**
Having a diet for people on a budget would be amazing - **PT153**
Not getting off so easy if you were supposed to go home and do homework and you came back without – 'oh, I didn't have time', you know […] Penalize us. Charge us. [Both laugh] Charges for the course. [Both laugh] It's free but unless you don't do it, then you have to pay back - **PT159**
They need more… like I said, the graphic stuff during education. The videos showing people with amputated feet. Or showing the inside, showing the heart disease and stuff like that. The severity of it so that they can grasp what will happen if they don't smarten up - **PT178**
Uh, also… to some degree, uh, probably dental. I am - I have a dental – regular dental routine, too. I see a periodontist very year and… pretty regularly my dentist **PT555**
An overall household plan for diet. But the biggest thing, and I'll you that is really… very specific, you know, if you're gonna down and have a breakfast, this is what a good breakfast it. This is what a bad breakfast is - **PT555**
Talking about the food groups is really helpful. Um… [Interviewer: Mhmm.] [Smacks lips] 'Lean animal proteins.' When you're talking about, okay, maybe if it was, like, if you're – it depends if it's in a class or an individual setting but as an individual if you're talking to someone, I'd say, like, 'what kind of meat do you usually eat?' Or 'what kind of protein do you eat?' Like what's a typical week [Unclear] like. You know, and then you can start to get into, 'okay, you already eat turkey, that's awesome. That's a lean protein.' Or, you know, you can kind of make it, um… [Smacks lips] personal? Like… uh, relevant, I guess, to that person. Um, and you can do that in a group setting too it's just like shout out some foods that you would typically eat and then let's talk about 'is that lean? Is it not?' What could you – you know? [Interviewer: Mhmm.] Just to get people, like, to understand what do they already eat and how does it fall into the food groups - **PT623**
There were dietitians, there were kinesiologists - **PT70**
I do enjoy water walking and so… um, when I stopped being able to go for my hot tub and swim three times a week – sometimes I would even go more, um… That would really help - **PT97**
A swimming pool is vital for a good exercise programs. And, um, [smacks lips] because I'm – I'm thinking that… What I've noticed in my life with people like me, um… people who have diabetes, people who have overweight, um… it is the ideal way to not wreck your joints more than you already have. [Interviewer: Mhmm.] 'Cause carrying around, you know, a couple 100 extra pounds is not healthy. And, uh… Um… And the best way is a – is a very good, um, swimming programs - **PT97**

Program characteristics - Applicability, practicality and realistic

How to do healthy eating outside in the market. As in, how to order a subway sandwich that is healthy enough to eat - **PT115**

You want to train somebody to not feel a need to eat the whole bag, just eat a quarter of the bag and save the rest the next day or two days from now - **PT115**

Kind of train people to look for what that looks like at the drive through window at Tim Hortons or McDonalds - **PT132**

At some point I decided to go for personal trainer because exercise was not my fortitude. [Both chuckle] Still isn't. [Laughs] So, like, maybe perhaps someone, uh, to go with me, to train me, that would work - **PT153**

Cooking classes would be really fun. We will learn how to make things that actually interesting, tasty [Interviewer: Mhmm.] and we have made them ourselves so yeah. And I think going through the process of cooking your own food, especially if it is for your own health, it will also help you –help your mental health - **PT153**

Stay around the outside of the store is healthy. [Interviewer: Okay.] As soon as you go into the middle, [chuckles] it becomes unhealthy. Um… And to just, yeah, that. Reading labels. Being taught this bring stuff, actual, um, demonstrations. [Interviewer: Mhmm.] Um, maybe calculating in class, giving an exercise. Um, but again all this needs to follow up support, because doing it once and retaining it and then, um… You know, you need to back it up to –to – and I'm guessing, I might be wrong [Interviewer: Mhmm.] but the demographics of this is probably older people like myself. [Chuckles] And that we've been doing things wrong for a long time so we need – uh, and which means – also means that we don't learn as well. Or as quick. So… the more enforced – that reinforcement is – is better for us - **PT159**

Shopping trips in the stores - **PT159**

Teaching them how to go from very big portions to smaller - **PT178**

Learning to wean yourself off of your portion sizes - **PT178**

As long as you have help understanding… don't use butter, use olive oil and – and… use lean ground beef if you gotta use gr-ground beef instead of just the regular ground beef. Anybody can… you know, as long as they know what the alternative is - **PT300**

Or what they can add to this vegetable and this vegetable… or this vegetable doesn't taste that great by itself. Put these 2 vegetables together and it tastes better, or… that kind of thing, right? - **PT300**

Glucose meter and being shown how to do that - **PT364**

Some sort of exercise program where [Interviewer: Okay.] you can encourage people to maybe get together even if it's just something as simple as walking. You know. Meet every few days, once a week or whatever and just… [Interviewer: Mhmm.] go for a walk somewhere where you can talk to each other. [Smacks lips] You're doing the same activity, you can support each other and, you know, okay, well, you know, you're getting tired. Well, why don't you go just a little bit farther and you'll feel better type of thing - **PT364**

Much more specifics about which things and what you shouldn't be eating - **PT555**

Previously my blood sugars had been when I initially started was taking my blood 3 times a day, right? With the prick, with the finger pricks? [Interviewer: Yeah. With the finger pricks, yeah.] And, and I do that – I do that religiously and I would do it all

the time. I never really understood what I was doing as I – as I said. I always thought it was make sure that my blood sugar wasn't high - **PT555**

well, what is the healthiest version of that that we can make and… how much of it should you have, right? - **PT623**

After every meal that we had there, there was time provided for us to go for a brief walk for 10-15 minutes. And then, because we were measuring blood sugars pretty constantly through the day, you could see the impact of the exercise after a meal… and then see the impact of, you know, not exercising after a meal - **PT70**

What the – what the time you might need to undertake that activity in order to burn so many calories and – and the [Interviewer: Hmm.] impact on – on blood levels – blood sugar levels. And so, you know, there – there was a – just a whole range of stuff there offered. It – which made it easier for me to understand, you know, the things that I… [Clears throat] will do or like to do, so I know how much of that would I need to do, you know? - **PT70**

Food choices, cooking ideas -**PT87**

Getting the cognitive understanding or practicality in regards to that instead of just saying well you should just have less. Well then, with the program of feeling full they said have a hamburger, but cut it in half and have half now and have half later. That was a practical application of exactly what you should do and how to do it. Right - **PT87**

Making healthy easy

It's got to become as simple as opening a bag of potato chips and I haven't figured that out yet - **PT115**

Maybe you should come up with a line of diabetic fast foods. There's my assignment for you - **PT115**

Somebody else cooking **- PT38**

No shopping for food, no looking for food, no guessing - **PT38**

Not having to deal with food - **PT38**

Maybe, uh, fast food. [Chuckles] For diabetes. Diabetics… [Both chuckle] I don't know - **PT555**

List of tips. And you get those sometimes, but tips are continued application - **PT87**

Meal plans - **PT87**

What other choices you could make - **PT87**

But if there's a guideline like this, [Interviewer: Mhmm.] uh, that helps people choose the right foods - **PT98**

Experiential learner

Trying to do water aerobics there, because, again, I'm fighting, you know, some… physical issues that limit on what I can do - **PT159**

The cinnamon was the first that I went – was the cinnamon extract - **PT178**

They put me on CBD oil and I vape, uh, THC to go to bed, because I wasn't sleeping very much. Uh, that's the only time I'm using it, I don't use it during the day or anything else, it's only to go to bed. It really made a difference on balancing my numbers. [Interviewer: The sleeping.] It really, really helped… - **PT178**

I came across the mulberry leaf extract online so I started taking it and… New Nordic puts one out and it's actually for weight loss and I started taking it and I noticed that my numbers were being levelled out. They were staying lower. I wasn't spiking as much.

I think if people – if I hadn't had that experience of, you know, how – how truly uncontrolled behaviour can result in really, really bad results, [Interviewer: Mhmm.] Um, I – I might not have had the same kind of reaction - **PT70**

Um, diabetic, uh… food teachers, they have a – they used to have a really good, um… a program, you'd count your carbs and your proteins and – and they set you up a diet, so many carbs, so many fats, so many proteins. And when I would stick to that, I would – I would have more success in maintaining good, um, numbers for the diabetes control - **PT97**

Incremental steps

I think what – what maybe help – would help people is instead of just doing a… a whole – well, we gotta change from here to here, um, we need to change your – basically your whole eating habits, maybe – maybe just start 'okay, we're gonna try… no pop for these two weeks' and then 'okay, you can do that. Alright. Um… the next 2 weeks, let's not have hamburger. Or if you gotta have hamburger, make it lean' or… you know, that kind of thing. Uh, 'eat chicken instead of beef.' Um… do incremental steps maybe, um… instead of doing the whole – the whole… the whole big change - **PT300**

Somebody who can make a small step in, um, better – better habits, is at least headed on the right direction, right? Uh, particularly if they can – if they're steps that they can maintain and continue. Um, rather than kind of inspiring the – you know, if it's a ten step program, that they are – that they can get to step ten and then fall back and forget all of the steps, right - **PT70**

Trying to encourage people to… [Smacks lips] undertake things that're a big stretch for them is, um… is, you know – some will succeed at a big stretch. I think many won't succeed at the big stretch. And will – or – and then are more likely to, kind of, fall off the wagon - **PT70**

What's feasible for you to do without demanding some extraordinary effort or some kind of effort that's – that's really not natural to you. That – that is too significant a change for you to make. [Interviewer: [coughs]] Maybe by taking a smaller step, you may eventually achieve a larger set of steps, but, um… So I – to me, I think that's – that's part of the core of the practicality of some programs, is that, you know, while holding out sort the ideal… um, showing people that you can – you can at least make progress towards the ideal by taking a small step or two small steps, or [Interviewer: Mhmm.] you know… Along that line. [Inhales] [Short pause]- **PT70**

Group support

Being with other people that were also diabetic and hearing some of their experiences and realizing that I was getting it fairly easy compared to some of them - **PT364**

I think people are incredibly lonely. I think there is a case to be made for, um, a support group that doesn't stop. A support group that genuinely cares about one another - **PT132**

If in the program, you had an element of, um, people emailing or texting people outside of the actual meetings, you know keeping in touch or sort of a, an internet pen-pal kind of thing to encourage one another. Then when the program formally comes to an end maybe they would continue to email one another and support one another that way. That might be really helpful - **PT132**

It's support group. So there are people who have the same struggles as you, [Interviewer: Mhmm.] and they've made it - **PT149**

If it's like an app you have maybe sending messages to the person - **PT153**

Support group - **PT153**

Clubs or groups out there that meet on a regular basis to help the people that don't have the willpower or don't have a support system - **PT178**

Maybe even sort of a – a mentorship or a one-on-one [Interviewer: Mentorship.] where somebody that's had diabetes for a few years can kind of look after or talk to somebody that's just starting on the – the – the journey through and can let them know that, you know, some of the things that they're gonna find, some of the problems they may have and that just… I guess let them that there's somebody there that can help them or just – just talk to them and support them - **PT364**

A focus group or some sort of group that, uh, empowers people to – to… to decide what changes they want to make and to actually make them - **PT364**

Cause you get a lot of stupid questions when you first get new information, right? And they're not stupid questions, but… [Interviewer: Yeah.] you might feel stupid asking them. So it's nice to be like 'hey guys, like… give me the low down on the lima bean. Like, is it true that, you know, I read on Facebook that it's poisonous. Is that true?' Right? Like you can just… do stuff like that which is [Interviewer: Mhmm.] also helpful - **PT623**

We can still check in and, you know, doesn't matter where we're from… who we're married to or whatever's going on, like, you can – you have this, like, group outside your life - **PT623**

A powerful piece was just that group setting and the – the range of people and the range of, uh, experiences that I – that I saw within that group. And sort of, you know, helping me put myself on some kind of spectrum as to where I sit and, um – and then the information was – was good in terms of, you know… well managed. [Interviewer: Mhmm.] You know, what would my future be like? And that – and that is – that's 25 years ago - **PT70**

Maybe pairing people would help. [Interviewer: [unclear]] Cause sometimes we are ashamed to ask the doctor some questions because we are afraid to feel – to ask stupid questions. So if you can ask your friend and be like 'what do you think?' And she's going to be like 'that's not a stupid question. Let's ask the doctor.' You feel less, um, ashamed to ask the question that could save your life - **PT153**

Follow up

I really do need a coach in a way. I don't know how assertive the coach has to be with me but just something to remind me or to give me the incentive to keep going - **PT115**

It's an ongoing thing - **PT149**

It's just that 'oh okay, I went to that class. That's fine.' You know what? But you're not now committed to following it, eh? You know? [Interviewer: Mhmm.] So… [Smacks lips] I – I think continuously if it – it was kind of, okay, you –you've gone to like the five classes now let's go back over and review. What did you find out out of these 5 classes? Just like you're doing right now in a sense. You're trying to, uh, see what do I really know about diabetes over my 10 years that I've had it? And what have I done to, you know, basically try and to improve upon it, you know? - **PT149**

I think reminders help a lot. I have reminders on my phone… [Interviewer: Okay.] Uh, for like water, food, breaks… So this helps a lot [Interviewer: Mhmm.] [unclear] ones that remind you of, like, [unclear] I would just go and drink water right –right away but it makes me, um, think that at some point, for example I have to drink more water. So remin-reminder [unclear] replace the fact that I don't have my family to take care me anymore. Cause that was – like I said in the beginning – I'm a really dependant person and I need to replace that with something else – or someone else - **PT153**

Support afterwards - **PT159**

I think they were good. I… You know, I wish they had continued on with them and doing them because I think taking something like that every couple of years as sort of a refresher just helps kind of confirm that you're doing what's right and, you know, the – you know, the recommendations are changing over time so to make sure you're doing what they're recommending nowadays, you do and opposed to what they recommended 5 years ago - **PT364**

It has to be ongoing, the learning. So you'd have an initial course to learn that stuff - **PT555**

Follow-up, partnerships, groups. It's the same as dealing with a, a 12-step program. You keep on going to meetings to reinforce. And that's what weight watchers uses. Right? The support systems - **PT87**

Follow-up supports - **PT87**

Individualized attention

What is the actual breakup of how much protein, how much carbohydrate, how much fat… stuff like, a person of – at – at – let's say at my age and my weight level, what should I actually be intaking? - **PT132**

I think if I had someone to kind of maybe, um… talk – talk to me about why I'm not doing the right thing. Like, is there something underlying… [Interviewer: Okay.] in my history or something… that – that – that keeps me from going on this mission to – to be healthy. [Interviewer: Mhmm.] You know? So I'm not sure if it's like… you know, psychological diagnosis or something or – or – I don't – I don't know if – if that's just me or that's everybody, but I know for me, it's just that, um… [Scoffs] I don't – I don't know if I really grasp the importance of eating healthy - **PT132**

Getting, um, uh, [smacks lips] oh, like a guideline, do you know what I mean? [Interviewer: Yeah.] As to what I should be eating, how much I should be eating or what – what – how much amount of carbohydrate, protein, and fat and – and – that I should be having at my age and my weight - **PT149**

So having someone help me, for example, going for the low-the glycemic index food. And explain how it works. That would be amazing. Because I go for the – I know what it is. Like I said I have a bachelor degree in science, but even that is not helping because I'm just overwhelmed with the fact that I'm the sick person - **PT153**

Having someone going through the list again and explaining in light of… the dia – the diabetes I have, will be, actually, more effective. Why do you want have low glycemic index food in your – your plate? Uh, how much of this do you want to have? That would be great - **PT153**

Somehow we still deal with what we should be doing and maybe more one-on time, going over it and asking where we were struggling. What is it, you know, um, allowed us to not complete it? Or just the follow through on it all. I mean, do we have to be babysat? Again, I'm thinking this is an older group that you're working with, more so, and, um – I don't know, maybe we need more hand-holding. - **PT159**

Cause the North American diet's changed so much and as Indigenous people, that was not our diet. Uh, I mean, before contact, you know, we had a very specific diet and probably a very limited diet. And with the in-introduction to refined foods and such, it's… it's been really, really bad for Indigenous people so… what is that dietary pattern? What it is? Should – when should we be eating? And what should we be eating - **PT364**

You get the 1-on-1. Like it serves my needs a little bit - **PT38**

How have you changed because of the information you've gotten? What have you been able to stick to? What do you have trouble with? And let's, you know, let's take another step.' You know? Or I would even, um, [smacks lips] you know, at first, maybe just – let's just talk breakfast for a week, right, like just revamp breakfast and then 'what did you like? What sticks with you?' You know, it's just – it's just that learning isn't a one-time thing. It has to evolve and change. [Interviewer: Yeah.] You know? - **PT555**

Know your audience

Understanding who's in your program. 'Cause if – if I lived with somebody who did not like to cook, and did not like flavourful food, like the lady next door to me, [Interviewer: Mhmm.] um… I would have some problems. I would have to come up with some different food strategies, right? [Interviewer: Yeah.] For myself. [Interviewer: Definitely.] Or I would – or I would be going out, eating out, um, probably eating more fast food or prepared food anyways. Uh, so I – I think part of it is – is that sort of the – the social interpersonal environment that the person is living in, is being important in terms of, um, helping people think through what they can do and what, you know, how they can do it. [Inhales] - **PT70**

As you're researching programs – I – I do think the idea of trying to… um… trying to understand who the participant and – and sort of where they're coming from, what they're… possibilities, opportunities, you know, life style, um… their whole life situation is, uh… will make it easier to… to figure out… how they – what kind of changes they can make most readily that will, you know, be good changes for them to make - **PT70**

My experience with change in organizations, which I… kind of relate to change in – in the individual… [Interviewer: Mhmm.] um, is that, you know, there're about a third of the people who except the need and… do their best to get on with changing. And then there's about a third of the people who are kind of in denial or reject the need to change. And just won't. And, uh… I'll tell you quite honestly… in an organizational setting, [Interviewer: Mhmm.] you're gonna end up being fired at the end of the day if they don't get their act together and get on with it. Um, [Interviewer: Mhmm.] which is the equivalent to, you know, being in denial about your diabetes and becoming more and more ill and dying it from it, right? [Interviewer: Yeah.] Um, but in – in an organization, there's maybe a third of the people who're kind of on the fence, right? [Interviewer: Mhmm.] They – they – they may understand some need to change, they – they may hear the words you're telling them. But for various reasons, whether there's a lack of confidence or a lack of trust or, you know… a number of reasons, they're just on the fence. And they're looking for… [Clears throat] some indication that – that will push them in the right direction, off the fence. To make the change, right? - **PT70**

Because everyone is so different, they may struggle at something else- **PT149**

You gotta kind of understand what – you know, where people are at for that. 'Cause if they're just like, you know, say you're overweight and you feel terrible and you're – you're gonna lose your foot and all these kinds of things, like maybe you'd be more highly motivated to do something because this stuff looks bad. But if you're just kind of… you're having a good life and nothing's bad except that somebody told you you have diabetes and the you gotta watch out, like, you kind of gotta understand what are the consequences for your body and, you know, why it's important to you or just find people's 'whys.' People have a 'why.' You just gotta find it and then relate it to them. And so that will help them… be on track for things - **PT623**

Mental health

I think with anybody it's kind of like a psychological thing. That, uh, they have – we have difficulty with that. And, uh, I think that's – I think in most of the people's world, unless you're totally on a mission for health, it's very difficult to get there, unless you don't have that mission or that insight to 'well, do something about it', you know? - **PT149**

Having a support system, uh, ack – acknowledging that there's a, um, there's a mental, uh, a mental side [chuckles], um, helps fight the – the disease is really important, cause if you don't address that… it's not going to work. [Unclear] For me it's not working, and if you think about my mental health… when it comes to food too. Like the diet. All the stress - **PT153**

Lots of anxiety. And I need to learn how to deal with it. And it affects everything in my life - **PT153**

I think the psychological, uh, [Unclear] side of this disease is really, really important - **PT153**

Having the mental health improved is… I think it's primary. If you need to… If you're gonna have success with something, I think you need to make sure your brain is working right - **PT97**

Policy change
To have, uh, from the side of the people that are running these stores, spaces that are clearly marked with the good choices, with the good snacks, uh to do something on that side, so that people know this is a good choice. You know, even if it's a, you know, seal of approval or something from somebody that says this a good thing to eat [...] Have an awards program for the, the, uh, the convenience stores of who does it and how well they do it, and to actually give them some kind of trophy or cash-incentive or something for their good work towards, you know, the health - **PT132**
I think starting back in, you know, early grade school. [Interviewer: Okay.] Giving people – giving people some information on healthy living and that, um, I think I was 9 or 10 or whatever when we took home economics and we learned some very, very basic things about cooking and eating in general and so on, and I think some of lesson have kind of stuck all the way through. I was… learning how to do some of the stuff way back when. [Interviewer: Okay.] So, you know, rather than learning it when I was 30 or 40, I was learning it when I was 9 or 10, and I think… you retain more of that knowledge… when you're doing it at a younger age - **PT364**
Access to the medication, access to healthy food. Whether… with medicine it's whether or not you have the money to be able to afford to, you know, buy your test strips and your lancets and… pay for your medication, whatever it might be. And I realize a lot of people are in financial difficulties to you really need… [Inhales] I suppose a government strategy that's gonna say, okay, you know, 'we'll pay some of – some or all of the cost for these for people that can't afford it.' - **PT364**
If you can get young people where they can get that education, it – it probably is going help them a lot more than… [Inhales] just, you know, us talking about it all the time. If you're learning it when you're young… [Interviewer: Mhmm.] then you got a better chance of following through later in life - **PT364**
Educating people and I think the earlier you can get to it, the better. So I'm almost, you know, we talk about it within the school system. I'd – I have not looked at the… school curriculum in years 'cause my kids haven't gone. But I don't know if they teach any – any, uh, dietary education within the school system [...] governments have a role in – in –in that sense that, uh… so – for education and such. And legislation. To look at that - **PT555**

Table 6.7. Type 2 Diabetes programs

	Example quotes
Advice from people with diabetes to people with diabetes	
Track food intake	Limiting the amount of something that you might really want - **PT115** Measuring your food - **PT159** I honestly think… I'm overweight, for the most part of – because of the… size of portions I was having. [Interviewer: Okay.] Um… so I… watched the… quantity I'm actually eating. And… I… I had a bad habit of having soda for super. [Interviewer: Okay.] Um… so I don't have that anymore and I have – try having water. Um… and yeah. Um… I try to… instead of just having meat and – and pasta and that kind of stuff I try to have a side of salad or vegetables or something like that to go along with the meal - **PT300** Monitor how much you're eating. [Interviewer: Okay.] No matter what type of food it is, you've gotta… understand the calories that are in there, um… and really understand the amount of food you're taking in and I think most people probably don't realize how much they actually eat - **PT364** Make you log your food for a week. Super annoying, but you could it – you could do it on my fitness pal or something now, right? [Interviewer: Mhmm.] So you log your food for a week and then they would talk about… what did we eat, what, you know, what kind of choice was that. What could be better and they'd make suggestions and that was really helpful - **PT555** Eating in response to hunger, so, it tries to get you to recognize that - **PT87**
Importance of food choice	Just try and remember, eat veggies - **PT115** I don't put salt on things - **PT132** Lots of water. Lots of water - **PT132** Getting the sugar out of your system is a big things. But that takes several weeks, you know, where you're – you're – you don't have – it's like weening off or detoxing from the sugar, right? [Interviewer: For sure.] From the sugar rush, right? And that – that's hard because we're so used to the sweetness and the processed foods and the – the, you know, like I said, the white bread, the – the cakes and things. We're so used to that, that that's what our taste buds want. - **PT149** Trying to have fresh vegetables around - **PT300** I don't eat things that I don't love - **PT623** Try to eat seasonally - **PT70** Have a vegetable garden - **PT70**
Practical advice	Have buddy-system - **PT153** Continuing to be involved, weekly. You know like you have to stay involved. In any of them for them to work - **PT159** Really planning your day around your energy. When are you gonna do the most work? That's when you can eat the most… food - **PT178**

	Two, take up a hobby or start doing something instead of sitting to snack. When you wanna snack the most, do something. Take your – take up, uh, building something, play cards with the family, play a game, but do something to occupy yourself - **PT178** Plan your – plan your meals when you shop and such. Think about what you're gonna… what you're gonna need and – and then plan ahead. Do some meal planning - **PT555** Anything that you can maintain for the rest of life is the kind of change that you want to make - **PT623** I always read labels on processed foods - **PT149** Having strategies to just not feel guilty and to – to navigate normal life? That's really important - **PT623**
Team support	Having a good relationship with your doctor - **PT364** Working with a team probably would help, working with the wife [partner] - **PT87** Speak with someone, a professional - **PT153** Fight for what I wanted from the system - **PT132**

Chapter 7: Conclusion

The main purpose of the present thesis was to evaluate the effectiveness of the PPLP to improve and facilitate healthy eating in adults with type 2 diabetes (T2D) in Alberta and to optimize its potential. The key findings are:

7.1. Key findings of the present reseach

7.1.1. There are a range of dietary patterns available for people with T2D to manage CVD risk.

The review in Chapter 2 was essential to establish the importance Nutrition Therapy plays in managing and preventing complications in T2D and CVD. Given that in the past 5 years, most Dietary Guidelines undertook a very important shift in focus away from single nutrient recommendations to a more holistic dietary pattern approach (Diabetes Canada Clinical Practice Guidelines Expert Committee, 2018; Dietary Guidelines Advisory Committee, 2015; Lloyd-Jones et al., 2010), the main objective was to discuss and integrate current knowledge of dietary patterns and their potential health outcomes for minimizing CVD risk of adults with T2D.

