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CLINICAL STUDY DESIGN

WILEY

Rationale and design of a parallel randomised trial of a plant-based intensive lifestyle intervention for diabetes remission: The REmission of diabetes using a PlAnt-based weight loss InteRvention (REPAIR) trial

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Abstract

Aims: As type 2 diabetes (T2D) continues to rise globally and remains a major driver of cardiovascular disease, its remission has emerged as a therapeutic target. Current evidence supports bariatric surgery and low-calorie diets with meal replacements. No clinical trial to date has evaluated plant-based dietary alternatives as an intensive lifestyle intervention (ILI) strategy, despite the emphasis on plant-based diets in current clinical practice guidelines for diabetes and cardiovascular disease. The REmission of diabetes using a PlAnt-based weight loss InteRvention (REPAIR) trial will assess whether a 52-week plant-based ILI targeting ≥15% weight loss is effective for diabetes remission in a multi-ethnic Canadian population.

Materials and Methods: The REPAIR trial is a prospective, randomised, 2-arm, open-label, blinded-endpoint efficacy trial. Participants will include 160 adults with early T2D (<6 years) and living with obesity. They will be randomised to standard of care or a 2-phase ILI targeting ≥15% weight loss consisting of a 12-week weight loss phase on a plant-based total diet meal replacement, followed by a 40-week weight loss maintenance phase on a plant-based dietary pattern combined with a 16-week structured exercise program, and a 52-week (19-session) sustainable behaviour change curriculum. The primary outcome is diabetes remission (HbA1c <6.5% without glucose-lowering medication for ≥3 months) and the key secondary outcome is the proportion achieving ≥15% weight loss at 52 weeks.

Conclusions: This trial will provide high-quality clinical evidence on the use of plant-based ILIs to address the epidemics of obesity and diabetes to inform public health policies and programs in Canada and beyond.

KEYWORDS
clinical trial, dietary intervention, exercise intervention, plant-based, type 2 diabetes, weight management

1 | INTRODUCTION

Despite numerous public health strategies, we are confronted with a rapidly increasing global pandemic of type 2 diabetes (T2D)[1,2] and its downstream cardiometabolic complications impacting both individuals and health care systems.[3,4] The prevalence of T2D globally and in Canada is currently ~11% and is on the rise across all regions.[5] Obesity is the single most important causal driver,[6,7] affecting 90% of those with T2D.[8]

Diabetes remission has emerged as a major clinical target with observational data showing important reductions in all-cause mortality, cardiovascular events, microvascular disease and other downstream complications that contribute to the personal and economic burden of diabetes.[9] Early evidence from studies of metabolic/bariatric surgery showed large weight loss and diabetes remission,[10–12] with remission seen especially in those with T2D diagnosed within 6 years when residual pancreatic beta-cell function is preserved.[13] Intensive lifestyle interventions (ILIs) combining dietary modification with the use of meal replacements, physical activity, and behavioural strategies that target ≥15 kg or 15% weight loss have been recognised as less invasive alternatives to metabolic surgery for remission.[14] The landmark Diabetes Remission Clinical Trial (DiRECT) demonstrated that an ILI using calorie-restricted total diet replacement (TDR) for 12 weeks targeting ≥15 kg weight loss followed by stepped- and then full-food diet reintroduction for 40 weeks resulted in 46% achieving diabetes remission at 12 months, and 36% remained in remission at 24 months.[15,16] With replication of DiRECT-style programs in Qatar,[17] UK in residents of South Asian origin,[18] Australia[19] and Nepal,[20] these interventions, when compared to metabolic surgery, realise lower rates of serious adverse events (10% vs. 62%)[15,21] and greater cost effectiveness ($2517 vs. $18 375 USD/remission).[22,23] These results have directly impacted care, leading to publicly funded programs: specifically, the

National Health Service (NHS) in the UK has funded the NHS Type 2 Diabetes Path to Remission Programme based on the findings of DiRECT.[24]