Based on the results of this review, there is a range of dietary patterns options available that have positive impact on macro-vasculature protection and create a healthier balance of LDL-C and HDL-C in people with T2D. Dietary patterns that have been identified to provide this macrovascular benefit are The Korean Traditional Diet (KTD), Traditional Mediterranean Diet (TMD), Dietary Approaches to Stop Hypertension (DASH) Diet and, Low Glycemic Index (GI). Overall, higher consumption of fruits and vegetables (F&V), legumes, fish and, poultry is recommended in these patterns but lower consumption of red or processed meat, butter, fast food, sweets, pastries and sugar-sweetened beverages.

Damage to small vessels relates, in part, to a chronic hyperglycemic state and excessive reactive oxygen species (ROS) (Tiwari, Pandey, Abidi, & Rizvi, 2013), leads to nephropathy, retinopathy and neuropathy complications in T2D (Brownlee, 2001). Dietary patterns with high content of unsaturated oils like extra virgin olive oil and nuts have shown the greatest benefits on decreasing these microvascular complications because of their capacity to decrease ROS (Díaz-

López et al., 2015). Moreover, the chronic pro-inflammatory state in T2D and CVD benefits from dietary patterns that are rich in anti-inflammatory properties and antioxidant capacity such as TMD, DASH and Vegetarian because of their emphasis on F&V intake.

Hypercoagulation, developing as a result of hyperglycemia and insulin resistance, may lead to heart attacks and strokes from clots (Vazzana, Ranalli, Cuccurullo, & Davì, 2012). Even though more research is needed to identify possible benefits of dietary patterns on pro-thrombotic parameters, those dietary patterns with high consumption of F&V have been linked to reduce hypercoagulation (Salau, Adeyanju, Odufuwa, & Osilesi, 2012). Furthermore, dietary patterns associated with reduced heart failure include DASH, KTD and TMD.

This review has presented the different dietary patterns that have a beneficial effect on reducing T2D and CVD complications. Healthcare professionals and researchers may find it useful when re-orienting their practices towards recommending dietary patterns and moving away from individual nutrient recommendations. Furthermore, TMD, DASH diet, Vegetarian Diet, TKD, Japanese diet, and GI diet provide a range of possibilities to allow for individualized recommendations, where values and preferences should be considered in order to enhance adherence.

7.1.2. Effectiveness, acceptability and validity of dietary assessment tool development is crucial to understand the relationship between dietary - energy intake and health - disease

The narrative review in Chapter 3 addressed one of the major methodology limitations of nutrition research. Given that dietary assessment methods rely on self-reported data, this information is not 100% accurate for a number of reasons. We wanted to present some of the new technologies and strategies being developed to overcome this limitation, and to evaluate their strengths and weaknesses in regards to their ability to assess energy intake.

There were five different types of monitors or sensors, five camera-scan-sensor technologies, and one mathematical method being developed to improve assessment of energy intake. Overall, these tools were able to record and report food/energy intake more accurately than participants, increasing accuracy and decreasing participant and researcher burden. However, given their early stage of development, caution is needed until these tools are validated and further research is

carried out to investigate participants' acceptance. One of the present limitations of self-reported methods is that participants can modify their intake as a result of being evaluated, thus this effect should also be considered when evaluating these new methods. Recommendations for future directions included the collaboration of dietitians and engineers to co-develop and evaluate the tools and methods and to also shift their focus to detecting overall dietary patterns to align with dietary guidelines and our results from Chapter 2.

7.1.3. The modest positive effects of the PPLP intervention reflect the challenge of translating lifestyle interventions to real-world primary care settings

The purpose of the RCT in Chapter 4 was to evaluate the effectiveness of the Pure Prairie Living Program in improving health outcomes and increasing dietary adherence in adults with T2D in Alberta. In order to carry out this study, we partnered with healthcare providers (HCP) at Sherwood Park Primary Care Network (PCN) and worked together to apply principles of knowledge synthesis and translation to make sure that the program fitted their context.

Subsequently, adults with T2D were randomized into intervention (PPLP) and wait-listed controls (CON). The PPLP group participants attended and participated in 5 weekly nutrition education session. They received the PPLP resource pack that consisted of the following: i) Education sessions, ii) PPLP workbook, iii) Pure Prairie Eating Plan. The Program spanned 6 months from recruitment to the final participant visit. Baseline, 3- and 6-month assessments were carried out in both groups to assess anthropometric, metabolic, demographic and T2D management information.

The intervention yielded no significant within-group changes in HbA1c at three-month (-0.04 (-0.27 to 0.17) and -0.15 (-0.38 to 0.08)) or six-month (-0.09 (-0.41 to 0.22) and 0.06 (-0.26 to 0.38)) follow-ups in either CON or PPLP groups, respectively. Dietary adherence scores improved in the PPLP group ($p < 0.05$) at three and six months but were not different in the between-group comparison. No changes in diabetes self-efficacy scores were detected. In the qualitative analysis, participants described the program as clear and easy to understand. Knowledge acquired influenced their everyday decision-making but participants faced barriers that prevented them from fully applying what they learned. Healthcare professionals enjoyed delivering the program but described the "back-stage" workload as detrimental.

Findings from this study reflect the challenge of moving lifestyle interventions to real-world scenarios. This program provided important information to participants, yet this was not enough for them to modify their self-care behaviours over the long run, reflecting that further work is needed to close the knowledge-action gap, highlighting the necessity of the development of tools to help participants adhere to the guidelines and reduce HCP workload to facilitate and improve this process. One of the main learnings from this study was the need to understand participants' context in order to facilitate and ease the management of DM. These results guided our subsequent studies.

7.1.4. Interventions that include the main pillars of DM management have improved efficacy and effectiveness.

Chapter 5 provides a systematic review that analyzes to what extent lifestyle interventions (LI) align with the cornerstones of T2D treatment. The rationale behind this study was guided by our previous results from the RCT and other studies reporting a decrease in effectiveness of interventions when moving through the scale-up process (Blonstein et al., 2013; Costa & Mestre, 2019; Kahn & Davidson, 2014). Furthermore, given the multifactorial etiology of T2D, the recommended multidisciplinary treatment approach suggested by the guidelines, and the uncertainty of LI true effects, we wanted to systematically evaluate to what extent did current interventions aimed at improving DM management align with the four pillars of DM management.

LI programs, reporting on two or more of T2D management pillars, which reported HbA1c and had gone through scale-up process were included. Ovid MEDLINE, EMBASE (OVID interface) and CINAHL were searched in May 2020. Five RCTs studies conducted in real-world setting in male and female adults with T2D were included. The counterpart studies of the RCTs were included regardless of the study design. The main results from this review found that all the studies analyzed reported a decrease in HbA1c values in the intervention group. A scale up penalty was detected ranging from 0 to 35%. The limitations of this review include difficulty in comparing study outcomes due to differences in data reported and analysis, the lack of standardized statistical analysis between baseline and follow up times and the lack of description of intervention characteristics. Future research should design LI that provide similar importance to each cornerstone of T2D management and maintain its intensity over the long term. The

generally modest scale-up penalty found does not negate that real-world application of LI can result in clinically relevant improvements in diabetes outcomes.

7.1.5. People living with T2D request a more extensive and comprehensive treatment. Adjustments to programs' content, delivery and support is required to meet their needs.

The study in Chapter 6 elucidates the potential of understanding participants' context, which could improve the development and effectiveness of LI. The use of qualitative methods, essentialist paradigm and inductive thematic approach enabled the report of experiences, meanings and the reality of participants. Our data provides information in five key areas for T2D management, in which participants' characteristics, background and health were also presented. Furthermore participants' feelings, motivators and personal attributes when living and managing their T2D and the impact external forces have on their management were presented and interpreted. Participants had considerable knowledge regarding T2D and nutrition but experienced health behavior cycles of good versus poorer adherence that was influenced by many factors in their lives. Participants provided valuable and insightful information about what they would like to see in a program.

Our data presents the complexity of factors that influence T2D management. It provides insight into possible intervention components and indicates that shifts to adjust programs to mirror participants' needs could benefit long-term behavior changes and improved self-care of T2D.

7.2. Implications of Research Findings

Designing LI that are effective in shifting behaviours towards health, benefit from the use of theory throughout their process (Atkins & Michie, 2015). Thus, throughout the development of the tools and educational programs that informed the development of the PPLP, the application of behavioural theories and frameworks were used (Asaad, Soria-Contreras, Bell, & Chan, 2016; Chan & Bell, 2013; Raj et al., 2018; Soria-Contreras, Bell, McCargar, & Chan, 2014). Furthermore, in order to enable behaviour change it is crucial to first understand why behaviours are as they are and identify what needs to change in order to achieve those behaviours (Atkins & Michie, 2015).

Throughout the different stages of conducting this thesis research, the importance of facilitating and guiding participants through their T2D journey has been the main focus. Recognizing and understanding the difficulties that they face everyday is a start to beginning to develop and provide more effective LI. The main T2D management pillar researched in this thesis was nutrition therapy, and evidence of its beneficial effect to manage and prevent complications through different dietary patters was reviewed in chapter 2. These results support the shift of focus from single nutrients to dietary patterns. These results could be use as a guide for those HCP shifting towards the same recommendations. Providing evidence of different tools and technologies being developed to overcome some of the present limitations of nutrition research highlights the effort that is being donet to improve current limitations in this area. Bridging this gap in knowledge will improve our understanding of the nutrients/health relation. This is an ongoing area of research.

The findings from the RCT reflect the reality of knowledge translation in which a decrease in effectiveness was observed when compare to our prior research-setting counterpart that was also evident in the systematic review in Chapter 5. Furthermore, our results show that when applying interventions in real-world settings there is a considerable organizational burden on HCP. Thus future research focusing on designing different tools that could facilitate the transition towards healthy eating and at the same time alleviate HCP workload is required to facilitate long-term buy-in of these types of programs into real-world settings. Furthermore, the findings from this research reflect an important knowledge-action gap, providing the rationale to conduct the last study of this thesis.

The results obtained in our qualitative study reflect the importance of moving away from delivering “off the shelf” programs and moving towards a more pragmatic approach that takes into account the input from participants about their context, experiences and needs. This approach would provide more sustainable and realistic LI programs.

7.3. Future directions

Based on the results of the present research, the recommendations for future studies in this research area include:

1) Future research in the development of dietary assessment tools should include dietitians and other health care providers on research teams to co-develop and evaluate their validity, a process that would likely increase their effectiveness and acceptability. These developers of these tools should also consider working together to merge their strengths and mitigate their limitations.

2) Energy intake assessment tools should not only evaluate energy intake but shift their focus from single nutrients into identifying dietary patterns aligning with current guidelines and contributing to closing the gap between dietary pattern and metabolic health.

3) Future effective LI designers should emphasise collaborating between research groups to incorporate expertise of each pillar (SMS + SME, nutrition therapy, physical activity and pharmacological therapy), into one complete, holistic, effective intervention, in which the desires of participants are also included.

4) Having now described and analysed what components participants expect from a LI program, the next step would be to begin building the intervention. The use of Behavioural Change Wheel would be a suitable framework for guiding the process.

5) Given the important role HCP play in how participants respond to programming and subsequently manage their disease, it is fundamental to conduct a similar study but from the HCP perspective.

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Appendices

Apendix 4.1. Pure Prairie Living Program: Facilitator guide and program resources

Lesson Plan Baseline session

BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing the activity "paper toss". Participants will be asked to write their personal fears anonymously on pieces of paper which are "tossed to the garbage". Then each person reads someone else's fear to the group and explains how the person might feel. This will help get participants interest and encourages participation. The goal of this activity is to ask them to leave their fears in the garbage, put them aside, and forget about them for the next 5 weeks. Let them know that the objective of the course is to empower them with the knowledge for them to be able to handle their T2D. For this activity you will need: Paper and pen/pencil per participant, tin or a bag The plan for today's class will be presented: ● Introduction ● Course overview ● The Pure Prairie Living Program ● Let's talk about diabetes ● Physical Activity ● Goal setting for success Introduce yourself! Let them know general information about yourself. Give them your contact information, office hours; how available are you going to be?	20 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn:	3 min

<table>
<tr><td colspan="3">

- What is the Pure Prairie Living Program – general overview
- What is T2D and how does it affect the human body
- Blood glucose testing guide
- What is physical activity and its benefits
- Canadians guidelines for physical activity

The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level of knowledge through different active and learning strategies.
</td><td></td></tr>
<tr><td colspan="3">Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What is their interest in the topic? What is their motivation to learn this material?

Ask about their personal goals. This activity will be useful as an icebreaker activity and it will help evaluate what they already know. Ask them to create a concept map. This concept maps will be saved until the end of the course and we will come back to them to see if they want to add or modify something else as a closure activity.</td><td>15 min</td></tr>
<tr><td colspan="3">Participatory Learning (Active Learning-Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson? How will I shape my lesson to incorporate universal course design?</td><td></td></tr>
<tr><td>What will I do?

(Content and Delivery)</td><td>What will my learners do?</td><td>Instructor aids/resources needed</td><td></td></tr>
<tr><td>Hand out flipchart sheets to each group. Ask participant to find the other participants with the same card number as them. This is their group.</td><td>Introduce themselves

Create a mind map answering:

• What brought them here?
• What do they hope will be different after attending the program?
• What would they like to learn?
Designate a speaker</td><td>Computer, projector, speakers

Deck of cards

Flipchart sheets

Markers</td><td>15 min</td></tr>
<tr><td>Deliver content of diabetes in their body</td><td>Listen to instructor

Take notes</td><td>Computer, projector, speakers.</td><td>10min</td></tr>
<tr><td>Demonstrate high blood sugar levels in people with T2D</td><td>Reflect

Discuss</td><td>Blood sugar test tubes,

Red blood sugar pillow

Computer, projector</td><td>5min</td></tr>
</table>

Blood Sugar Testing Ask: How does stress/illness/injury affect blood sugar?	Reflect Discuss Think of a plan to test their blood sugars	Workbook pg. 6 and 9 Handouts on blood sugar control	
Balancing Blood sugars in Diabetes	Listen to instructor Take notes	Computer, projector	5min
Explain: SMART Goal Setting for Success	Understand how SMART goal setting works.	Computer, projector	5min
Let's look at a record for testing blood sugars and think of a plan to test your blood sugars	Think of a plan to test your blood sugars	Computer, projector Workbook pg. 9	5min
Let´s practice: Guide participants to observe and identify what their baseline number of steps was, and add 10%.	Find their baseline number of steps from their pedometers and add 10%. Record their steps. Discuss: How does it feel to do an extra 10%?	Computer, projector Workbook pg. 6	5min
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? Show them how to set goals for the week. - Explain to them how can they be a blood sugar detective - Show them how to record their steps			5min
Summary: What were the key points of the day's lesson learners should take away with them? Instructor will summarise the key points of the day´s lesson followed by a slide for any questions participants may have.			5min

Adapted from Johnson, Janice (2006) *Instructional Skills Workshop (ISW) Handbook for Participants.* The Instructional Skills Workshop International Advisory Committee. Originally developed by Douglas Kerr (1978/9) for use in ISW Facilitator Development Workshops.

Lesson Plan Session 1

BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing recap of last lesson. Participants will be asked to summarize the main points from the last class. • PPLP overview • Let's talk about diabetes • Physical Activity • Goal setting for success The plan for today's class will be presented: • Healthy eating • Canada´s guidelines for eating healthy • Glycemic index • Goal setting for success This will help get participants interest and encourages participation. During the class, we will refer back to this plan in order to answer any questions and keep participants engaged.	5 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn: • Why healthy eating is important? • What is the best diet? • Canadian guidelines for healthy eating • Glycemic Index • Portion guide	

- Goal setting for success

The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level through different active learning strategies.

Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What is their interest in the topic? What is their motivation to learn this material?

10 min

The first activity will be to break the participants into two groups. Ask them to write in their **workbook (page 10)** what they think they will gain from taking part in this program and what they think they will lose. Also what the people around them (family, friends, co-workers) will gain and lose.

Then participants will be asked to share with each other about the most important challenges that they face. It will be really important to get people to talk about potential solutions, strategies or plans, not just how hard it's going to be.

Gather responses on the white-board. Underscore how these answers will be addressed by different aspects of the program.

Participatory Learning (Active Learning-Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson?

What will I do? **(Content and Delivery)**	**What will my learners do?**	**Instructor aids/resources needed**	
Show a short video clip that outlines some key aspects of a healthy diet.	Debrief What did you learn? What struck you as interesting? What questions did the video raise?	Computer, projector, speakers.	20min
A Mediterranean diet? Have you seen where I live?	Talk about an Alberta version of the Mediterranean diet. What do they think some of	Computer, projector	2min

	the differences might be?		
Introduction to the book Pure Prairie Eating Plan	Look at the book, start to get familiarized with it.	Pure Prairie Eating Plan book	3min
Introduce Canada's Food Guide Acknowledge participant familiarity with this tool and some likes and dislikes about it.	Analyse: How do you think we can use Canada's Food Guide in our daily choices?	Computer, projector Workbook pg.11	5min
Talk about the role of the different food groups in our general health and what nutrients they provide.	Participants will discuss vegetable and fruit consumption, different grain products, processed foods, milk and alternatives, meats and alternatives, oils and fats. They will have the opportunity to observe and interpret features of images of processed foods and share their thoughts	Computer, projector Food labels that contain whole grains Handouts: • *Eat More Vegetables and Fruit* • *Choose Whole Grains* • *Choose Healthy Food Portions*	10min
Let´s practice – Guide participants to observe and identify how one meal contains foods from different food groups.	Write down all the ingredients used to make that meal and then identify in which food groups they belong. Identify highly processed foods. Propose what could be used instead to make it healthier.	Computer, projector Workbook pg. 13	10min

Strategies that help to eat healthy portions of food.	Think about what would be the effect on blood sugar if the balance of the meals changes.	Computer, projector Workbook pg. 14 Food models (vegetables, fruit, whole grain rice, potato, cheese, meat/chicken/fish, meat alternatives)	5min
Glycemic Index – explain low and high glycemic index and their impact on blood sugar. Strategies to lower post meal blood sugars	Identify the effects on their bodies after having a high glycemic index meal. Discuss how combining groups of food affect the glycemic index	Computer, projector	5min
Explain the handy portion guide	Practice a convenient way to measure portions.	Computer, projector Workbook pg. 15 Hand out: - Choose healthy portions	5min
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? Set goals for the week. Participants will be asked to use the balanced plate to track their food intake (Workbook pg. 17) On page 17 the strategies for ways to help keeping on track with serving sizes will be available.			5min
Summary: What were the key points of the day's lesson learners should take away with them? Participants will be asked to summaries the key points of the day´s lesson followed by a questions and answers.			5min

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Lesson Plan Session 2
BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing a reflection on last lesson. Participants will be asked to share, debrief and have a group discussion regarding what are their thoughts about: • Healthy eating/ video • Canadian guidelines for eating healthy/healthy plate • Glycemic index • Goal setting for success The plan for today's class will be presented: • Menu planning basics • Planning ahead • Grocery lists • Storing and leftovers This will help get participants interest and encourages participation. During the class, we will refer back to this plan in order to answer any questions and keep participants engaged.	5 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn: • The four Ps for menu planning • Importance of planning ahead • How to make a grocery list • Storing and leftovers	

<table>
<tr><td colspan="3">The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level through different active learning strategies.</td><td></td></tr>
<tr><td colspan="3">Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What it their interest in the topic? What is their motivation to learn this material?

Participants will be asked:

● What are some benefits to meal planning?
● What are some challenges to meal planning?
● How can we overcome these challenges/barriers?</td><td>10 min</td></tr>
<tr><td colspan="3">Participatory Learning (Active Learning--Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson?</td><td></td></tr>
<tr><td>What will I do?

(Content and Delivery)</td><td>What will my learners do?</td><td>Instructor aids/resources needed</td><td></td></tr>
<tr><td>Explain and guide participants about the different ways or formats for planning meals.

Use the flip chart/white board to practice planning a meal as a group.

Ask participants to chose between planning a meal for lunch or supper</td><td>Participants will plan a balanced meal and discuss tips and strategies to get around some of the challenges they may come across.

They will come up with some ideas for easy breakfast and easy lunches?</td><td>Computer, projector.

Use the flip chart/white board to practice planning a meal a group.

Use the meal planning sheet workbook pg. 22 -23

PPEP pg. 178 – 184

Hand-outs:

AHS Wake up to breakfast everyday

AHS What’s for Lunch</td><td>10min</td></tr>
</table>

Ask the group to identify the food groups in the recipe they chose. Refer to PPEP for recipe ideas if needed.			
Acknowledge the importance of doing grocery lists to help with staying focused & limit impulse buying.	Make a grocery list	Computer, projector Flip chart/white board PPEP pg. 94. Hand-outs: *AHS: Grocery Shopping the Healthy Way*	5 min
Give some planning tips and explain that planning takes time, but in the long run, can save time, money, energy and stress. Give some example of meal planning tips.	Discuss: What are some time savers they have tried? • Freeze leftovers into small portions for lunches • Cook extra rice and freeze leftovers • Batch cook • Others?	Computer, projector Optional hand-out: *PCN Quick Fix Meal Tips*	5 min
Packing: Food Safety tips	Take notes	Computer, projector	5 min

Discuss the temperature danger zone		Workbook pg. 24 Government of Canada Safe food storage website: http://healthycanadians.gc.ca/eating-nutrition/healthy-eating-saine-alimentation/safety-salubrite/tips-conseils/storage-entreposage-eng.php	
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? Participants will be asked to set SMART goals for the week. ● Practice a meal plan or try recipes out of the PPEP ● Continue to track your divided plate servings ● Track their steps/activity ● Monitor their blood sugar levels			5min
Summary: What were the key points of the day's lesson learners should take away with them? How will this information be unfolded (e.g. will the instructor invite participants to identify key points or will this be done by the instructor)? Participants will be asked to summaries the key points of the day´s lesson followed by a slide for questions and answers. Next session there will be a taste tasting. **Inquire about food allergies!**			5min

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Lesson Plan Session 3

BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing a summary of last lesson. Participants will be asked to summarize the main points from the last class. • Menu planning basics • Planning ahead • Grocery lists • Storing and leftovers And to **share, debrief and have a group discussion** on how did they do on their goals during last week The plan for today's class will be presented: • Customizing your menu plan • Menu planning tips • Recipe sample taste testing This will help get participants interest and encourages participation. During the class, we will refer back to this plan in order to answer any questions and keep participants engaged.	5 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn: • How to customize their menu plan according to their preferences. • Take home some menu planning tips • Have a recipe sample taste testing The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level through different active learning strategies.	
Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What is their interest in the topic? What is their motivation to learn this	10 min

<table>
<tr><td colspan="3">material?

The first activity will be to analyze participants' meals plans from past week.

ASK:

Would anyone like to share what he or she liked about his or her meal plan?

What would you they do differently next week?

Talk about some reasons and ways to customize or modify your meal plan….</td><td></td></tr>
<tr><td colspan="3">Participatory Learning (Active Learning-Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson? How will I shape my lesson to incorporate universal course design?</td><td></td></tr>
<tr><td>What will I do?

(Content and Delivery)</td><td>What will my learners do?</td><td>Instructor aids/resources needed</td><td></td></tr>
<tr><td>Explain that depending on their requirements and situation, they may have to adjust menu plans and recipes to suit them better.

Adjustments can be made according to: calorie requirement, family size, culture and lifestyle not to mention different diseases including allergies.

Focus on encouraging being creative, rather than avoiding that dish.

Explain the formula:

Needed yield/recipe yield</td><td>Look for yield or serving sizes in recipes, and adjust recipe ingredients according to their needs

Compare their recipe/meal to the divided plate. Evaluate:

• What food groups does the recipe include?
• What foods groups are missing?
• Is there anything they could add to this recipe/meal to make it fit within the divided plate?</td><td>Computer, projector.

Workbook pg.30 – 31

PPEP pg. 15 – tips for using herbs and spices to lower salt use.</td><td>10min</td></tr>
</table>

Multiply the ingredients with the resulting factor How can the PPEP help them reach their health goals?			
Making modifications Explain that when replacing ingredients: • Serving sizes should be comparable • The ingredients should be from the same food group - Consider potential changes to texture/flavour **ASK**: What portions would they use when making substitutions?	Read through the ingredient on **pg. 101 PPEP** for the Mediterranean Chicken Stir-fry. Discuss possible ingredient substitutions for: - Barley: - Chicken: - Canola oil: - Vegetables:	Computer, projector. PPEP pg. 101 and 125 Workbook pg. 32	5min
ASK participants: How can they… - Increase fibre? - Reduce sodium? - Use healthy fats? - Reduce added sugar? - Other ideas?	Read through and discuss as a group the tips to modify recipes to make them healthier. Participants should circle any of the tips they think they can try at home.	Computer, projector. **PPEP:** P**g. 59** - nutrient comparison for <u>rice, spaghetti and barley</u> **Pg. 65** – nutrient comparison for <u>milk products</u> **Pg. 119** – nutrient comparison for <u>oils</u> **Pg. 145** – nutrient comparison for <u>steak chicken, salmon</u> AHS Handouts: AHS Reducing Fat and Sugar, Fibre facts, Sodium and your	5min

		Diet	
Refer to **PPEP pg. 100**, week 3, day 2 menu. Review the menu for the day as a group. **ASK:** What if there was a meal or snack that they didn't want or like? How could they modify the menu to suit their preferences? Choose a meal or snack as an example and have class brainstorm ways to modify.	Brainstorm ways to modify a meal or snack. - Look for a different recipe to have instead. - Substitute some of the ingredients to make it suitable to your preferences	Computer, projector. **PPEP pg. 100** **Workbook pg. 33-34**	5min
Food preparations tips - Batch cook - Planned overs - Double recipe Keep it simple! **ASK:** Does anyone have some quick, easy and simple meals you have tried that you can share?	Analyze/think: What else do they need to make a complete meal? Make a plan of when they will eat each meal. Think about what food groups might be missing. What will they need to add to this meal to make it balanced?	Computer, projector. Workbook pg. 34	5min
Open **cookspiration** web page and demonstrate briefly how they could use it.	Observe	Computer, projector. PCN Meal Planning Resources	5min
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? As participants are tasting the samples, **discuss** how the recipes could be modified to suit personal preferences, allergies etc. Explain which recipes the participants will be taste testing. Describe any modifications to the recipes that were made.			20min
Summary: What were the key points of the day's lesson learners should take away with them? ● Practice a meal plan or try a recipe out of the PPEP			5min

• Continue to track their divided plate servings • Track their steps • Monitor their blood glucose levels.	

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Lesson Plan Session 4

BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing a recap of last lesson. Participants will be asked to summarize the main points from the last class. • Customizing menu plans • Menu planning tips • Recipe sample taste testing And to **share, debrief and have a group discussion** on how did they do on their goals during last week The plan for today's class will be presented: • Recipe review • Buying healthy and label reading **ASK:** What are your thoughts about the samples they tried? Did they incorporate any lentils, or pulses into your diet? Did anyone try any of the recipes in the Pure Prairie Eating Plan cook book? This will help get participants interest and encourages participation. During the class, we will refer back to this plan in order to answer any questions and keep participants engaged.	15 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn: • To do label reading to help with making healthy choices.	

<table>
<tr><td colspan="3">The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level through different active learning strategies.</td><td></td></tr>
<tr><td colspan="3">Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What is their interest in the topic? What is their motivation to learn this material?

ASK: the participants:

● “If I am doing too much label reading, am I eating too many processed foods?”
● What are their thoughts about this?”</td><td>10 min</td></tr>
<tr><td colspan="3">Participatory Learning (Active Learning-Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson? How will I shape my lesson to incorporate universal course design?</td><td></td></tr>
<tr><td>What will I do?

(Content and Delivery)</td><td>What will my learners do?</td><td>Instructor aids/resources needed</td><td></td></tr>
<tr><td>Deliver content on:

• Serving Size and Calories
• How to Use the % Daily Value
• A Closer Look at Fat
• Which Meat/Protein and Dairy Products are Good Choices?
• Dairy Products
• Are Packaged Low Fat Foods a Good Choice?
• We can use the % Daily Value for Sodium
• Carbohydrates on the Nutrition Facts Table
• Sugar is Sweet, but…
• Limit Intake of Sugar Alcohols
• Let’s Look at the Fibre and Sugar
Remember to give lots of example and make sure everyone is with you. Use the power point notes to guide you with questions and</td><td>They will be handed an example of a label from different products to do label reading as the instructor goes through each of the different food groups.

Go through an example of label reading on their workbook as a group.</td><td>Computer, projector.

• Workbook pg. 41 - 42
Refer to Pure Prairie Eating Plan cookbook

Labels for label reading (starchy/grain based foods, dairy, canned goods, crackers, granola bars etc.)

Handouts of:

• Label Reading the Healthy Way
• Fibre Facts</td><td>50 min</td></tr>
</table>

examples for each food group.			
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? Set goals for the week to keep track of what has been learnt. **ASK** participant to: ● Practice a meal plan or try a recipe out of the PPEP ● Continue to track their divided plate servings ● Track their steps ● Monitor their blood glucose levels ● Read labels when grocery shopping			5min
Summary: What were the key points of the day's lesson learners should take away with them? Participants will be asked to summaries the key points of the day´s lesson followed by a slide with the content of next week (We will be looking at pre-prepared meals/frozen meals and some restaurant menus. We will also be thinking about some strategies for special occasions etc).			5min

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Lesson Plan Session 5

BOPPPS Model

Lesson Components	Time (min)
Bridge/Hook: How will I open the lesson and connect the learners to the material? What will I do to interest them in the lesson? The lesson will be opened by doing a summary of last lesson. Participants will be asked to summarize the main points from the last class. • Buying healthy and label reading • Read labels when grocery shopping And to **share, debrief and have a group discussion** on how did they do on their goals during last week. The plan for today's class will be presented: • Questions about label reading • Convenience foods/ready-to-eat foods • Restaurant eating • Special occasions/holidays • Moving forward This will help get participants interest and encourages participation. During the class, we will refer back to this plan in order to answer any questions and keep participants engaged.	15 min
Outcomes: What do I want my learners to know or be able to do by the end of the lesson? Outcomes should be SMART! (specific, measureable, actions oriented, results oriented, timely and tangible) By the end of this lesson participants will learn: • How to choose healthier prepared foods • Understand and use the carbohydrate counting system • Portion control and healthy eating when dining away from home The lesson will target foundation knowledge, application, comprehension and analysis. Participants will get to this level through different active learning strategies.	
Pre-assessment (Formative Feedback): What will I do to find out what learners already know about the topic? What is their interest in the topic? What is their motivation to learn this	10 min

material? Ask participants about **Prepared Meals** and its challenges around them. Jot the strategies on flip chart /white board. Focus on label reading and Canadian guidelines. What should they keep in mind.			
Participatory Learning (Active Learning-Content and Delivery): What content will I deliver? What teaching and learning activities will I use during the lesson? How will I shape my lesson to incorporate universal course design?			
What will I do? **(Content and Delivery)**	**What will my learners do?**	**Instructor aids/resources needed**	
Choosing Prepared Meals Introduce the concept of Carbohydrate Counting system. Present what the Canadian Diabetes Association recommends.	Participants will discuss the key points they should consider when buying and eating prepared meals.	Computer, projector.	10min
Dining Away From Home Focus on why restaurant food can be challenging because it's designed to be tasty and sell well, and even menu items which tout themselves as "healthy" may not be so healthy. Point out that portion control also becomes a problem when eating out because restaurant portions are so unrealistically large.	Break up into groups of 2 or 3 and come with 2 strategies to help with eating away from home. Jot the strategies on flip chart /white board.	Computer, projector White board Workbook pg.49 Handout *"Eating Out the Healthy Way"*	15min

Dining out tips Give out menus for the restaurant/fast food establishments. **ASK** participants to each pick out one item that they would usually get at this restaurant from the menu, without looking at the nutrition information. Now ask them to take a look at nutrition info. How much carbohydrate, sodium and fat do these products contain? Increase awareness of the need of healthy food choices	Discuss reactions and opinions with other participants about their chosen item. Take a look at the menu with the nutrition info, and pick out an alternate healthier menu item to their original.	Computer, projector Restaurant/fast food establishment menus	10min
Planning for delayed meals: present a scenario	Think what to do in this situation: • What do you do if you've been invited to supper and you know supper will be served later than your usual time?	Computer, projector	5min
Ways to eat healthy on different situation Divide participants into groups and have each group pick one special occasion and write down some strategies for dining/choosing healthy	Choose a special occasion, and write down some strategies for finding/choosing healthy foods. Share their ideas with the	Computer, projector Workbook pg.50	15min

foods. Have them share their thoughts	group.		
Continue stepping towards success Motivate students Set goals	Think, pair, share What motivates them?	Computer, projector Workbook pg. 53 - 57	5min
Post assessment (Formative/Summative Feedback): How will I know learning has taken place? Closing Activity: Post around the room the flipchart sheets that were done at the beginning of the course. Ask participants to see if they want to add or modify something else as a closure activity.			5min
Summary: What were the key points of the day's lesson learners should take away with them? Explain to participants **What to Expect Next?** Regarding the three and six months evaluations and the focus group Talk about **What other supports they can access?**			5min

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Pure Prairie Living Program

HEALTHY EATING FOR TYPE 2 DIABETES

Name: _____

Date: _____

PURE PRAIRIE LIVING PROGRAM-A LIFESTYLE INTERVENTION

Welcome! To the Pure Prairie Living Program based on the PANDA Project. Healthy lifestyle is important in managing diabetes but many people find it hard to achieve a lifestyle pattern that is healthy yet easy to follow in the long term. Many others don't know where to start.

This program will show you in bite-sized pieces, how to eat healthier, and incorporate other lifestyle changes to manage your diabetes.

Syllabus 2017

Course Description: A nutrition and physical activity education course to develop skills, strive to promote behaviour change, skill development and practice in promoting better nutrition choices, critical assessment of healthy lifestyle and overall improvement of diabetes self-efficacy. The course includes practical application of these tools.

Session times:
Tuesday from 9:30 – 11:30pm (Group A)
Thursday from 6:00 – 8:00pm (Group B)
Location: Sherwood Park PCN Suite 108

Instructors contact information:

Karen Watkins
Registered Dietitian
Sherwood Park Primary Care Network
150 Broadway Crescent, Suite 108
Sherwood Park, AB
T8H 0V3
Phone: 780.410.8003 | Fax: 780-416-0139
karenw@sherwoodparkpcn.com

Cathy Sakowsky
BSc*, Registered* Dietitian
Sherwood Park Primary Care Network
150 Broadway Crescent, Suite 108
Sherwood Park, AB
T8H 0V3
Phone: 780.410.8225 | Fax: 780-416-0139
cathys@sherwoodparkpcn.com

Research team contact information
Carolina Archundia Herrera
MSc, PhD Student, Nutrition and Metabolism
6-126 Li Ka Shing Centre for Health Research Innovation,
Dept. of Agriculture Food and Nutritional Science
University of Alberta,
Edmonton, Canada T6G 2E1
+1 (780) 492 9939
archundi@ualberta.ca

Fatheema Begum Subhan
PhD, RD, Post-Doctoral Fellow
6-126 Li Ka Shing Centre for Health Research Innovation,
Dept. of Agriculture Food and Nutritional Science
University of Alberta.
Edmonton, AB.
+1 (780) 492 9939
fatheema@ualberta.ca

Principal investigator
Catherine B. Chan
PhD, Professor, Nutrition and Physiology, University of Alberta
Scientific Director: Alberta Health Services
Diabetes, Obesity and Nutrition Strategic Clinical Network
President: Canadian Physiological Society
Pure Prairie Eating Plan (PPEP)
Fresh food, practical menus and a healthy lifestyle!

Office Hours:
Appointments with the research group can be booked through email or in class for a mutually acceptable time. If you send an e-mail please put Sherwood Park- PCN PPLP in the subject line.

Intended Audience and Prerequisites:
This course is intended for adults with type 2 diabetes who are able to read and write English.

Course Readings and Fees:
Please note that there is a required textbook for this course that will be provided to you; *The Pure Prairie Eating Plan* by *Dr. Catherine Chan and Dr. Rhonda Bell* (www.pureprairie.ca). Required readings and extra materials will be handed out in each session.

Course Objectives:
To enrich participants' understanding of type 2 diabetes management through nutrition and physical activity education sessions strive to promote behaviour change, skill development and practice. This is accomplished through integrating theoretical and conceptual information, and applying this information through class discussions and designing, selecting and comparing healthy life skills from unhealthy ones, interpretation of nutrition data and understanding the implications of this on health.
Additional objectives of the course include:

a) Enhanced knowledge and practical suggestions about healthy eating for better blood sugar control.
b) To enable participants to understand and comprehend the importance of healthy lifestyle on their diabetes control.
c) To assist participants in increasing healthy eating knowledge and skills including meal planning and facilitate participants in acquiring and practicing skill to live well with diabetes long-term.
d) Opportunity to meet others with diabetes and share experiences and ideas

Course outcomes:
Participants will gain skills, and make sustainable behaviour changes to manage type 2 diabetes resulting in better health.

Evaluation:

Each week, participants will be asked to work on their personal goals and complete different activities on their workbook. You are expected to fulfill all the activities on your workbook. All participants must complete the following evaluations:

	Group A	Group B
Baseline evaluation	Tuesday May 9th 9:30-11:30pm	Thursday May 11 6:00-8:00 pm
3 months evaluation	Tuesday August 1st 9:30-11:30pm	Thursday August 3rd 6:00-8:00 pm
6 months evaluation	Tuesday Oct 31 9:30-11:30pm	Thursday Nov 2 6:00-8:00 pm

Policy for Evaluation: If a participant misses the evaluation, they need to contact the instructor within 24 h and a new time will be set between the instructor and participant to write the evaluation.

Notes:

- Evaluation of lifestyle choices (adherence to recommendations from eating well with Canada´s Food Guide (EWCFG) and Canadian Diabetes Association (CDA), nutrition self-efficacy and participation in physical activity) will be examined at 3 months and 6 months period and compared to assessments conducted at the beginning of the course. This will shed light on the participants improved nutrition and physical activity-related knowledge and skills to manage type 2 diabetes.

Course etiquette:
This course will include a lecture-style format, group work, and discussion. A workbook will be a major part on the course, so please ensure that you complete the assignment. Please be considerate of your colleagues: be on time, listen to others and do not talk when someone else is speaking. Please silence your cell phones before entering the sessions.

Recording of Lectures:
Audio or video recording of lectures or any other teaching environment by students is allowed only with the prior written consent of the content author(s) or as a part of an approved accommodation plan. Recorded material is to be used solely for personal study, and is not to be used or distributed for any other purpose without prior written consent from the instructor.

Attendance and Absences:
Regular attendance is essential for optimal performance in any course. In cases of potentially excusable absences due to illness or domestic affliction, notify your instructor by e-mail within two days.

Participants' accessibility services:
If you have special needs that could affect your performance in this course, please let us know during the first week so that appropriate arrangements can be made.

Ethics:
If you have any questions or concerns about your rights as a participant, or how this study is being conducted, you may contact the Research Ethics Office at 780-492-2615. This office has no affiliation with the study investigators.

Lecture Outline –2017 (note that the order of the topics covered may change a little and some topics may be a little shorter or longer)

Session		Topic
Group A	**Group B**	
Tuesday May 16 9:30-11:30pm	Thursday May 18 6:00-8:00 pm	**The Pure Prairie Living Program** • Introduction • Course overview • The Pure Prairie Living Program • Let's talk about diabetes • Physical Activity • Goal setting for success
Tuesday May 23 9:30-11:30pm	Thursday May 25 6:00-8:00 pm	**Healthy eating** • Healthy eating • Canada's guidelines for eating healthy • Glycemic index • Goal setting for success
Tuesday May 30 9:30-11:30pm	Thursday Jun 1 6:00-8:00 pm	**Meal Planning** • Menu planning • Planning ahead • Grocery list/food safety • Storing and leftovers
Tuesday Jun 6 9:30-11:30pm	Thursday Jun 8 6:00-8:00 pm	**Customizing meals** • Menu planning tips • Recipe sample taste testing
Tuesday Jun 13 9:30-11:30pm	Thursday Jun 15 6:00-8:00 pm	**Buying healthy and label reading** • Review taste testing • Recipe review • Buying healthy and label reading
Tuesday Jun 20 9:30-11:30pm	Thursday Jun 22 6:00-8:00 pm	**Eating away from home and convenience foods** • Review progress • Convenience foods/ready-to-eat foods • Restaurant eating • Special occasions/holidays • Moving forward

Pure Prairie Living Program
Baseline Session

Blood Sugar Management

Managing blood sugars is a balancing act between:

a) _____
b) _____
c) _____

There are many factors that can cause blood sugar to go up or down. These include:

- _____
- _____
- _____
- _____

Blood Sugar Target Ranges

- ✓ Before Meals: 4-7 mmol/L*
- ✓ 2 hours after meals: 5-10 mmol/L*
- ✓ HbA1C target ≤7.0%

*These blood sugar targets are general guidelines. Your doctor may have set different blood sugar targets for you. Always follow the advice of your doctor.