Dietary and clinical practice guidelines have recently shifted to recommending various plant-based dietary patterns for obesity, diabetes and cardiovascular disease management.[25–27] Given the evidence for plant-based dietary patterns in diabetes prevention[28] and management[29] and their potential to provide metabolic benefits beyond weight loss,[30–33] there is an opportunity to assess the effect of a plant-based ILI for diabetes remission since all previous studies on ILIs have used dairy-based meal replacements and mainly omnivorous dietary patterns. Structured exercise with both aerobic and resistance training can also support weight loss maintenance,[34] as well as prevent lean mass loss,[35] a concern highlighted in the recent trials on emerging glucagon-like peptide-1 (GLP-1) receptor agonist therapies with major weight loss.[36] Evidence also supports exercise to improve glycemic control, independent of weight loss.[37] As a country with rich ethnocultural diversity, expanding on evidence-based strategies for diabetes remission will allow for a transcultural approach to be taken in nutrition and lifestyle counselling for remission in Canada and globally. No Canadian data yet exists to support remission programs in Canada, similar to the NHS program in the UK. One ongoing trial conducted at 2 sites (Canada and the UK) investigates the effect of a dairy-based TDR for 2 weeks followed by a 12-week low calorie omnivorous diet and structured exercise program and 12-week weight maintenance on remission and cardiac health at 24 weeks.[38] The REmission of diabetes using a PlAnt-based weight loss InteRvention (REPAIR) trial will provide Canadian evidence by evaluating whether a plant-based DiRECT-like 2-phase ILI targeting ≥15% weight loss can achieve diabetes remission compared to standard of care in a multi-ethnic Canadian population over 52 weeks with post-intervention follow-up at years 2 and 5. The intervention includes a 12-week weight loss phase on a plant-based TDR, followed by a 40-week weight loss maintenance phase on a plant-based dietary pattern with a 16-week structured exercise program and 52-week (19-session) sustainable behaviour change curriculum. The primary objective is to determine the effect of a plant-based ILI targeting ≥15% weight loss on diabetes remission (HbA1c <6.5% without glucose-lowering medication for ≥3 months) in adults with early T2D and obesity at 52 weeks. The key secondary objective is to determine the effect on the proportion of participants achieving ≥15% weight loss at 52 weeks.

2 | MATERIALS AND METHODS

2.1 | Overall study design and setting

The REPAIR trial is a prospective, randomised, parallel, 2-arm, open-label, blinded-endpoint (PROBE)[39] efficacy trial evaluating a 52-week plant-based ILI targeting ≥15% weight loss compared to standard of care for diabetes remission in 160 adults with early T2D and obesity with post-intervention follow-up at years 2 and 5. Figure 1 presents the trial design.

Clinical activities will be conducted in an outpatient setting at the Clinical Nutrition and Risk Factor Modification Centre at St. Michael's Hospital, including dietary intervention, behavioural support, and clinical visits, as well as the Nutrition Intervention Centre, Department of Nutritional Sciences, University of Toronto for functional tests and body composition, and the Rumsey Centre—Diabetes, Exercise and Healthy Lifestyle Program at the University Health Network (UHN) Toronto Rehabilitation Institute for a 16-week in-person exercise program. In alignment with Canadian Obesity Guidelines,[40] all staff will receive weight bias and stigma training through Obesity Canada[41] to ensure the team recognises obesity as a chronic disease, addresses any personal biases, uses respectful language, and applies individualised, person-centered care focused on health behaviours and goals.

2.2 | Study participants

Eligible participants will be adults >18 years of age with T2D diagnosed within the past 6 years, HbA1c between 6.0 and 10.0% on glucose lowering medication and with elevated body mass index (BMI) and waist circumference according to sex and/or ethnic specific criteria (Appendix 1). Table 1 presents the full inclusion and exclusion criteria.

2.3 | Randomisation, allocation concealment and blinding

Block randomisation with 1:1 allocation will be generated before initiation of the study by an off-site statistician (RJdS) and uploaded to the study's Research Data Capture (REDCap) platform. Allocation concealment will be maintained through secure electronic delivery of a single assignment sequence for each consecutively enrolled participant after successful completion of the run-in phase. Treatment allocation will be revealed to the coordinator only after participant identification at the baseline visit, in the presence of the participant.

The statistician will be blinded to treatment assignment, with groups coded numerically. Due to the nature of the intervention, participants and study personnel will not be blinded; however, outcome assessors and the statistician conducting the primary analyses will remain blinded throughout.