Record your steps

Time/date pedometer was first worn: _____, _____
Time Date

	Number of steps taken	Time and date this number was recorded from pedometer
Day 1		
Day 2		
Day 3		

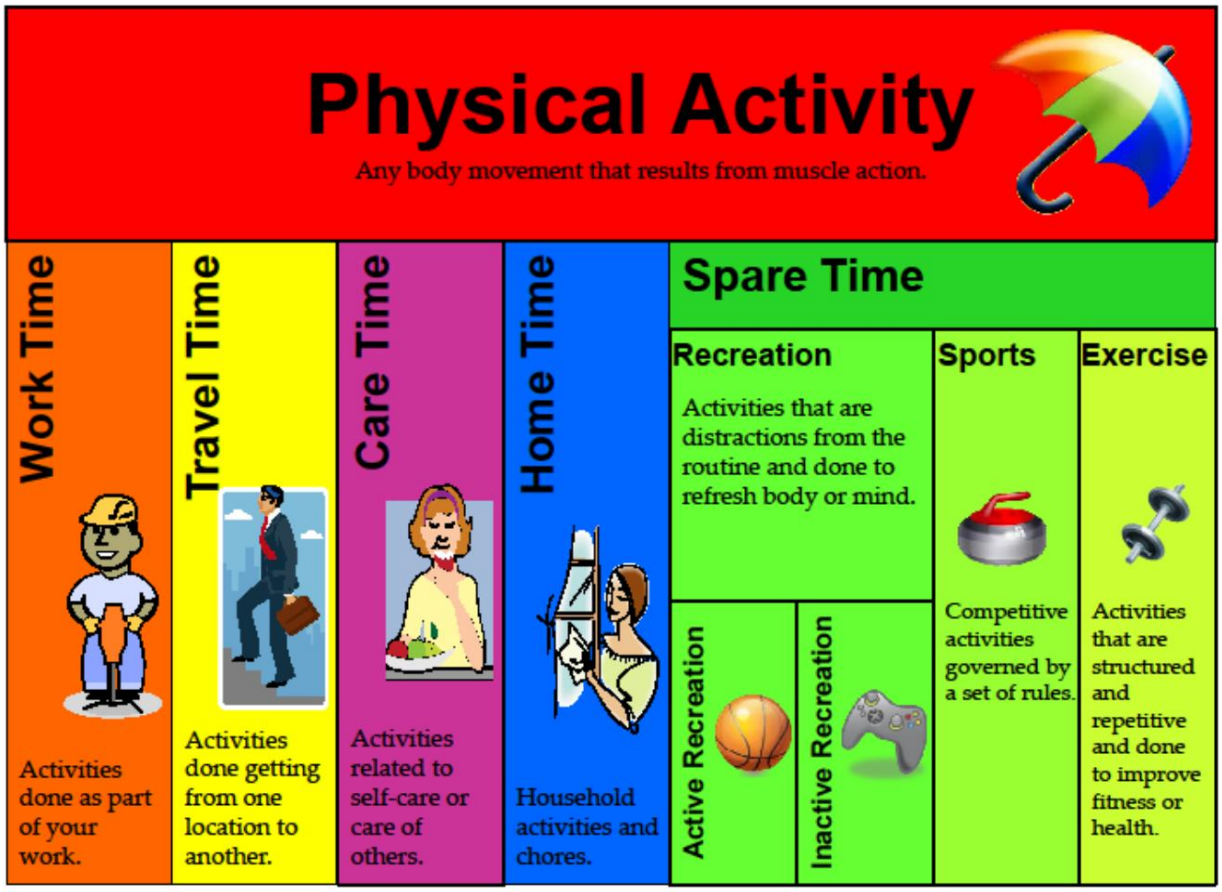
You should affix the pedometer to their clothing (as described in the pedometer instructions) as you get dressed at the beginning of Day 1. This will ensure that pedometers capture steps for as close to a full day as possible, every day. Also, check every morning that the pedometer has been reset to zero steps. Each night, the pedometer should be removed before bedtime.

The Importance of Physical Activity

- Makes you physically fit, stronger and more flexible
- Reduces the risk of diseases and health complications
- Improves mental health

Recommendations for Physical Activity

- **Being** active for at least 150 minutes per week
  - Walk for 30 min on most if not all days of week
  - Short bouts of 10 mins or more 3 times a day
  - Choose your favorite activity



Goal Setting Success - Set SMART Goals

S pecific
M easurable
A chievable
R ewarding
T ime

Physical activity tracking sheet

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
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ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
TOTAL TIME	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**

YOUR BLOOD GLUCOSE TESTING GUIDE

Ask your diabetes healthcare professional to mark the times on this two-week chart, or use the following guide to get started by testing at least twice a day

Test where you see the grey shaded areas each day This will allow you to see how your blood sugar changes throughout the day							
	Before Breakfast	**2 hours after** Breakfas	**Before** Lunch	**2 hours after** Lunch	**Before** Dinner	**2 hours after**	Bedtime
Sunday							
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Wednesday							
Thursday							
Friday							
Saturday							
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
2/ week Average							

Healthy Eating
Week 1:

Healthy Eating is important in managing diabetes but many people say they find it hard to eat healthy, or they don't know where to start.

This program will show you in bite-sized pieces, how to plan, choose, cook and eat healthier to manage your diabetes.

Something to think about:
Changing eating habits can be hard to do. Begin by thinking about what you can get out of eating healthier, and what you may have to give up.

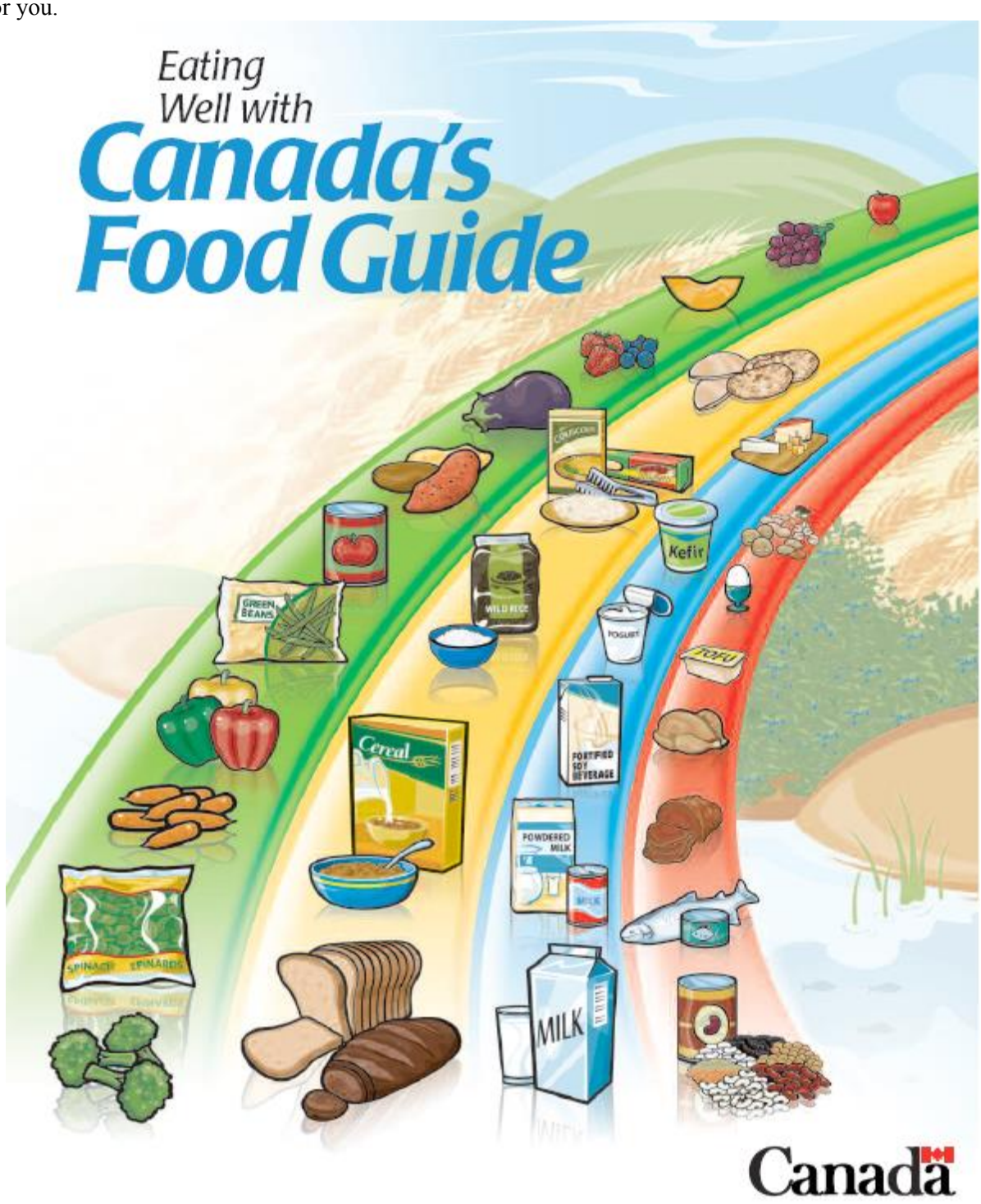
Gains for me	Losses for me	Plans (getting the most without giving up too much)
Gains for people around me	Losses for people around me	Plans

Not
es - Healthy Eating Video by Dr. Mike Evans:

- https://www.youtube.com/watch?v=fqhYBTg73fw

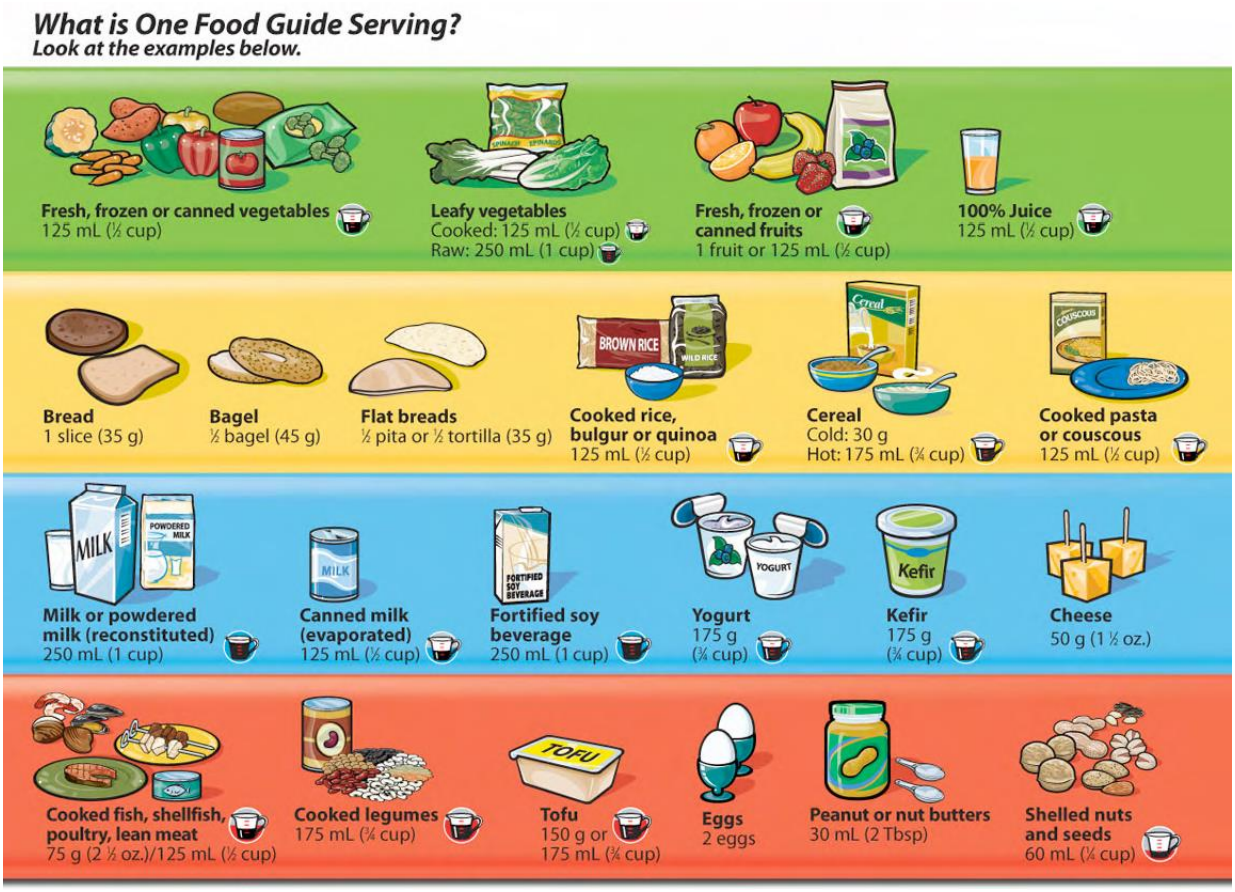
Canada's Guidelines for Healthy Eating

Canada's Food Guide will help you know how much food you need, and what types of foods are better for you.



Name the food groups:_____

What do we know about Food Guide Servings?

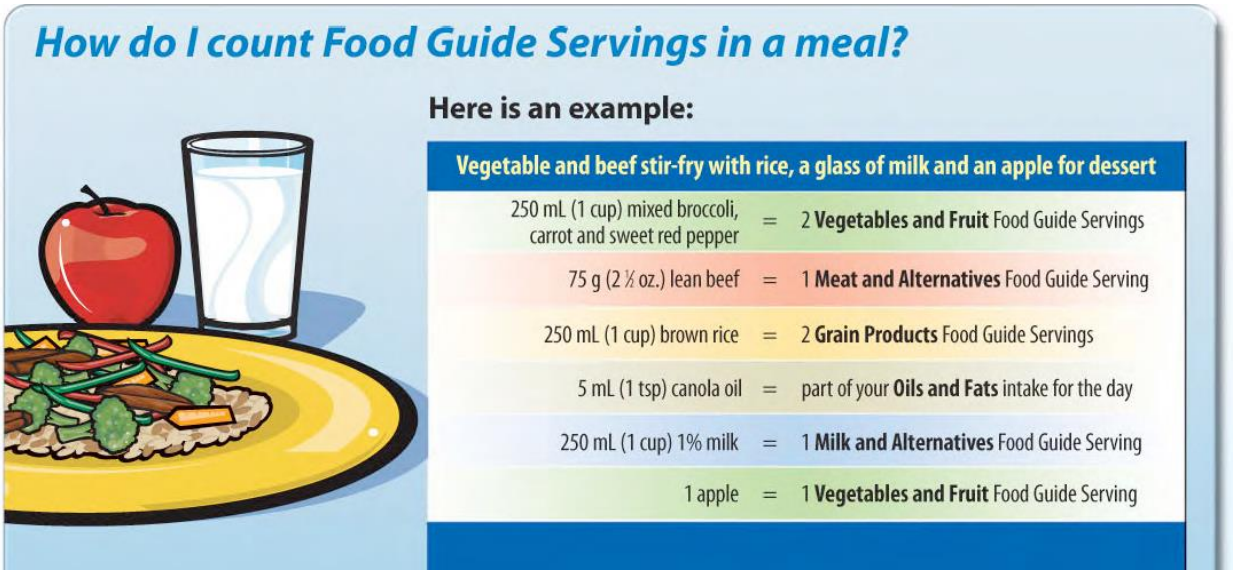


Healthy Eating Principles

- Plan to eat within 1 hour of waking, and every 4-6 hours
- Aim for 3 meals, and 1-2 snacks (only if needed) per day
- Choose foods from Canada's Food Guide for snacks. For example, a piece of fruit, vegetable sticks, low fat cheese, low sugar yogurt, or a small handful of unsalted/dry roasted nuts, are nutritious light snacks (look at your cookbook for more snack recipes and ideas).

How to count Food Guide Servings in a meal:

Meals typically consist of different foods from each food group. First you need to know what foods are in a meal, as well as how much of each food was used to prepare the meal.



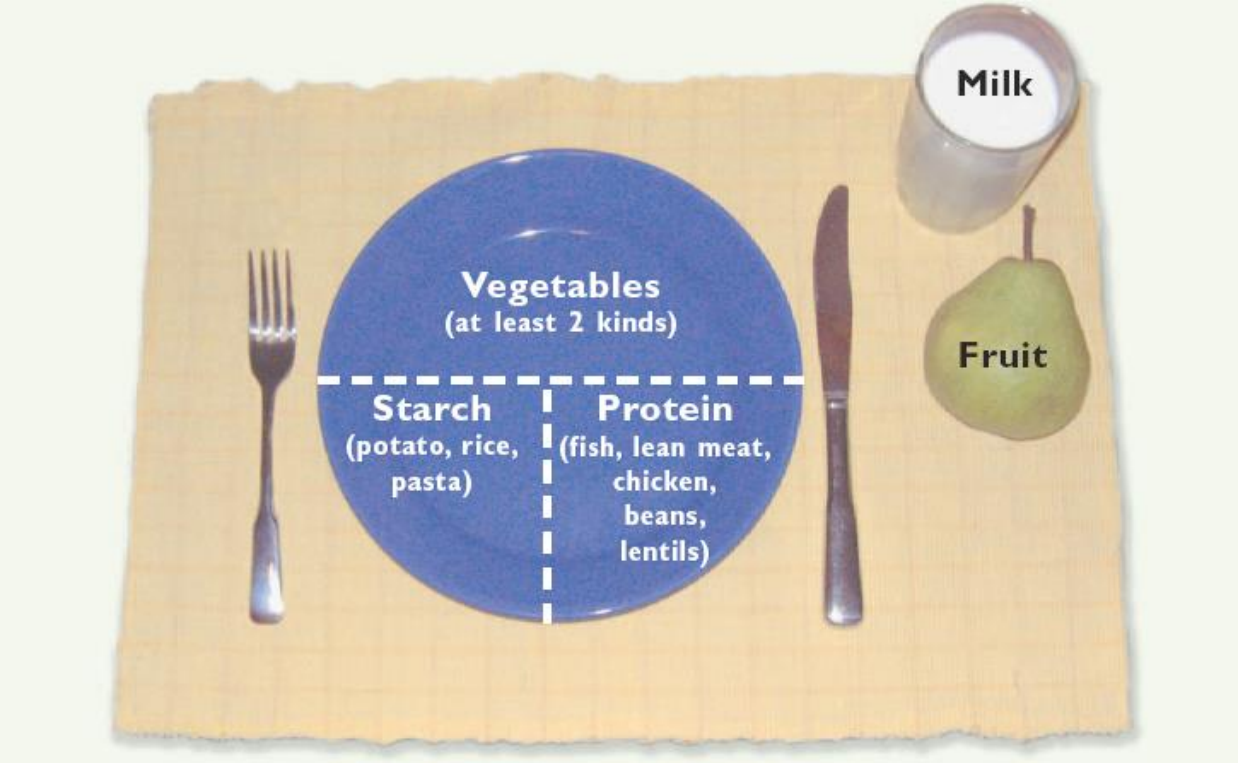
Let's practice!
First, write down all the ingredients used to make that meal and then identify which food groups they belong. Next, compare the amounts of the main ingredients in a portion of the meal to the amounts that make up a Food Guide Serving in Canada's Food Guide.

Main ingredients used to make one portion of Beef Lo Mein	**Number of food guide servings**				
	Vegetables & fruits	**Grain products**	**Milk & alternatives**	**Meat & alternatives**	**Added oils & fats**
Chinese egg noodles 250 ml (1 cup) of cooked Noodles					
Sirloin steak strips 75 grams (2.5 oz) cooked					
Broccoli, red pepper, celery, onion 250 ml (1 cup) chopped vegetables					
Cashews 30 ml (2 Tbsp)					
Peanut oil 5 ml (1 tsp)					
Totals					

Portion Planning Tips

How do I measure what I eat?

When you have a meal, how do you know your meal is well balanced? There is a simple way that helps you eat a balanced diet.



Evaluate Your Meal!

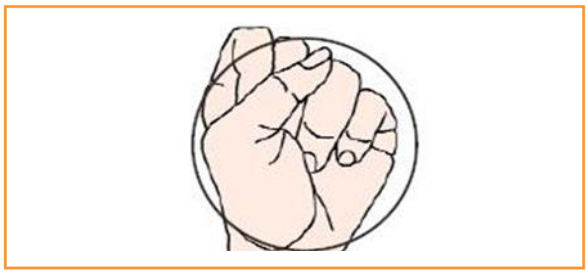
Check List

- ✓ Fill ½ your plate with vegetables, choose at least 2 kinds.
- ✓ Choose whole grain pasta, rice, noodles or bread, or starchy vegetables such as sweet potatoes, or white potatoes for ¼ of your plate.
- ✓ ¼ of your plate should be a food high in protein such as fish, lean meat, chicken without the skin, low fat cheese, eggs, beans, or lentils as part of your meal.
- ✓ You can have a glass of milk, low sugar yogurt, and/or a piece of fruit to complete your meal if you are still hungry.

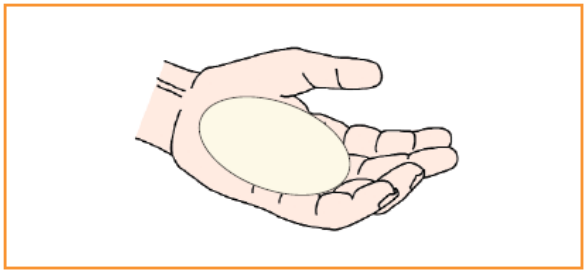
Handy Portion Guide

Your hands can be very useful in estimating appropriate portions. They're always with you, and they're always the same size!

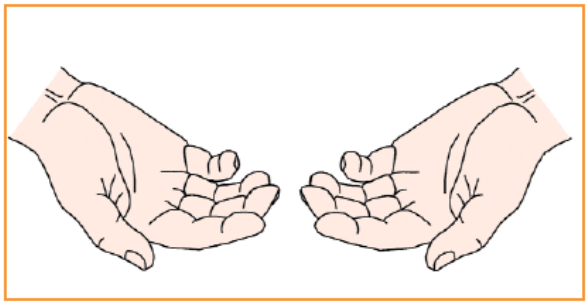
When planning a meal, use these portion sizes as a guide



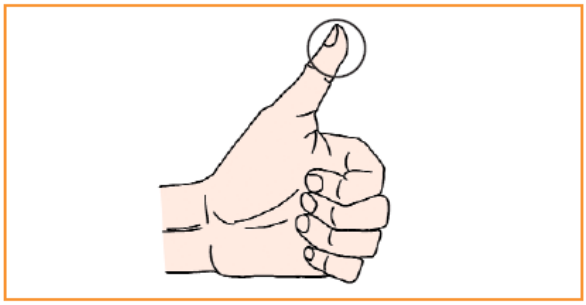
CARBOHYDRATES: Grains, starches, or fruit- choose an amount the size of your fist



PROTEIN: Choose an amount the size of the palm of your hand and the thickness of your little finger.



VEGETABLES: Choose as much as you can hold in both hands. Choose low-carbohydrate vegetables (e.g. green or yellow beans, broccoli, lettuce).



FAT: Limit fat to an amount the size of the tip of your thumb.

(Canada Diabetes Association, Nov 2004)

Ways to help me eat healthy:

<u>Instructions:</u> Use the suggestions below to set a SMART goal (or choose your own goal)

- **I will track and reflect on my meals and snacks each day** ☐
- **I will use the Handy Portion Guide** ☐
- **Other: _____** ☐

SMART Goals:

Specific_____

_____

Measurable_____

_____

Achievable_____

_____

Rewarding_____

_____

Timely_____

_____

How confident are you that you can stick to your goal over the next week?

Not at all Confident	Not very Confident	Moderately Confident	Very Confident	Extremely Confident
1	2	3	4	5

How many days this week are you confident you will reach your goal?

0	1	2	3	4	5	6	7

Setting Goals

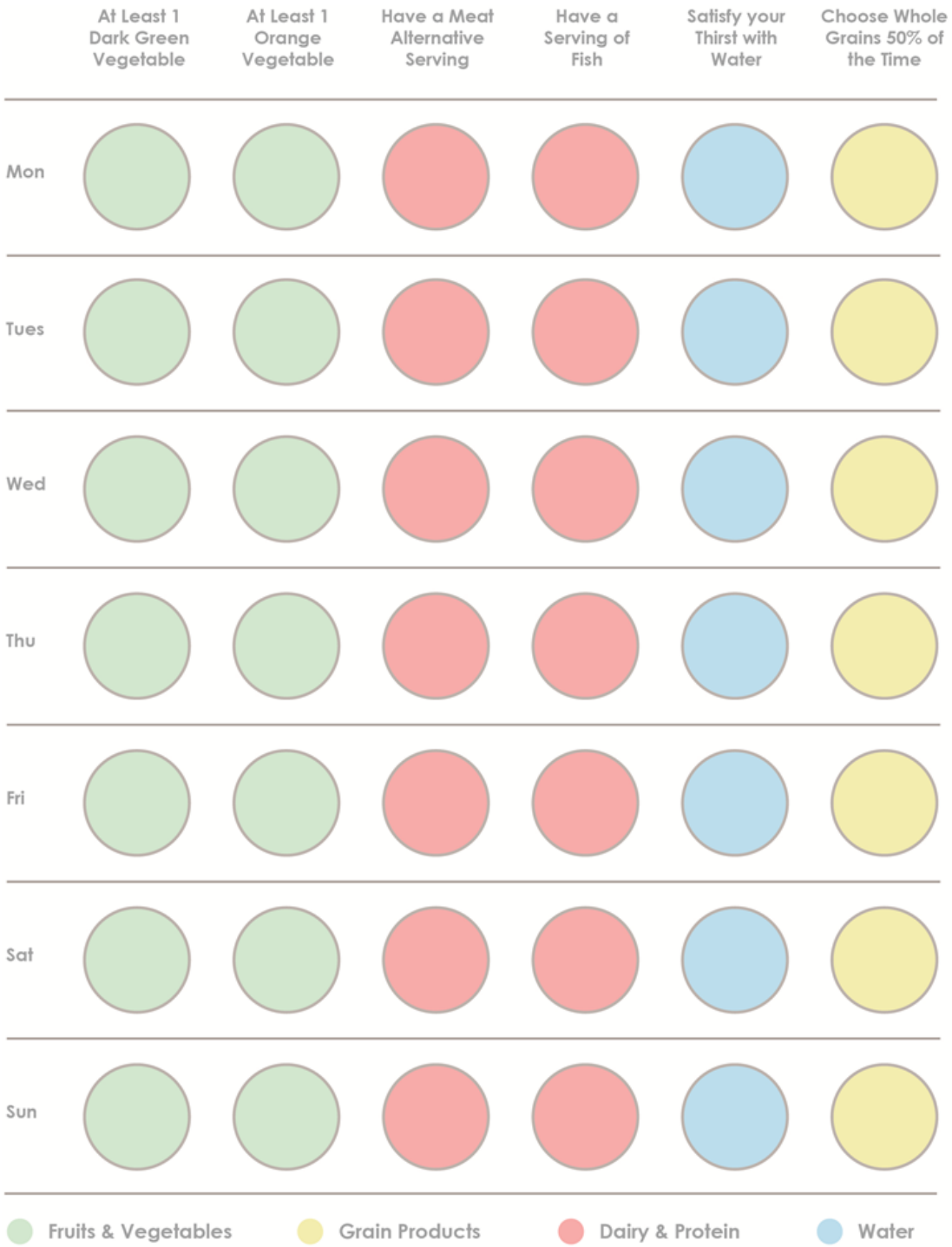
Setting Goals ***Week 1***	Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:	
	Breakfast Add Milk and Alternatives as needed	Snack if needed	Lunch Add Milk and Alternatives as needed	Snack if needed	Supper Add Milk and Alternatives as needed	Snack if needed
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						

Vegetables and Fruit  Grain Products  Meat and Alternatives 

Gather Bonus Nutrition Points!

Place a ✓check mark in each circle for each healthy eating strategy you meet each day.

Aim for consistency not perfection!



Physical activity tracking sheet

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
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YOUR BLOOD GLUCOSE TESTING GUIDE

Ask your diabetes healthcare professional to mark the times on this two-week chart, or use the following guide to get started by testing at least twice a day

Test where you see the grey shaded areas each day This will allow you to see how your blood sugar changes throughout the day							
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Saturday							
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
2/ week Average							

Meal Planning
Week 2

HOW DID YOU DO LAST WEEK?

How many days did you meet your goal during the past week?

_____

WHAT WORKED?

On the days when you met your goal, how did you do it? What strategies did you use?

_____

_____

WHAT DIDN'T WORK?

On the days when you didn't meet your goal, what challenges did you face? What strategies didn't work?

_____

_____

_____

WHO HELPED?

Did you tell anyone about your goals?
Y N

Do you have anyone who could help to meet your goals?
Y N

How can your friends, co-workers, or family help you to meet your goals?

_____

_____

Challenges	Strategies

Menu Planning

List some benefits of planning your weekly menus

_____

_____

List some challenges you might face when planning your weekly menus. If you don't plan your menus, what are the barriers that are stopping you?

_____

_____

How can you overcome these barriers/challenges?

_____

_____

Steps to Easy Menu Planning:

1. Choose a meal to plan – breakfast, lunch, or supper.
2. Choose a meat and alternative (e.g. chicken). Find a recipe.
3. What food groups are missing in the recipe? Do you need to add any food groups?
4. Choose your vegetable(s).
5. Choose a whole grain or starchy vegetable.
6. Choose your milk, dairy or fortified soy beverage.
7. Use your recipe to make a grocery list. Set aside time to shop and prepare your meal(s)
8. Cook once and eat twice! Use those leftovers.

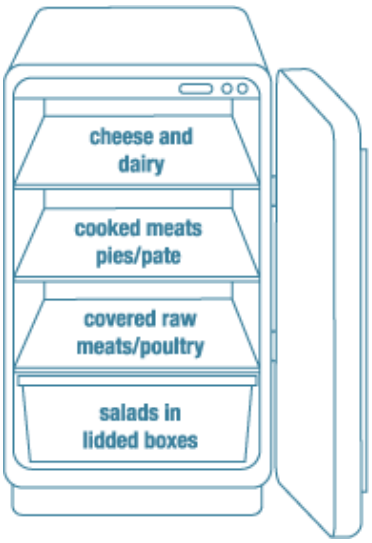
Sample Menu Plan

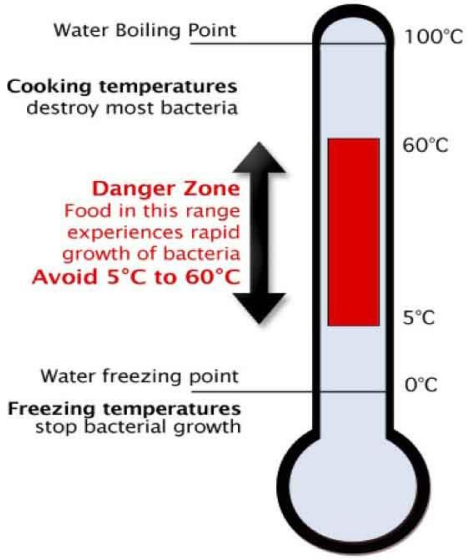
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Breakfast							
Morning Snack							
Lunch							
Afternoon Snack							
Dinner							
Evening Snack							

Food Safety

Government of Canada **Safe food storage website:**

http://healthycanadians.gc.ca/eating-nutrition/healthy-eating-saine-alimentation/safety-salubrite/tips-conseils/storage-entreposage-eng.php





Make sure your refrigerator is set at 4 °C (40 °F) or lower and your freezer at -18 °C (0 °F) or lower. This will keep your food out of the temperature danger zone (between 4 °C (40 °F) to 60 °C (140 °F)) where bacteria can grow quickly.

Place raw meat, poultry, fish and seafood in sealed containers or plastic bags on the bottom shelf of your refrigerator so raw juices won't drip onto other food.

Ways to help me eat healthy:

<u>Instructions:</u> Use the suggestions below to set a SMART goal (or choose your own goal)

- **I will track and reflect on my meals and snacks each day** ☐
- **I will use the Handy Portion Guide** ☐
- **I will use the PPEP cookbook.** ☐
- **I will make a Grocery List** ☐
- **Other: _____** ☐

SMART Goals:

Specific_____

_____

Measurable_____

_____

Achievable_____

_____

Rewarding_____

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Timely_____

_____

How confident are you that you can stick to your goal over the next week?

Not at all Confident	Not very Confident	Moderately Confident	Very Confident	Extremely Confident
1	2	3	4	5

How many days this week are you confident you will reach your goal?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**

Setting Goals

Setting Goals ***Week 2***	Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:	
	Breakfast Add Milk and Alternatives as needed	Snack if needed	Lunch Add Milk and Alternatives as needed	Snack if needed	Supper Add Milk and Alternatives as needed	Snack if needed
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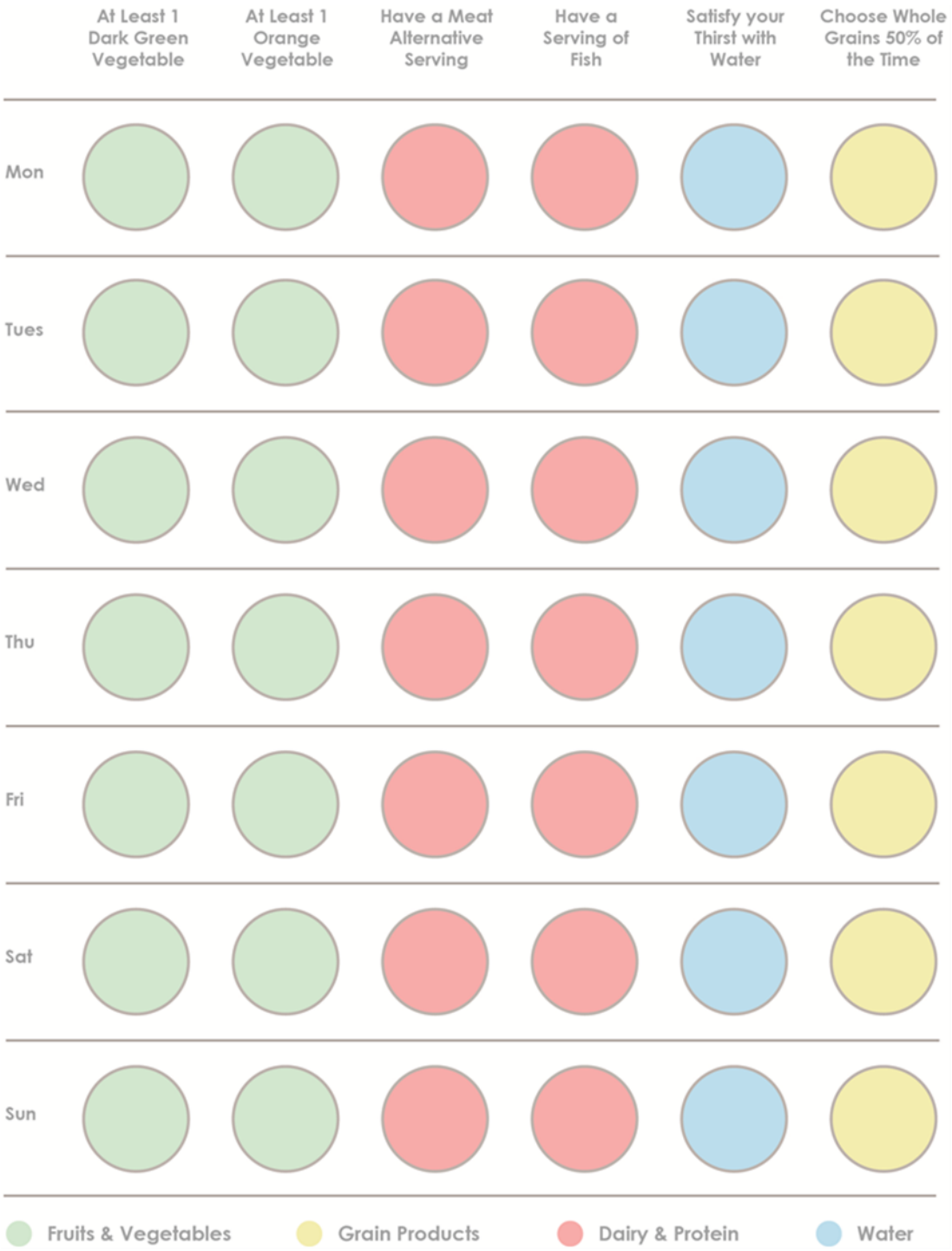
Vegetables and Fruit  Grain Products  Meat and Alternatives 

Gather Bonus Nutrition Points!

Place a ✓check mark in each circle for each healthy eating strategy you meet each day.

Aim for consistency not perfection!



Physical activity tracking sheet

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TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
TOTAL TIME	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**

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Saturday							
2/ week Average							

Customizing Meals
Week 3

HOW DID YOU DO LAST WEEK?

How many days did you meet your goal during the past week?
_____

_____

WHAT WORKED?

On the days when you met your goal, how did you do it? What strategies did you use?

_____

_____

WHAT DIDN'T WORK?

On the days when you didn't meet your goal, what challenges did you face? What strategies didn't work?

_____

_____

WHO HELPED?

Did you tell anyone about your goal?
Y N
Do you have anyone who could help to meet your goal?
Y N
How can your friends, co-workers, or family help you to meet your goal?

_____

_____

More Help with Menu Planning

What did you like about the PPEP? The recipe(s) you tried?

_____
_____
_____

What would you do differently with the meal plan? With the recipe(s) you tried?

Let's figure out ways to make the PPEP menu your own.

What are some of your reasons to change recipes and menu plans?

_____
_____

Adjusting for Family size

- You may have to adjust your recipes to cook for families, or for yourself
- Look for yield or serving sizes in recipes, and adjust recipe ingredients according to your needs
- A good formula to use is: needed yield/recipe yield. Multiply the ingredients with the resulting factor.
    - E.g. If a recipe serves 4 and you're cooking for 6
        - 6/4= 1.5
        - multiply each of the ingredients by 1.5

Cultural Background

- Let's think about your cultural background. Are there foods that you like to eat that are special to your culture?

  _____
  _____

- Let's share a couple of examples of traditional recipes that you like to make and check to see how they contribute to servings from the four food groups.

Making Modifications

Ways to adapt the recipes/ PPEP menus:

_____

_____

How can the PPEP menu help you meet your health goals?

_____

_____

What ingredients could be substituted to make recipes with these ingredients healthier?

- Enriched wheat flour, unbleached flour, or wheat flour can be replaced with:
  _____
- Shortening or lard can be replaced with:
  _____
- Sugar, honey or molasses can be replaced with:
  _____
- Salt, seasoning salt, sea salt can be replaced with:
  _____

Making Modifications: Making Recipes Healthier:

ACTIVITY: circle the healthy recipe modifications tips below that you would like to try at home.

Adding Fibre:

- Try adding sources of fibre (bran flakes or buds, psyllium husk, flax/chia seed, etc.) to cereals, puddings, ground meat, salads etc.
- Try adding legumes to casseroles, salads, soups etc.
- Bulk up the veggies in your recipe by doubling or tripling and pureeing into sauces
- Other ideas: _____

Reducing Sodium:

Tips for using Herbs and Spices to lower salt use: PPEP page 15

- Don't add salt while cooking or at the table
- Use herbs and spices instead
- Buy canned vegetables, soups, beans etc. with little or no added salt (packed in water) and rinse before using
- Packaged/jarred food usually has lots of added sodium. Make your own or read labels to choose food with less sodium.
- Other ideas: _____

Cooking Healthy with Fat:

Further information on Fats and Trans fat: PPEP page 161

- Use lower fat versions of whole foods (i.e. skim milk, 20% MF (or less) cheese, 0% or 1% MF cottage cheese etc.)
- Switch up your cooking method: broil, bake, roast, steam, poach, simmer, BBQ, or grill. LIMIT frying/deep frying.
- Use healthy oils-canola or olive.
- Skip or switch up high-fat toppings and spreads (use fat free Greek yogurt in place of sour cream; low fat cheese).
- Replace store bought dressing with oil and vinegars. Add lemon juice, garlic and/or herbs & spices for extra flavor. *Tips for healthier salads: PPEP page 119.*
- Trim fat and skin from meats before cooking or buy leaner cuts. Substitute ground turkey for ground beef.
- Add in legumes for lower fat, higher fiber, protein sources.
- In baking replace up to half the fat of a recipe with applesauce.
- Toast nuts or use a sharper cheese to get more flavor from a smaller portion.
- Other ideas: _____

Reducing Added Sugar:

- In baking replace up to half the sugar of a recipe with applesauce or fruit puree.
- Try a less sweet version than your traditional recipe (example: cut the sugar in half).
- Use more cinnamon, cocoa, etc. for richer flavoring without the sugar.
- Other: _____

Curious how substituting an ingredient will affect the nutritional value of your recipe? Check out these pages in PPEP for more information:

- *Cereal grains (wheat, barley, oats, rye, triticale): page 125*
- *Grain products: page 59*

- *Cooking and Salad oils: page 119*
- *Dairy Products (breads, rice, pasta, barley): page 65*
- *Fruit: page 33*
- *Vegetables: page 21*

Food Preparation Tips:

Cook in bulk and store food to have easy access to it on busy days

- Grocery shopping on Saturday, cooking on Sunday
- Double recipes
- Planned overs
- Batch cook and freeze:
    - Foods that freeze well are:
        - Broth based soups
        - Stew or chili
        - Casseroles
        - Lasagna
        - Roasted meats
        - Baked beans and legumes

Make a plan for when you will eat each meal. What else do you need to make a complete meal? For example, think about what food groups might be missing. What will you need to add to this meal to make it balanced?

What are some quick and easy meals I can make?

_____

_____

_____

Recipe ideas: http://www.cookspiration.com/

Ways to Help Me Eat Healthy:

<u>Instructions:</u> Use the suggestions below to set a SMART goal (or choose your own goal)

- **I will track and reflect on my meals and snacks each day** ☐
- **I will use the Handy Portion Guide** ☐
- **I will use the PPEP menu** ☐
- **I will make a Grocery List** ☐
- **Other: _____** ☐

SMART Goals:

Specific_____

_____

Measurable_____

_____

Achievable_____

_____

Rewarding_____

_____

Timely_____

_____

How confident are you that you can stick to your goal over the next week?

Not at all Confident	Not very Confident	Moderately Confident	Very Confident	Extremely Confident
1	2	3	4	5

How many days this week are you confident you will reach your goal?

0	1	2	3	4	5	6	7

Setting Goals

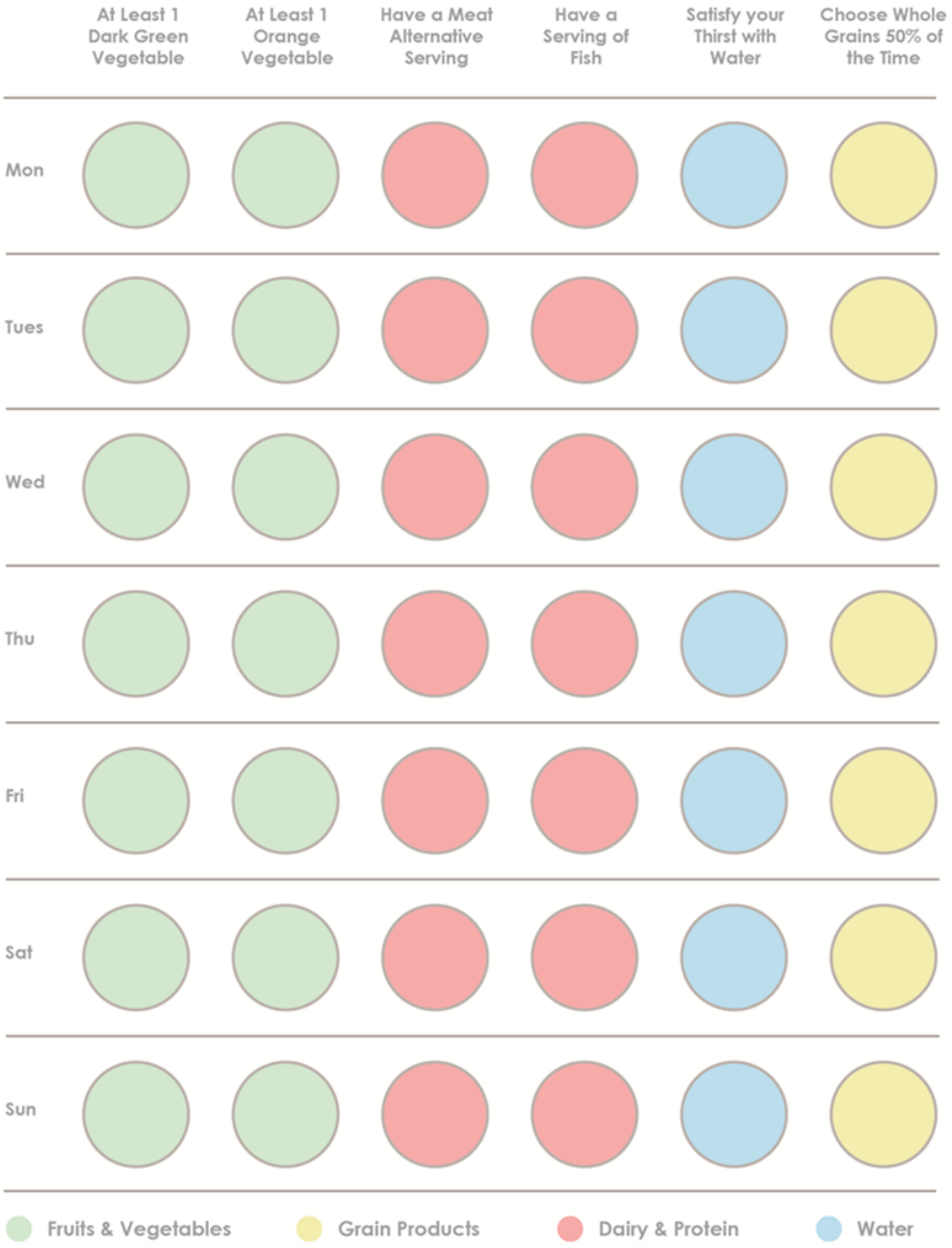
Setting Goals ***Week 3***	Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:	
	Breakfast Add Milk and Alternatives as needed	Snack if needed	Lunch Add Milk and Alternatives as needed	Snack if needed	Supper Add Milk and Alternatives as needed	Snack if needed
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						

Vegetables and Fruit  Grain Products  Meat and Alternatives 

Gather Bonus Nutrition Points!