2.4 | Enrolment and recruitment

We intend to recruit equal numbers of male and female participants through social media and other forms of media, clinics and family practices, and internal registries of individuals who have consented to future research contact, targeting areas across the Greater Toronto Area with high diabetes prevalence.

Interested individuals will complete an online pre-screening questionnaire and view an information video. A telephone and in-person

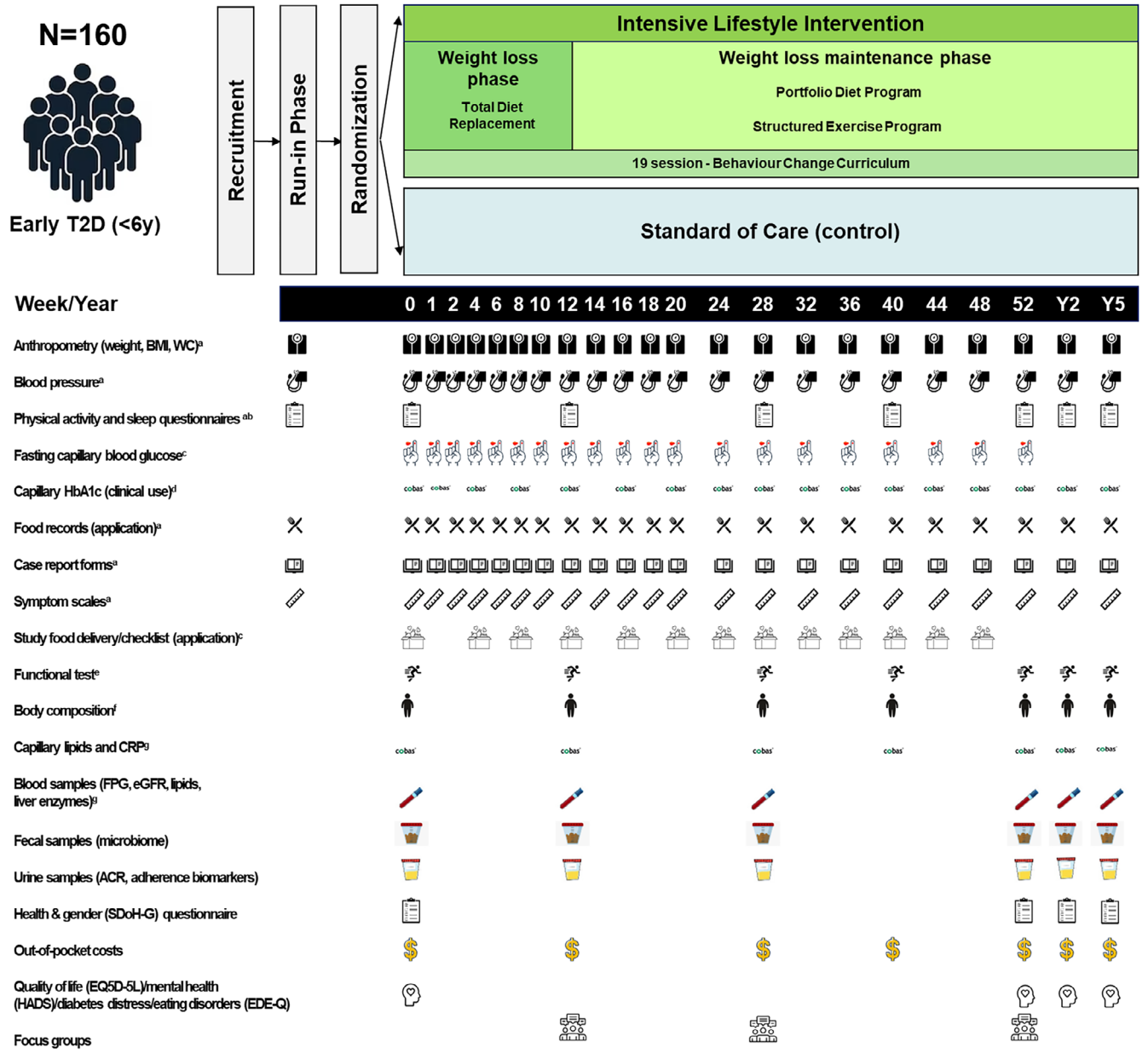

FIGURE 1 Trial design. ACR, albumin creatinine ratio; BMI, body mass index; EDE-Q, eating disorder examination - questionnaire; eGFR, estimated glomerular filtration rate; EQ5D-5L, European Quality of Life 5 dimensions 5 Level version; FPG, fasting plasma glucose; HADS, Hospital Anxiety and Depression Scale; HbA1c, glycated haemoglobin; hs-CRP, high sensitivity-c-reactive protein; ILI, intensive lifestyle intervention; SDoH-G, Social Determinants of Health & Gender Questionnaire; T2D, type 2 diabetes; WC, waist circumference; Y2, year 2; Y5, year 5. [a]Assessments will be done at run-in and week 0, and then every 2 weeks for the first 12 weeks and every 4 weeks thereafter for the plant-based ILI (active intervention) group and at 12, 28, 40, and 52 weeks for the standard of care (control) group. Y2 and Y5 assessments will be done on both groups; [b]Physical Activity and Sleep Questionnaires include International Physical Activity Questionnaire (IPAQ), Pittsburg Sleep Quality Index (PSQI), Insomnia Severity Index, Berlin Sleep Questionnaires, and Morningness-Eveningness Questionnaire (MEQ); [c]Assessments/deliveries restricted to the plant-based ILI (active intervention) group only; [d]Assessments will be done at week-0 and then every 4 weeks for the plant-based ILI (active intervention) group and at 0, 12, 28, 40 and 52 weeks for the standard of care (control) group. Y2 and Y5 assessments will be done on both groups; [e]Functional testing includes sit-to-stand chair and grip strength assessments; [f]Body composition includes body weight, BMI, waist circumference, body fat and lean body mass. Body fat and lean body mass will be assessed by bioelectrical impedance analysis (BIA) using the Inbody 970; [g]Capillary lipid and CRP will be assessed using Roche Cobas at 0, 12, 28, 40, and 52 weeks, and at Y2 and Y5.