Place a ✓check mark in each circle for each healthy eating strategy you meet each day.

Aim for consistency not perfection!



Physical activity tracking sheet

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
TOTAL TIME	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**

YOUR BLOOD GLUCOSE TESTING GUIDE

Ask your diabetes healthcare professional to mark the times on this two-week chart, or use the following guide to get started by testing at least twice a day

Test where you see the grey shaded areas each day This will allow you to see how your blood sugar changes throughout the day							
	Before Breakfast	**2 hours after** Breakfas	**Before** Lunch	**2 hours after** Lunch	**Before** Dinner	**2 hours after**	Bedtime
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
2/ week Average							

Buying Healthy and Label Reading
Week 4

HOW DID YOU DO LAST WEEK?

How many days did you meet your goal during the past week?

_____

WHAT WORKED?

On the days when you met your goal, how did you do it? What strategies did you use?

_____

_____

WHAT DIDN'T WORK?

On the days when you didn't meet your goal, what challenges did you face? What strategies didn't work?

_____

_____

_____

Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

Using the Nutrition Facts Table: % Daily Value

How to CHOOSE

The Nutrition Facts table gives you information on calories and 13 core nutrients. Use the amount of food and the % Daily Value (% DV) to choose healthier food products.

Follow these three steps:

1 LOOK at the amount of food

Nutrition Facts are based on a specific amount of food (also known as the serving size). Compare this to the amount you actually eat.

2 READ the % DV

The % DV helps you see if a specific amount of food has a little or a lot of a nutrient.

5% DV or less is **a LITTLE**
15% DV or more is **a LOT**
} This applies to all nutrients.

Yogurt

Nutrition Facts
Per 3/4 cup (175 g)

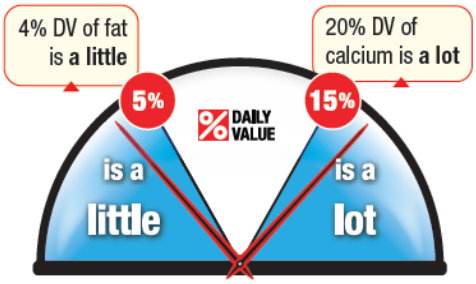
Amount	% Daily Value
Calories 160	
Fat 2.5 g	**4** %
Saturated 1.5 g + Trans 0 g	**8** %
Cholesterol 10 mg	
Sodium 75 mg	**3** %
Carbohydrate 25 g	**8** %
Fibre 0 g	**0** %
Sugars 24 g	
Protein 8 g	

Vitamin A	2 %	Vitamin C	0 %
Calcium	20 %	Iron	0 %

3 CHOOSE

Make a better choice for you. Here are some nutrients you may want…

less of	more of
• Fat	• Fibre
• Saturated and trans fats	• Vitamin A
• Sodium	• Calcium
	• Iron



Here is an example of how to choose:
You are at the grocery store looking at yogurt. The small container (175 g) of yogurt you pick has **a little** fat (4% DV) and **a lot** of calcium (20% DV) – this is a better choice if you are trying to eat less fat and more calcium as part of a healthy lifestyle!

Également disponible en français sous le titre : Utilisez le tableau de la valeur nutritive : % de la valeur quotidienne.

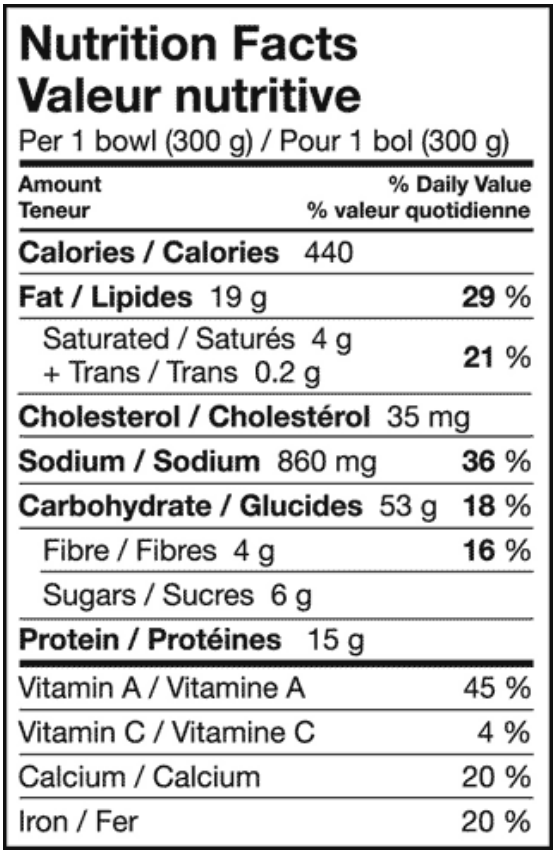
HC Pub.: 100539
Cat.: H164-127/2011E-PDF
ISBN: 978-1-100-19881-1

Canada

How do you think label reading can help you at the grocery store?

_____
_____
_____

Let's look at this label:



Nutrition Facts
Valeur nutritive

Per 1 bowl (300 g) / Pour 1 bol (300 g)

Amount / Teneur	% Daily Value / % valeur quotidienne
Calories / Calories 440	
Fat / Lipides 19 g	**29** %
Saturated / Saturés 4 g + Trans / Trans 0.2 g	**21** %
Cholesterol / Cholestérol 35 mg	
Sodium / Sodium 860 mg	**36** %
Carbohydrate / Glucides 53 g	**18** %
Fibre / Fibres 4 g	**16** %
Sugars / Sucres 6 g	
Protein / Protéines 15 g	
Vitamin A / Vitamine A	45 %
Vitamin C / Vitamine C	4 %
Calcium / Calcium	20 %
Iron / Fer	20 %

What will you pay attention to on this label? _____

Is this meal a good choice in terms of:

- Saturated and trans fat? _____
- Sodium? _____
- Fibre? _____

Ways to Help Me Eat Healthy:

Instructions: **Use the suggestions below to set a SMART goal (or choose your own goal)**

- **I will track and reflect on my meals and snacks each day** ☐
- **I will use the Handy Portion Guide** ☐
- **I will use the PPEP Menu** ☐
- **I will use Recipes from the PPEP** ☐
- **I will use the Ready-to-Eat meals that I have prepared** ☐
- **Other: _____** ☐

SMART Goals:

Specific_____

_____

Measurable_____

_____

Achievable_____

_____

Rewarding_____

_____

Timely_____

_____

How confident are you that you can stick to your goal over the next week?

Not at all Confident	**Not very Confident**	**Moderately Confident**	**Very Confident**	**Extremely Confident**
1	2	3	4	5

How many days this week are you confident you will reach your goal?

0	**1**	**2**	**3**	**4**	**5**	**6**	**7**

Setting Goals

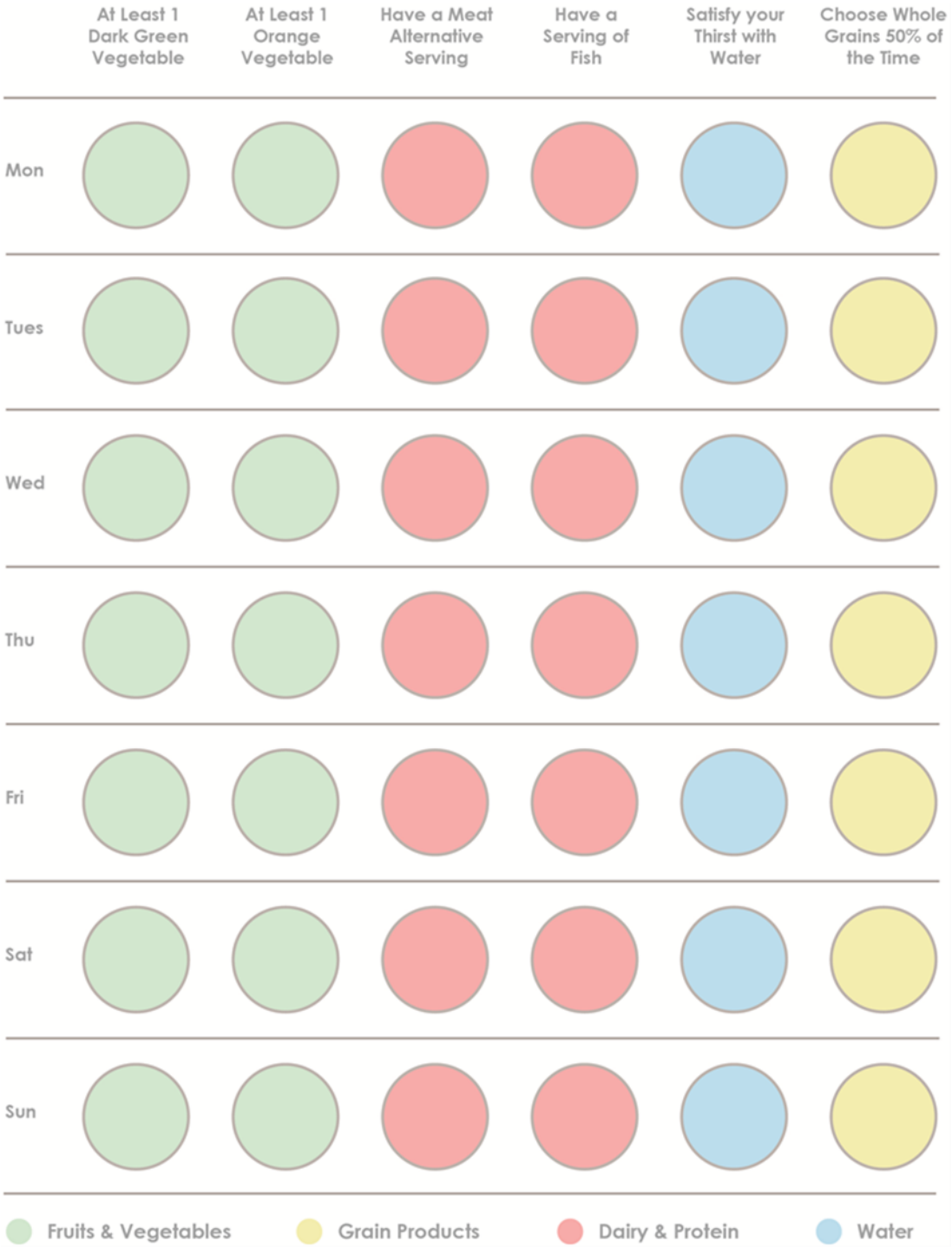
Setting Goals ***Week 4***	Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:	
	Breakfast Add Milk and Alternatives as needed	Snack if needed	Lunch Add Milk and Alternatives as needed	Snack if needed	Supper Add Milk and Alternatives as needed	Snack if needed
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						

Vegetables and Fruit  Grain Products  Meat and Alternatives 

Gather Bonus Nutrition Points!

Place a ✓check mark in each circle for each healthy eating strategy you meet each day.

Aim for consistency not perfection!



Physical activity tracking sheet

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY	SUNDAY
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
TOTAL TIME	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**

YOUR BLOOD GLUCOSE TESTING GUIDE

Ask your diabetes healthcare professional to mark the times on this two-week chart, or use the following guide to get started by testing at least twice a day

Test where you see the grey shaded areas each day This will allow you to see how your blood sugar changes throughout the day							
	Before Breakfast	**2 hours after** Breakfas	**Before** Lunch	**2 hours after** Lunch	**Before** Dinner	**2 hours after**	Bedtime
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
2/ week Average							

Eating Away from Home and Convenience Foods
Week 5

HOW DID YOU DO LAST WEEK?

How many days did you meet your goal during the past week?
_____

WHAT WORKED?

On the days when you met your goal, how did you do it? What strategies did you use?

_____

_____

_____

WHAT DIDN'T WORK?

On the days when you didn't meet your goal, what challenges did you face? What strategies didn't work?

_____

_____

_____

WHO HELPED?

Did you tell anyone about your goal?
Y N

Do you have anyone who could help to meet your goal?
Y N

How can your friends, co-workers, or family help you to meet your goal?

_____

_____

Dining Out Strategies

Restaurant eating can make it more challenging to eat healthy. Most restaurant meals have larger portions than you would eat at home (especially of grain/starch type foods). They also contain high amounts of salt, fat, and sometimes sugar.

- To help you make a healthier choice learn to read the restaurant menus and check the nutritional information when it's available.
- Check if your restaurant has online nutrition information (or they may have information at the restaurant) to help you make an informed choice.
- Choose grilled foods instead of fried or breaded, and whole grain or whole wheat breads and pastas.
- Ask for sauces, dressings etc. to be served on the side, so you can control how much you use.
- Remember the plate method, but keep in mind plate size as well.
- Order half-portions if possible.
- Eat a satisfying amount, stopping before you are stuffed. If it was delicious you can take the rest home, or share with a friend.
- Plan outings at restaurants that you know have healthy choices.
- At buffets, look at all items available and decide what to choose before filling your plate.
- Other tips?
  _____
  _____

Think about your specific lifestyle. You've already been trying to set goals that are consistent with your lifestyle, but let's see if Menu Plans can help to reduce some challenges. First, make a list of the kinds of situations when it's difficult to choose healthy foods. Here are some ideas to get you started.

Weekends	Eating out	Work
Holidays	Travel	Busy times

For example, if we just consider holidays, think about how many "eating occasions" are linked to the holidays in a calendar year:

Month	**Examples of holidays**
Jan	New Year's Day, Chinese New Year, Ukrainian Christmas
Feb	Valentine's Day, Family Day, Mardi Gras
Mar	Shrove Tuesday, St. Patrick's Day
Apr	Passover, Good Friday, Easter
May	Mother's Day, Cinco de Mayo, May long weekend
Jun	Father's Day, St. Jean Baptiste Day, Shavuot
Jul	Canada Day
Aug	August long weekend
Sep	Eid ul Fitr, Rosh Hashanah, September long weekend
Oct	Thanksgiving, Halloween, Diwali
Nov	Remembrance Day
Dec	Hanukkah, Christmas Eve, Christmas Day, Boxing Day, Kwanzaa, New Year's Eve

As you can see from this table, even if you only "celebrate" ½ of these holidays with special meals or gifts of food, that's an extra 15 "eating occasions" in a year to consider. When you add in family birthdays, work celebrations, or travel, every few weeks may have an important "eating occasion" to consider.

To start, pick one of those occasions, and write down some strategies for finding and eating healthy foods. Use the PPEP to help you.

_____

_____

Turn Stumbling Blocks into Stepping Stones

Going back to unhealthy food choices might be considered a STEP backward. It could be hard to ALWAYS meet your goals due to lots of demands on your time due to illness, family obligations, work or other reasons.

How would you feel if you slipped up?

_____

_____

Slip-ups can be used as a learning opportunity. Ask yourself some questions and make a plan for next time you hit a stumbling block.

Why did you slip-up?

_____

_____

What was happening? How were you feeling?

_____

_____

Where was I? Who was I with? What were the circumstances?

_____

_____

What is my plan for next time?

_____

_____

So what if you slip-up, you can just get back on track at your next meal.

Planning to Continue Stepping Forward

What are some of your barriers to making healthy food choices?

_____

_____

_____

How can you get around some of these barriers?

_____

_____

_____

What do you think you need to make healthier choices?

_____

_____

_____

What can you do?

_____

_____

_____

Who can help you to continue to step forward when it becomes difficult?

Friends	Co-worker	Family	Pet

To help you to continue to step- forward complete the table below.

Trouble Spots	Planning
Days when you think you won't be able to reach your goal	**Plans to overcome the trouble spots and maintain your goals**

Ways to Help Me Eat Healthy:

Instructions: Use the suggestions below to set a SMART goal (or choose your own goal)

- **I will draw a picture and evaluate my meals every day.** ☐
- **I will use Handy Portion Guide.** ☐
- **I will use the PPEP menu** ☐
- **I will use the recipes for the PPEP** ☐
- **I will make healthier choices when I dine out by_____** ☐
- **Other: _____** ☐

SMART Goals:

Specific_____

_____

Measurable_____

_____

Achievable_____

_____

Rewarding_____

_____

Timely_____

_____

How confident are you that you can stick to your daily goal over the next week?

Not at all Confident	Not very Confident	Moderately Confident	Very Confident	Extremely Confident
1	2	3	4	5

How many days this week are you confident you will reach your goal?

0	1	2	3	4	5	6	7

Setting Goals

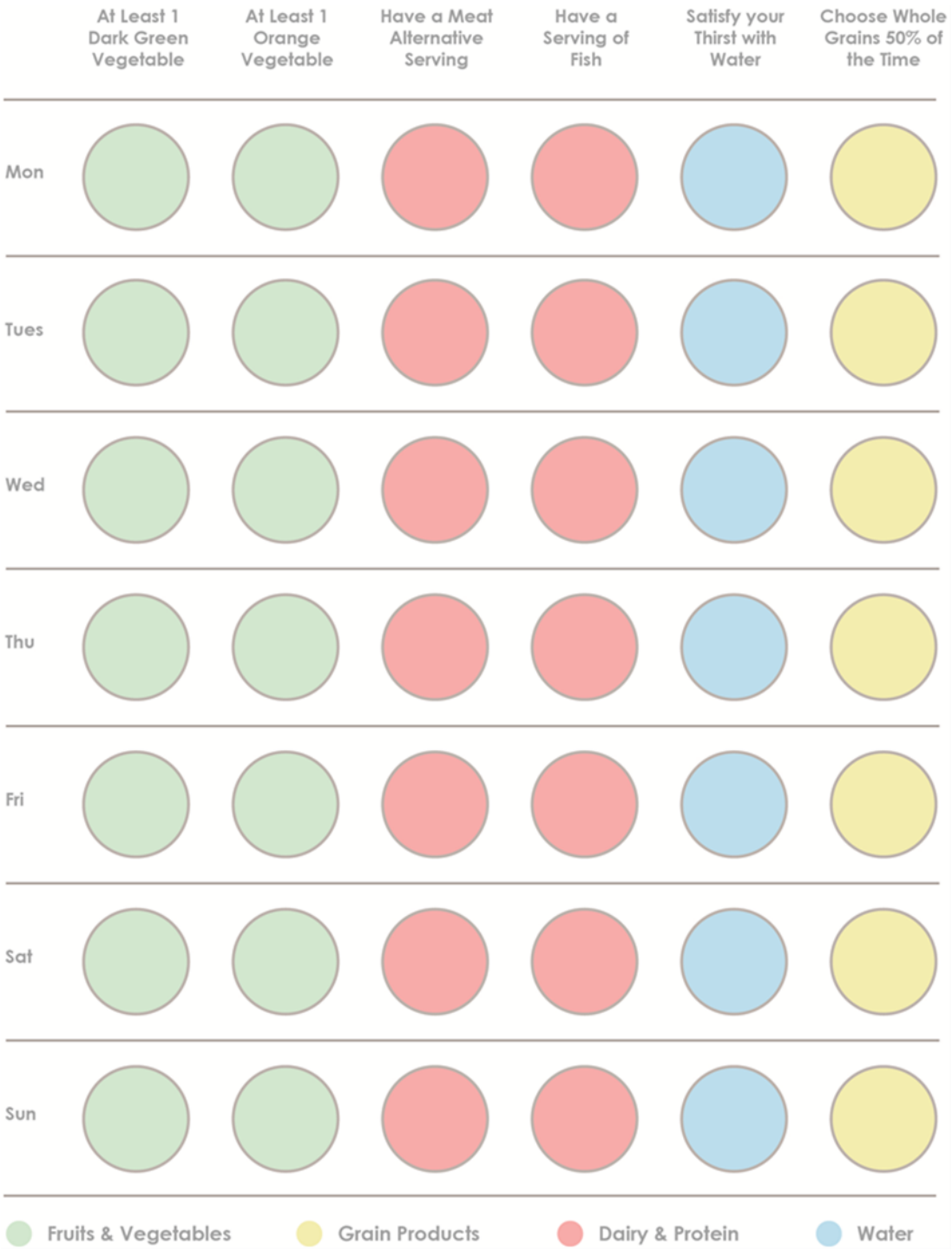
Setting Goals ***Week 5***	Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:		Make a check mark if your plate looks like this:	
	Breakfast Add Milk and Alternatives as needed	Snack if needed	Lunch Add Milk and Alternatives as needed	Snack if needed	Supper Add Milk and Alternatives as needed	Snack if needed
Monday						
Tuesday						
Wednesday						
Thursday						
Friday						
Saturday						
Sunday						

Vegetables and Fruit  Grain Products  Meat and Alternatives 

Gather Bonus Nutrition Points!

Place a ✓check mark in each circle for each healthy eating strategy you meet each day.

Aim for consistency not perfection!



Physical activity tracking sheet

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ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY	ACTIVITY
TIME	TIME	TIME	TIME	TIME	TIME	TIME
TOTAL TIME	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**	**TOTAL TIME**

YOUR BLOOD GLUCOSE TESTING GUIDE

Ask your diabetes healthcare professional to mark the times on this two-week chart, or use the following guide to get started by testing at least twice a day

Test where you see the grey shaded areas each day This will allow you to see how your blood sugar changes throughout the day.							
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Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
Sunday							
Monday							
Tuesday							
Wednesday							
Thursday							
Friday							
Saturday							
2/ week Average							

Appendix 5.0. PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1 - 3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	3 - 4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5 Appendix 2

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	3, 5 - 6
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	6
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5 - 6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	N/A

Appendix 5.1. Search strategies with appropriated key words and MeSH terms

Database	Search strategy (May 30, 2020)
MEDLINE	1. Diabetes.tw,kf. 2. Type 2 diabetes.tw,kf. 3. Diabetes Mellitus*.tw,kf. 4. 1 or 2 or 3 5. Lifestyle Intervention*.tw,kf. 6. Program*.tw,kf. 7. Lifestyle counselling*.tw,kf. 8. Behaviour modification*.tw,kf. 9. Program evaluation*.tw,kf. 10. RCT*.tw,kf. 11. Randomized Control Trial*.tw,kf. 12. Nutrition*.tw,kf. 13. Nutrition therapy*.tw,kf. 14. Diet*.tw,kf. 15. Pharmaceutical*.tw,kf. 16. Functional foods*.tw,kf. 17. Food peptides*.tw,kf. 18. Physical Activity*.tw,kf. 19. Exercise*.tw,kf. 20. 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 21. Real world setting.tw,kf. 22. Translation*.tw,kf. 23. Primary care*.tw,kf. 24. Family practice*.tw,kf. 25. Primary prevention*.tw,kf. 26. Implementation*.tw,kf. 27. Research setting*.tw,kf. 28. 5 or 6 or 7 or 8 or 9 or 10 or 11 29. 21 or 22 or 23 or 24 or 25 or 26 or 27 30. 4 and 20 and 28 and 29 31. limit 30 to (english language and yr="2000 -Current" and "all adult (19 plus years)")
Embase	1. Diabetes.tw,kw. 2. Type 2 diabetes.tw,kw. 3. Diabetes Mellitus*.tw,kw. 4. 1 or 2 or 3 5. Lifestyle Intervention*.tw,kw.

	6. Program*.tw,kw. 7. Lifestyle counselling*.tw,kw. 8. Behaviour modification*.tw,kw. 9. Program evaluation*.tw,kw. 10. RCT*.tw,kw. 11. Randomized Control Trial*.tw,kw. 12. 5 or 6 or 7 or 8 or 9 or 10 or 11 13. Nutrition*.tw,kw. 14. Nutrition therap*.tw,kw. 15. Diet*.tw,kw. 16. Pharmaceutical*.tw,kw. 17. Functional food*.tw,kw. 18. Food peptides*.tw,kw. 19. Physical Activit*.tw,kw. 20. Exercise*.tw,kw. 21. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 22. Research setting*.tw,kw. 23. Real world setting*.tw,kw. 24. Translation*.tw,kw. 25. Primary care*.tw,kw. 26. Family practice*.tw,kw. 27. Primary prevention*.tw,kw. 28. Implementation*.tw,kw. 29. 22 or 23 or 24 or 25 or 26 or 27 or 28 30. 4 and 12 and 21 and 29 31. limit 30 to (english language and yr="2000 -Current" and (adult <18 to 64 years> or aged <65+ years>))
CINAHL	S1. TI (diabetes or t2dm or t2d or type 2 diabetes or type two diabetes or type 2 diabetes mellitus or type two diabetes mellitus) OR AB (diabetes or t2dm or t2d or type 2 diabetes or type two diabetes or type 2 diabetes mellitus or type two diabetes mellitus). S2. TI (lifestyle intervention* or program* or lifestyle counseling* or behaviour modification* or program evaluation* or RCT* or randomized control trial*) OR AB (lifestyle intervention* or program* or lifestyle counseling* or behaviour modification* or program evaluation* or RCT* or randomized control trial*) S3. TI (nutrition* or nutrition therap* or diet* or pharmaceutical* or functional food* or food peptide* or physical activit* or exercise*) OR AB (nutrition* or nutrition therap* or diet* or pharmaceutical* or functional food* or food

	peptide* or physical activit* or exercise*) S4. TI (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) OR AB (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) S5. (TI (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) OR AB (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*)) AND (S1 AND S2 AND S3 AND S4) S6. (TI (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) OR AB (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*)) AND (S1 AND S2 AND S3 AND S4) S7. (TI (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) OR AB (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*)) AND (S1 AND S2 AND S3 AND S4) S8. (TI (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*) OR AB (research setting* or real world setting* or translation* or primary care* or family practice* or primary prevention* or implementation*)) AND (S1 AND S2 AND S3 AND S4) Limiters - English Language; Published Date: 2000-01-01 - 2020-05-30 Narrow by Subject Age: all adult Search modes - Find all my search terms

Appendix 5.2. Excluded full text screened articles and reasons for exclusion

Author / year	Reason
Andrews, R. C. et al, 2011	1
Askari, A. et al, 2018	2
Bennett, G. G. et al, 2018	2
Benson, G.A. et al, 2019	2
Bray, P. et al, 2005	1
Carrasquillo, O. et al, 2017	2
Chee, W. S. S. et al, 2017	2
Cohen, L. B. et al, 2011	2
Eakin, E. G. et al, 2012	2
Eakin, E. G. et al, 2013	2
Eriksson, K. M. et al, 2006	2
Farmanbar, R. et al, 2019	2
Farmer, A. J. et al, 2009	3
Glasgow, R. E. et al, 2006	2
Glasgow, R. E. et al, 2012	2
Griffin, S. G. et al, 2014	4
Jansink, R. et al, 2013	2
Harvinder Kaur, G.S. et al, 2018	2
Javaid, Z. et al, 2019	1
Johnson, S. T. et al, 2015	2
Liss, D.T. et al, 2018	4
Ma, J. et al, 2009	5

Mehuys, E. et al, 2011	2
Mohamed H. et al, 2013	2
Moncrieft, A. E. et al, 2016	2
Moriyama, M. et al, 2009	2
Rosal, M. C. et al, 2011	2
Tang, P. C. et al, 2013	1
Taylor, K. I. et al, 2005	2
Vadstrup, E. S. et al, 2011	2
Wolf, A. M. et al, 2004	2
Yun Johansen, M. et al, 2017	2

(1) Followed guidelines as comparison

(2) Studies without real -world or research setting counterpart

(3) Outside of the scope

(4) Design not appropriate for this review

(5) Incomplete data for the purpose of this review

Reference for excluded full text articles

1. Andrews, R.C., et al., *Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial.* Lancet, 2011. 378(9786): p. 129-139.
2. Askari, A., et al., *The effect of educational program based on belief, attitude, subjective norm, and enabling factors model on changing the metabolic indices in elderly patients with type II diabetes.* International Journal of Preventive Medicine, 2018. 9(1): p. 74.

3. Bennett, G.G., et al., *Effectiveness of an App and Provider Counseling for Obesity Treatment in Primary Care.* American journal of preventive medicine, 2018. 55(6): p. 777-786.
4. Benson, G.A., et al., *Impact of ENHANCED (diEtitiaNs Helping pAtieNts CarE for Diabetes) Telemedicine Randomized Controlled Trial on Diabetes Optimal Care Outcomes in Patients with Type 2 Diabetes.* Journal of the Academy of Nutrition and Dietetics, 2019. 119(4): p. 585-598.
5. Bray, P., et al., *Confronting disparities in diabetes care: the clinical effectiveness of redesigning care management for minority patients in rural primary care practices.* The Journal of rural health : official journal of the American Rural Health Association and the National Rural Health Care Association, 2005. 21(4): p. 317-21.
6. Carrasquillo, O., et al., *Effect of a Community Health Worker Intervention Among Latinos With Poorly Controlled Type 2 Diabetes: The Miami Healthy Heart Initiative Randomized Clinical Trial.* JAMA Internal Medicine, 2017. 177(7): p. 948-954.
7. Chee, W.S.S., et al., *Structured lifestyle intervention based on a trans-cultural diabetes specific nutrition algorithm (tDNA) in individuals with type 2 diabetes: A randomized controlled trial.* BMJ Open Diabetes Research and Care, 2017. 5(1): p. e000384.
8. Cohen, L.B., et al., *Pharmacist-led shared medical appointments for multiple cardiovascular risk reduction in patients with type 2 diabetes.* The Diabetes educator, 2011. 37(6): p. 801-12.
9. Eakin, E., et al., *Living well with Diabetes: Six-month randomised trial outcomes of a telephone-delivered weight loss intervention.* Journal of Science and Medicine in Sport, 2012. **15**: p. S202.
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11. Eriksson, K.M., C. Westborg, and M.C.E. Eliasson, *A randomized trial of lifestyle intervention in primary healthcare for the modification of cardiovascular risk factors.* Scandinavian Journal of Public Health, 2006. 34(5): p. 453-461.

12. Farmanbar, R., et al., *The effects of intervention based on the trans-theoretical model on physical activity and metabolic control of diabetic women.* Gazi Medical Journal, 2019. 30(2): p. 136-139.
13. Farmer, A.J., et al., *Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial.* Health Technology Assessment, 2009. 13(37): p. iii-50.
14. Glasgow, R.E., et al., *Twelve-month outcomes of an Internet-based diabetes self-management support program.* Patient education and counseling, 2012. 87(1): p. 81-92.
15. Glasgow, R.E., et al., *Robustness of a computer-assisted diabetes self-management intervention across patient characteristics, healthcare settings, and intervention staff.* The American journal of managed care, 2006. 12(3): p. 137-45.
16. Griffin, S.J., et al., *Multiple behaviour change intervention and outcomes in recently diagnosed type 2 diabetes: the ADDITION-Plus randomised controlled trial.* Diabetologia, 2014. 57(7): p. 1308-19.
17. Jansink, R., et al., *No identifiable Hb1Ac or lifestyle change after a comprehensive diabetes programme including motivational interviewing: a cluster randomised trial.* Scandinavian journal of primary health care, 2013. 31(2): p. 119-27.
18. Harvinder Kaur, G.S., et al., Dietary, lifestyle, and behaviour changes of patients with overweight/ obesity and type 2 diabetes participating in a structured lifestyle intervention based on a trans-cultural diabetes specific nutrition algorithm. Journal of Diabetes Investigation, 2018. 9: p. 152.
19. Javaid, Z., et al., *A randomized control trial of primary care-based management of type 2 diabetes by a pharmacist in Pakistan.* BMC health services research, 2019. 19(1): p. 409.
20. Johnson, S.T., et al., *Increase in Daily Steps After an Exercise Specialist Led Lifestyle Intervention for Adults With Type 2 Diabetes In Primary Care: A Controlled Implementation Trial.* Journal of physical activity & health, 2015. 12(11): p. 1492-9.
21. Liss, D.T., et al., *One-year effects of a group-based lifestyle intervention in adults with type 2 diabetes: A randomized encouragement trial.* Diabetes research and clinical practice, 2018. 140: p. 36-44.

22. Ma, J., et al., Case management to reduce risk of cardiovascular disease in a county health care system. Archives of internal medicine, 2009. 169(21): p. 1988-95.
23. Mehuys, E., et al., *Effectiveness of a community pharmacist intervention in diabetes care: a randomized controlled trial.* Journal of Clinical Pharmacy & Therapeutics, 2011. 36(5): p. 602-613.
24. Mohamed, H., et al., *Culturally sensitive patient-centred educational programme for self-management of type 2 diabetes: A randomized controlled trial.* Primary Care Diabetes, 2013. **7**(3): p. 199-206.
25. Moncrieft, A.E., et al., Effects of a Multicomponent Life-Style Intervention on Weight, Glycemic Control, Depressive Symptoms, and Renal Function in Low-Income, Minority Patients With Type 2 Diabetes: Results of the Community Approach to Lifestyle Modification for Diabetes Randomized Controlled Trial. Psychosomatic Medicine, 2016. 78(7): p. 851-860.
26. Moriyama, M., et al., *Efficacy of a self-management education program for people with type 2 diabetes: results of a 12 month trial.* Japan journal of nursing science : JJNS, 2009. 6(1): p. 51-63.
27. Rosal, M.C., et al., *Randomized trial of a literacy-sensitive, culturally tailored diabetes self-management intervention for low-income latinos: latinos en control.* Diabetes Care, 2011. 34(4): p. 838-844.
28. Tang, P.C., et al., *Online disease management of diabetes: engaging and motivating patients online with enhanced resources-diabetes (EMPOWER-D), a randomized controlled trial.* Journal of the American Medical Informatics Association : JAMIA, 2013. 20(3): p. 526-34.
29. Taylor, K.I., et al., *Promoting health in type 2 diabetes: nurse-physician collaboration in primary care.* Biological research for nursing, 2005. 6(3): p. 207-15.
30. Vadstrup, E.S., et al., *Effects of group-based lifestyle rehabilitation on glycaemic control, physical fitness and risk factors for cardiovascular disease in patients with type 2 diabetes.* Diabetologia, 2009. 52: p. S14.

31. Wolf, A.M., et al., *Translating lifestyle intervention to practice in obese patients with type 2 diabetes: Improving Control with Activity and Nutrition (ICAN) study.* Diabetes care, 2004. 27(7): p. 1570-6.
32. Yun Johansen, M., et al., *Effect of an Intensive Lifestyle Intervention on Glycemic Control in Patients with Type 2 Diabetes: A Randomized Clinical Trial.* JAMA: Journal of the American Medical Association, 2017. 318(7): p. 637-646.

Appendix 5.3. Risk of bias for individual studies.

A. Joanna Briggs template for non-randomized studies.

Item	Lim E. et al, 2011	Brown, A. et al, 2015	Al Asmary et al., 2013
1. Is it clear in the study what is the 'cause' and what is the 'effect'?	Y	Y	Y
2. Were the participants included in any comparison similar?	Y	Y	Y
3. Were the participants included in any comparison receiving similar treatment/care, other than the exposure or intervention of interest?	N/A	N/A	N/A
4.Was there a control group?	N	N	N
5.Were there multiple measurements of the outcome both pre and post the intervention/exposure?	Y	Y	Y
6. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Y	Y	U
7.Were the outcomes of participants included in any comparison measured in the same way?	Y	U	U
8. Were outcomes measured in a reliable way?	Y	U	U
9. Was appropriate statistical analysis used?	U	U	U

Abbreviations: Yes (Y), no (N), unclear (U); not applicable (N/A)

B. Joanna Briggs template for randomized studies.

Item	Foster G., et al., 2009	Foster G., et al., 2013	Lean M., et al., 2018	Duran et al., 2010	De La Torre et al., 2013	Taheri S., et al., 2020	Tourkmain et al., 2018
1. Was true randomization used for assignment of participants to treatment groups?	Y	Y	Y	U	U	Y	Y
2. Was allocation to treatment groups concealed?	Y	Y	U	U	U	Y	Y
3. Were treatment groups similar at the baseline?	Y	Y	N	Y	N	Y	N
4.Were participants blind to treatment assignment?	N	N	N	N	N	N	N
5. Were those delivering treatment blind to treatment assignment?	N	N	N	N	N	N	N
6.Were outcomes assessors blind to treatment assignment?	U	U	Y	U	U	Y	Y
7. Were treatment groups treated identically other than the intervention of interest?	Y	Y	Y	Y	Y	Y	Y
8. Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?	Y	Y	Y	Y	Y	Y	Y
9. Were participants analyzed in the groups to which they were randomized?	Y	Y	Y	Y	Y	Y	Y
10. Were outcomes measured in the same way for treatment groups?	Y	Y	Y	Y	U	Y	U
11. Were outcomes measured in a reliable way?	Y	Y	Y	U	U	U	U
12. Was appropriate statistical analysis used?	U	U	Y	Y	Y	Y	Y
13. Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?	Y	Y	Y	Y	Y	Y	Y

Table S.5.1

Research setting				
Pillars for diabetes management according to Diabetes Canada Clinical Practice Guidelines				
Reference	**SME +SMS**	**Nutrition therapy**	**Physical Activity**	**Pharmacological therapy**
Foster et al., 2009	**Portion Control Diet (PCD)** **Group session:** These group attended 18 group session (weekly = week 1 - 12; biweekly = week 13 - 24) led by a HCP with expertise in behavioural weight control. **SME** **Self education topics:** Self-monitoring, stimulus control, goal setting and relapse management. Additional support material was provided by NutriSystem® D™	**Nutrition approach:** NutriSystem® D™. **Nutrient distribution:** 47% carbohydrate, 30% protein, and 23% fat. **Diet instructions:** Women 1250 cal/day - Men 1550 cal/day, 690 kcal/day were provided by NutriSystem® D™ (3 meals and 1 snack per day). The rest of the calories were added by conventional foods (2 additional sources of dairy, fruit, lean protein, and fat, and 4 sources of vegetables).	**PA:** primarily walking - beginning at week 4 with 4, 20 minute sessions/week and progressing to 5, 40 minute sessions by week 24.	N/A
Lim et al., 2011	**SMS:** Regular telephone calls were made to provide support and encouragement. **SME**: Portion size and healthy eating information was provided after the 8 week intervention.	**Nutrition approach:** Optifast, Nestlé Nutrition liquid formula. **Nutrient distribution:** 46.4% carbohydrate, 32.5% protein and 20.1% fat; vitamins, minerals and trace elements. **Diet instructions:** The liquid formula provided 600 kcal/day from which 510 kcal/day came from the liquid formula. The additional 90 kcal were provided with three portions of non-starchy vegetables. Recipes were provided to increase adherence. Participants were encouraged to drink 2L of water. At the end of the 8 weeks reintroduction of normal eating patterns was provided. **Dietary adherence:** Capillary ketone levels were used to assessed adherence.	**PA:** Participants were instructed to make no changes in their physical activity level.	N/A
Durán et al., 2010	**Lifestyle intervention**: Patient specific intervention were developed for each participant. **SME:** 1-h session were held to teach participant how to perform and collect SMBG test and data. **SMS:** At each follow up visit reinforcement of SMBG methodology was performed. Participants were followed every 2 weeks (first 3-months) and once every 3 months. **SMBG**: Six-point profiles every 3 days (before and 2 hrs. after breakfast, lunch, and dinner). If pharmacological therapy changes were done, profiles were also carried out. **SMBG stabilizatio**n: Five complete SMBG profiles within target in two consecutive visits reflected participant stabilization transitioning towards one profile every 2 weeks if they were on metformin or every week if they were in another treatment other than metformin and/or pioglitazone.	N/A	N/A	**Pharmacological therapy**: 850 mg of metformin. **FBG:** Fasting SMBG levels outside target (FBG >110 mg/dL) metformin was titrated if tolerated. If needed, pioglitazone was included. Basal insulin was added if target was not achieved. **PPBG:** If postprandial SMBG levels were outside target (PPBG between 145 and 160 mg/dL) glinide, a DPP-4 inhibitor, or sulphonlyurea was considered. Bolus insulin was added if target was not achieved.
Brown et al., 2015	Monthly group approach program during 6 months delivered by a trained facilitator. **SME** **Group session:** Weekly (60-90 min) **SME** **Self education topics**: Self-monitoring, goal setting, stimulus control, cognitive restructuring, eating behaviour, maintenance, all of nothing beliefs, reward and support, problem solving and self-stem. Homework between sessions.	Recommendations based on guidance for healthy eating designed by the UK Department of Health using the eat well plate. Encouragement of regular meal intake and techniques to reduce portions and identify satiation, and instructions about portions and serving control. **Diet instructions:** based on starchy foods, 5 servings of fruit and vegetables, reduce fat intake and replace them with unsaturated fat sources, and high-quality sources of protein and dairy foods.	**PA:** at least 30 min/day, 5 days/week.	Adjustments made by physicians.
Al Asmary et al., 2013	Followed ADA guideline. **Multidisciplinary team:** senior family physician, nurse, clinical pharmacist specialist, dietician, diabetic educator, health educator and social worker. **Intervention focus:** enhance clinic visits, monitoring of outcomes, improving interdisciplinary communication and coordination, evaluating the need of insulin titration, efficacy of the treatment. **SMS:** reminders, telephone calls and social worker support. **SME** **Self-education topics:** diabetes education, diets, medication adherence and self-management. **Clinic visits:** mean was 13 (range 6-26)	Dietician appointments	N/A	The pharmacist was the case manager and met the participants once a week to check adherence to the intervention, manage hypoglycaemia, medication side-effects, request renal and liver function tests and refer participants to another team member. Medications adjustment was done in collaboration with the physicians.

Real world setting				
Pillars for diabetes management according to Diabetes Canada Clinical Practice Guidelines				
Reference	**SME +SMS**	**Nutrition therapy**	**Physical Activity**	**Pharmacological therapy**
Foster et al., 2013	**Portion control diet (PCD)** **Group sessions**: (90min) led by experienced lifestyle and diabetes educators at weeks 0, 1, 2, 4, 8, 12, 16, 20 and 24. **SME** **Self education topics:** self-monitoring food intake and physical activity, stimulus control, goal setting, problem solving, cognitive restructuring and relapse prevention.	**Nutrition approach:** NutriSystem® D™ **Diet instructions:** PCD (three entrees and one snack daily) supplemented with conventional foods Goal: achieve ≈1250 kcal per day (women) or 1550 kcal per day (men) with the help of a calorie-counting guide. **Diet composition:** ≈55% of total energy from the packaged foods and 45% conventional food. (≈50–55% of energy from carbohydrate, 20–25% fat and 20–25% protein + ≈2300mg per day of sodium. Diet glycemic index: ≈34 (glucose scale).	**PA:** increase walking / aerobic activity) to >200 minutes/ week	Adjustment managed by respective providers. Self blood glucose recordings at least 2/day starting one week prior the intervention. If repetitive episodes of hyper- (three or more episodes >300mgdl-1) or hypoglycaemia (three or more episodes <60mgdl 1) were recorded, lifestyle strategies and medication adherence counselling was given.
Lean et al., 2018	**Treatment group:** Usual guideline-based care **SMS:** Participants attended 35 appointment over 2 years. **SME:** Support printed materials for each phase of the intervention was provided to all participants in this group. **TDR phase**: Review visits were schedule 1 week after initiation of TDR and at 2 weekly intervals there after. **FR phase:** Participants monitor their weight weekly and review visits were schedule every 2 weeks. **Weight loss maintenance phase:** Monthly review appointment.	**Nutritional approach:** Counterweight Plus. **Diet instructions:** This programme includes three phases: 1. Total diet replacement (TDR); 2. Structured food reintroduction (FR); 3. Structured support programme for long term weight loss maintenance. **Diet Composition:** **TDR phase (0-12wks):** Liquid formula diet in the form of soups and shakes were provided for a period of 12 weeks. 823 - 853 kcal/day (59% carbohydrates, 13% fat, 26% protein, 2% fibre). A soluble fibre supplement (Fybogel 2 x 3.5 g/day) and 2.25L of water were prescribed to reduce constipation. **FR phase (weeks 12- 18):** Based on Eat well guidelines and with a caloric distribution of about 50% carbohydrates, 35% fat and 15% protein, food based diet was reintroduce while reducing TDR. **Weight loss maintenance phase (weeks 19 - 104):** Participants provided with an individually tailored energy diet for weight stabilisation and to prevent weight regain. **Relapse management for weight regain or re-emergence of diabetes**: Rescue plans during the 18-month maintenance stage were offered. 1. Weight regain >2 kg: One or two meals per day were replaced by liquid formula for a period of 4 weeks. Additionally orlistat (120 mg) was prescribed with each meal. 2. Weight regain between 4 - 15 kg: Liquid formula was reintroduce for a 4 week period with nurse/dietician follow up every two weeks. Subsequent FR phase of 2-4 weeks with individualised dietary advised and physical activity reinforcement was provided.	**PA:** Step-counter and advice provided to increase daily PA to a maximum of 15,000 steps/day.	**TDR phase (0-12wks)**: Previous to the initiation of this phase, oral hypoglycaemic agents, antihypertensive and diuretic drugs were withdrawn and reintroduce if necessary. Beta-blockers and aspirin were continued if related to previous MI or angina management. Orlistat treatment with each meal was prescribed during relapse management phase.
De la Torre et al., 2013	Similar to Research setting	N/A	**PA:** Aerobic and resistance training: 50 min x 4 days/week (2 supervised; 2 unsupervised) for 20 weeks. **Aerobic:** 75% MaxHR **Resistance:** 3 sets x 8-10 repetition each. **Time:** warm up - 20min of aerobic - 20 min resistance - cool down Program was designed for each individual participant by a physiotherapist.	**Pharmacological therapy**: 850 mg of metformin. **FBG:** Fasting SMBG levels outside target (FBG >110 mg/dL) metformin was titrated if tolerated. If needed, pioglitazone was included. Basal insulin was added if target was not achieved. **PPBG:** If postprandial SMBG levels were outside target (PPBG between 145 and 160 mg/dL) glinide, a DPP-4 inhibitor, or sulphonlyurea was considered. Bolus insulin was added if target was not achieved.
Taheri et al., 2020 **Taheri et al., 2018**	Intervention protocol delivery by dieticians, personal trainers, and physicians. **SME** A dietician helped the participants to identify appropriate food and portion sizes. Recipes and meal plans were provided. **Self education Topics:** similar to research setting **Physician visits:** baseline and after every 3 months. Dietician and personal trainer visits every 2 weeks during diet replacement. **Clinic visits:** once a month after diet replacement.	**Diet approach:** Cambridge Weight Plan, Northants, UK. **Diet instructions**: total diet replacement followed by 12-week partial replacement and structured food reintroduction plan until achieve 3 meal/day pattern for 6 months guided by dietician. **Diet composition:** low-energy formula provided 800–820 kcal/day with a caloric distribution of 57% carbohydrate, 14% fat, 26% protein, and 3% fibre. Raw vegetables and salad were allowed. After food reintroduction phase, a similar macronutrients distribution and consumption of low glycemic index foods were recommended. For constipation a fibre supplement (psyllium/inulin) was prescribed. **Diet replacement:** low-energy formula followed by own participants management of their food intake and lifestyle changes for 6 months. During the diet replacement and food reintroduction period, participants visited dieticians every 2 weeks.	**PA:** initially walking (minimum 10,000 steps/day) followed by at least 150 min/week of exercise (moderate intensity). Aerobic exercise (3 days/week) and resistance exercise (at least 2 days/week) - gradual rate of progression.	Medication adjustments or discontinued as needed.
Tourkmani et al., 2018	similar to research setting Followed ADA guidelines but intensified for clinical and social factors.	similar to research setting	N/A	similar to research setting

Appendix 6.0. COREQ: 32-item checklist

Manuscript: 'Identification of contextually appropriate tools and solutions designed to optimize and enhance healthy eating in people with T2D'

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Supplemental Table S1. COREQ Checklist

No. Item	Guide questions/description	Location in manuscript
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	MCAH conducted all interviews.	Methods, line
2. Credentials	RD, M.Sc, PhD	-
3. Occupation	At the time of the interviews MCAH was a PhD candidate at the University of Alberta.	-
4. Gender	Female.	-
5. Experience and training	At the time of the interviews MCAH had a background in Nutrition and Dietetics and a master's degree in Medical Sciences. MCAH had previously conducted and participated in focus groups with participants with type 2 diabetes from Sherwood Park Primary Care Network as part of a previous research study from the University of Alberta.	Methods, line
Relationship with participants		

6. Relationship established	No.	-
7. Participant knowledge of the interviewer	Participants were briefed on the purpose of the study and understood the study was part of a research study for MCAH PhD.	-
8. Interviewer characteristics	MCAH was a PhD candidate during the time of the interviews and a junior researcher.	-
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	Thematic Analysis according to Braun and Clarke (2006).	Method, line
Participant selection		
10. Sampling	Purposeful sampling was used. This method allowed for the selection of information-rich cases from which we could learn, yielding insights and in-depth understanding. Additionally, participants were recruited from different age groups, gender identifications, socio-economic backgrounds, and cultural affiliations to maximize variation of participant context	Method, line
11. Method of approach	Participants were recruited from the 5AsT cohort and the Alberta Diabetes Institute Research Contact Registry. In both cases, the original databases were searched to identify possible participants. Once identified, those from the ADI Research Contact Registry were sent information about the study and asked if they were interested in participating. The list of possible participants was provided to MCAH who approached participants via telephone (**Appendix 6.1**). In this first contact, MCAH explained the purpose of the studied in more detailed, explain the procedure, time requirement, answered questions and invited participants to participate. They were provided with an information letter containing all the details of the study and researches contact information (**Appendix 6.2**)..	Method, line 69-70

12. Sample size	15	Method, line
13. Non-participation	There were 24 participants who refused to participate.	-
Setting		
14. Setting of data collection	Either face-to-face at [location removed for blind peer-review] or via telephone.	Method, line
15. Presence of non-participants	Two nutrition undergrad student were present for two interviews (only one per interview).	-
16. Description of sample	Age range: years. Age mean: years Female participants: Male participants: (see Table 2: General Characteristics of the Study Participants)	Results, line
Data collection		
17. Interview guide	Interviews were semi-structures using an interview guide (supplementary material, Supplemental Table S2).	Supplementary Material
18. Repeat interviews	No	-
19. Audio/visual recording	Each telephone interview was audio-recorded and Skype-for-business or Microsoft Teams was used during face-to-face interviews.	Method, line
20. Field notes	MCAH took journal notes during and after each interview to record researcher's reflections, feelings and interpretations.	Method, line
21. Duration	Interview durations ranged from 30 – 75 minutes	-
22. Data saturation	In this study, data saturation was not obtain since maximum variation purposeful sampling was used to capture a lot of different experiences.	Method,
23. Transcripts returned	No	-
Domain 3: analysis and findings		

Data analysis		
24. Number of data coders	Two independent coders (MCAH, CBC) coded four interviews using open coding, enabling the creation of initial codes from which two independent coding manual were created. MCAH and CBC compared and discuss the similarities creating a final coding manual. MCAH coded all interviews.	Method, line
25. Description of the coding tree	Coding described in methods.	Methods, line
26. Derivation of themes	Inductive approach was used, thus, no predefined outcomes were established, and instead, the coded categories were delivered directly from the data.	Methods, line
27. Software	CONSENTIA Inc. was used as a transcription service to transcribe verbatim audio-recorded interviews. They were then uploaded onto NVivo 10 (QSR), which was used to facilitate coding.	Method, line 108
28. Participant checking	No	-
Reporting		
29. Quotations presented	Yes, specific quotations were presented to help illustrate themes and provide examples. Quotations were identified by a participant number	Result section
30. Data and findings consistent	Yes	-
31. Clarity of major themes	Table ….	Table ….
32. Clarity of minor themes	Table …..	Table …..

Appendix 6.1. Telephone recruitment script

Project Title**: The Pure Prairie Living Program: Designing a contextually appropriate lifestyle intervention to facilitate healthy eating in people with T2D in Alberta - A mixed methods study**

Outgoing Phone Call:

1. Hello, may I speak with _____?

2. My name is Carolina and I'm calling from the 5AsT Study that you are a part of. It's the study about the evaluation of your weight management, that took place at the Edmonton South Primary Care Network (ESPCN).

3. As part of a partner study, we are interested in learning more about patients' views on healthy eating.

4. At your initial consent in the 5AsT study, you agreed that we could contact you about future studies.

5. The reason I am calling is that we would like to work with you to learn about your views on diabetes-friendly eating habits, what healthy eating looks like in your everyday life and what would help people adopt diabetes-friendly eating habits.

6. So, if you are interested in participating in research on your views on diabetes-friendly eating habits and your everyday life experiences with healthy eating habits, I can tell you details about the research process.

[to the best of knowledge and ability address patient's concerns and/or queries]

- *If patient agrees to hear more about the sub-study and the interview process, then continue with the following section.*

- *If patient does not wish to hear more, than thank them for their time and attention.*

Background and Purpose of Sub-study

As mentioned, we are interested in learning about your views on diabetes-friendly eating habits, what healthy eating looks like in your everyday life and what would help people adopt diabetes-friendly eating habits.

The study includes one-on-one interviews and a focus group. The procedure would look like this:

- First, you would meet a researcher form the University of Alberta for a one-on-one interview for about 45-60 minutes.
- Five to 8 months after your initial one-on-one interview, you will be invited to participate in a focus group for about 60-90 minutes. The goal of these focus groups is to get you advice and opinion on a program we are designing to facilitate healthy eating. All the interviews will be audio recorded and typed up.

Both audio recordings will be uploaded and stored on password-protected computers. Only research team members will have access.

Please know that your responses will remain confidential and will not be linked to any individual identification.

As an appreciation for giving us your time, we are **offering a copy of the Pure Prairie Eating Plan book which you can use as a guide to achieve a healthy diet.** We will also cover any parking expenses that you may incur through your participation in this sub-study. You will receive this honorarium at the end of your first one-on-one interview.

As a reminder, your participation in this sub-study is voluntary. You have the right to end the interview or focus group at any point and, decline to answer any question.

Are you interested in participating in this research?

[If not, address any questions. Then thank patient for their time and attention]

[If yes, then continue with the following information.]

Scheduling initial interview

The interview will take place at the Human Nutrition Research Unit at the University of Alberta. The address is 116 St & 85 Ave, Edmonton, AB. The unit is on the second floor room 2-004 at Li Ka Shing Center.

Dates and time available for the interview session are:

The person interviewing you is named Carolina.

When you arrive at the Edmonton Southside PCN, please check in with the receptionist and they will let Carolina know that you have arrived.

If you have to reschedule your appointment, please call **Carolina at (780) 819 5292** [please have the participant write this information down].

We will provide you with a reminder phone call about your appointment. However, if you'd like, I can also email you the information we covered. What is your email address?

Do you have any further questions?

Thank you for your time and we look forward to seeing you *(confirm time and date).*

Appendix 6.2. Information letter

INFORMATION LETTER

Study Title: The Pure Prairie Living Program: Designing a contextually appropriate lifestyle intervention to facilitate healthy eating in people with T2D in Alberta - A mixed methods study

Research Investigator	**Principal Investigator**	**Co-Principal Investigator**
M.Carolina Archundia-Herrera	Professor Catherine Chan	Professor Denise Campbell-Scherer
6-126 Li Ka Shing Center	6-126 Li Ka Shing Center	Faculty of Medicine and Dentistry
University of Alberta	University of Alberta	2-590 ECHA, 11405-87 Ave NW
Edmonton, Alberta, T6G 2R3	Edmonton, Alberta, T6G 2R3	Edmonton, AB, Canada T6G 1C9

Background

Your participation in a research study called "The Pure Prairie Living Program: Designing a contextually appropriate lifestyle intervention to facilitate healthy eating in people with T2D in Alberta - A mixed methods study" is being requested. This study is being done to determine enablers of healthy eating underpinned by experiences and perceptions from lived experiences of participants with T2D. Participation in this study is completely voluntary.

We need English-speaking adults, +18 years old with T2D, to participate in this study.

Purpose

Diabetes is a worldwide health problem. Increased efforts are being made to develop different strategies to manage diabetes complications. Diabetes guidelines have been developed to provide evidence-based care for people with diabetes. However, a guideline-practice gap exists, people with T2D do not necessarily follow what the guidelines recommend. In an effort to address this gap, different Lifestyle Interventions and educational programs have been developed to promote behaviour change and skill development for people to independently manage their diabetes. However, as reflected by previous studies from our group an others, in real life context, even after participating in programs and obtaining all the knowledge, it is sometimes not enough for people to modify their health behaviour, thus adhering and achieving diabetes-friendly eating habits is challenging.

The objective of this study is to work with people with T2D to determine enablers of healthy eating underpinned by experiences and perceptions from lived experiences of participants with T2D.

To meet the study objective, researchers will conduct one-on-one or videoconference interview with participants who have T2D. These findings will inform the design and incorporation of relevant intervention components identified through the interviews as enablers of healthy eating to the development of the contextually appropriate PPLP program for people with T2D. Furthermore, participants will participate in a focus group to evaluate the program.

Study Procedures

If you agree to participate in the study, you will participate in a one-hour, one-on-one or videoconference interview with one of the researchers, and will be invited to participate in a subsequent focus group. Thus, you will meet with the Study Team 2 times at your preferred location. The first option is at the Human Nutrition Research Unit at the University of Alberta. The address is 112 St & 87 Ave NW, Edmonton, AB. The unit is on the second floor room 2-004 at Li Ka Shing Center. There is parking available. However, in spite of resent events, and until further notice, the interviews will be taking place through videoconference software to align with the current social distancing guidelines for COVID-19 pandemic. Please find below details of the procedures:

Meeting 1, approximately 1 hour

During your first visit, you will complete an informed consent, fill in some surveys and participate in a one-hour, one-on-one or videoconference interview with one of the researchers. This interview will be audio or video recorded, hence audio/video recording equipment will be used during the interviews and the audio will be transcribed. This interview will be around helping us understand your context and environment to co-identify the barriers, facilitators and solutions encountered in your everyday life that prevent or facilitate modification of healthy eating behaviours.

Meeting 2, approximately 1 hr – 1 ½ hours

In the second visit, you will be invited to participate in a focus group with other people with T2D. The goal of these focus groups is to encourage conversation and get your advice and opinion on a programme we are designing to facilitate healthy eating in people with T2D. This focus group will last for about 1hr to 1 ½ hrs and it will take place five months after you initial one-on-one interview.

Confidentiality

- The information obtain from this study will be used specifically for research purposes.
- Personal information will be collected to contact and follow up with you if needed. However, we will not give your name or phone number to anyone or use it for any other purpose.
- During the study, only the researchers will be able to identify you.
- During data analysis, all your names and/or identifiers will be removed and replaced with numbers, and efforts will be made not to disclose your identity. You will be referred to anonymously in publications.
- The hard copy of the records will be secured in a cabinet in the Principal Investigator´s office; computers will be password protected and all digital files will be encrypted to protect your anonymity and confidentiality.
- Five years after publication of the data, all the questionnaires and digital files will be destroyed.

Risks

- If you participate in this study, any potential "risk" will be possible distress, frustration, shame or anxiety as a result of the discussions from the interview process.

Voluntary Participation

- Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions you don't feel comfortable answering, or withdraw from the study at any time without having to give any explanation to the research team.
- You may request 3 days after your interview, for your data to be withdrawn and it will be immediately destroyed. However, after these 3 days have passed, and the data has been analysed, it will be impossible to remove.

Incentives

- In appreciation for giving us your time, we are **offering a copy of the Pure Prairie Eating Plan book, which** you can use as a guide to achieve a healthy diet after the end of the one-on-one interview**.**
- If you do decide to participate in the follow-up focus group, a **$20.00 grocery story gift card** will be provided at the end of this.
- We will also cover any parking expenses that you may incur through your participation in this study.

Conflict of Interest

One of the study investigators is the author of "Pure Prairie Eating Plan" book.

Further Information

- If you have any questions about this study, please contact:

Carolina Archundia Herrera. 780-819-5292 archundi@ualberta.ca

PhD Candidate

- If you have any questions or concerns about your rights as a participant, or how this study is being conducted, you may contact the Research Ethics Office at 780-492-2615. This office has no affiliation with the study investigators.

Appendix 6.3. Interview guide

PPLP - One on one Interview guide

1. **CONSENT**
   - In advance
2. **INTRODUCTION**
   - Introduce yourself and the study clearly
   - Background and Study objective.
3. **CONFIDENTIALITY**

   Remind the participants
   - Participation is entirely voluntary.
   - We will be audio-recording the interview.
   - You are free to stop the recorder at any time.
   - You are free to not answer any questions you don't feel comfortable with.
   - Personal information will not be disclosed, and it will be removed from the report. You will remain anonymous.
   - You are free to withdraw your consent and if you wish to have your data removed from the study, you may do so up until data analysis has started. That is 3 days after your interview.
4. **GROUND RULES**
   - I want you to do the talking; share as much information as you want.
   - There are no right or wrong answers; I want to hear a wide range of opinions.
   - What is said in this room stays here; I want you to feel comfortable sharing sensitive issues.
5. **INTERVIEW**

- See question guide

6. **CLOSURE**

- So this brings out interview to an end. I'd like to thank you very much for taking part in this research project. We appreciate your time and the valuable information you have shared with us today.

7. **Travel expenses**
8. **Gift**

- Pure Prairie Eating Plan

INTERVIEW GUIDE

START INTERVIEW

- Ice-breaker: please could you briefly introduce yourself and tell me a bit about yourself. How long have you been diagnosed diabetes?
- Record participant´s NAME, AGE and YEARS WITH T2D.
-

PART 1- Diabetes-friendly eating habits

We want to understand the lived experience of adults living with Type 2 Diabetes (T2D), specially their experience with eating habits.

1. **What does 'healthy eating habits' mean to you?**
2. **How important is healthy eating to you when you think about your diabetes?**

PART 2 – Understanding past experiences*:*

I want you to think about, and

3. **Describe to me, any strategies you have use to help you eat healthy in the past**

Prompt - What specific changes have you used or have made to help you eat healthy?

From these experiences that you mentioned,

4. **Can you describe to me why you think they worked or did not work?**

Prompt - What specifically helped you?

Was there something that trigger you at this time or motivated you to adopt this change?

What have you found difficult about adopting these strategies?

Out of all of the programs or people that helped you,

5. **Who or what has helped you the most and in why?**

Prompt - What did they do that was most helpful?

What strategies or tools were helpful?

PART 3 – Key messages

For the last part of this interview, I am going to present to you a summary of the Key messages from the Diabetes Canada Nutrition Guidelines.

1. *Select whole and less refined foods instead of processed foods, such as sugar-sweetened beverages, fast foods and refined grains*
2. *Reduce caloric intake to achieve and maintain a healthier body weight*
3. *Pay attention to both carbohydrate quality and quantity*
4. *Select unsaturated oils and nuts as the preferred dietary fats*
5. *Choose lean animal proteins. Select more vegetable protein*

We are working on designing a program that would help people with T2D incorporate these guidelines to their everyday life. I want you to think about

6. What would you need to be able to follow these guidelines?

Prompt - What would help you be successful at following these guidelines?

What in your life, or what around you would need to change to allow you to make that change?

7. What type of activities could we offer to help people make these changes?

Prompt – What would help you to follow these guidelines?

Prompt - What would you need to allow you to make these changes?

8. What are the difficulties you foresee in being able to follow these recommendations?

Prompt - How is it going to get difficult?

9. What would you need to be able to overcome some of these barriers?

Prompt - From the health care system, in your personal life?

10. What would you need to follow these guidelines for the long term?

Prompt - What if anything would you like to try in the future?

PART 4 – SUMMARIZE

Summarize, ask the participant if the summary is correct or needs to be changed, or if they would like to add anything else. Thank them for their participation.

Appendix 6.4. Demographic questionnaire

Please write or mark the appropriate answer for the following questions.

- Date (mm/dd/yyyy): _____
- Age: _____
- Date of birth: _____
- Gender: Male / Female
- Years with diabetes diagnosis:_____
- Ethnicity:

Please circle the appropriate answer(s).

- White
- Chinese
- West Asian (e.g. Afghan, Iranian)
- Japanese
- Korean
- Aboriginal (e.g. First Nations, Metis or Inuit)
- Black
- Arab
- South Asian (e.g. East Indian, Pakistani, Sri Lankan)
- Filipino
- Latin American
- Southeast Asian (e.g. Cambodian, Indonesian, Vietnamese)
- Other ( )

For the following questions please put a checkmark in the box with the appropriate answer

1. **Education**:

- Less than high school
- High school graduate
- Some college or university (have some post secondary education, but not completed)
- College or university graduate or above

2. Employment:

- Wages and salaries
- Income from self-employment
- Retirement income (pensions, old age security and GIS, etc.)
- Unemployed (not including retirement)
- Other ( )

3. Household annual income:

< $ 10,000 if 1 to 4 people
< $ 15,000 if ≥ 5 people

$ 10,000 to $ 14,999 if 1 or 2 people
$ 10,000 to $ 19,999 if 3 or 4 people
$ 15,000 to $ 29,999 if ≥ 5 people

$ 15,000 to $ 29,999 if 1 or 2 people
$ 20,000 to $ 39,999 if 3 or 4 people
$ 30,000 to $ 59,999 if ≥ 5 people

$ 30,000 to $ 59,999 if 1 or 2 people
$ 40,000 to $ 79,999 if 3 or 4 people
$ 60,000 to $ 79,999 if ≥ 5 people

≥ $ 60,000 to $ 79,999 if 1 or 2 people
≥ $ 80,000 to $99,999 if ≥ 3 people

≥ $ 80,000 to $ 99,999 if 1 or 2 people
≥ $ 100,000 if 1 or 2 people
≥ $ 100,000 if ≥ 3 people

4. **Financial situation**: (How would you describe your financial situation?)

- I can meet my needs and still have enough money left to do most of the things I want
- I have enough money to meet my needs and to do many of the things I want if I budget carefully
- I have enough money to meet my needs but have little left for extras
- I can barely meet my needs and have nothing left for extras
- I am solely responsible for my treatment financially