screening visit will be conducted to determine eligibility. Eligible participants will be asked to provide consent for communication between the investigators and their family physician or healthcare provider managing their diabetes. Eligibility includes obtaining written support from participant providers, since providers will need to agree to the study physicians assuming care of their patients' antihyperglycemic

and/or antihypertensive medication for those randomised to receive the plant-based ILI or to continue standard obesity and diabetes care for those randomised to control.

Eligible participants will undergo an algorithm-scored barriers-and-motivators interview (consisting of a series of questions rated using a Likert scale ranging from 1 to 5) which was developed as part of a recruit-to-retain strategy with a behavioural scientist (MV). This semi-structured interview and mixed-format questionnaire will identify participants' barriers, motivators, and willingness to meet trial requirements (i.e., clinic visits, diet, exercise, behavioural curriculum, medication). Responses will be categorised into levels of readiness to change. Individuals with high motivation and minimal concerns will proceed through the consent process. Those with low motivation (Likert scale rating of 1–3 out of 5) or major concerns will undergo further discussion and be encouraged to reflect on the noted barriers to participation before proceeding to the consent process. The recruitment process is outlined in Figure 2.

2.5 | Run-in period

Consented participants will complete a run-in phase which includes a clinic visit to complete anthropometric measurements (body weight, waist circumference) and blood pressure assessments. Participants will be provided with a series of questionnaires to complete online (the International Physical Activity Questionnaire [IPAQ]; symptoms; sleep questionnaires, including the Pittsburgh Sleep Quality Index [PSQI], Insomnia Severity Index, Berlin Sleep Questionnaire, and Morningness-Eveningness Questionnaire [MEQ]; health and gender; out-of-pocket costs; quality of life [European Quality of Life 5 dimensions 5 Level, EQ5D-5 L]; mental health [Hospital Anxiety and Depression Scale, HADS]; eating disorders [Eating Disorder Examination – Questionnaire (EDE-Q)][44]; and diabetes distress[45]). Participants will be asked to provide a urine and faecal sample 1 day before the baseline study visit and to complete a food record using the Keenoa application (https://keenoa.com/) over 7 days before the baseline visit.

2.6 | Standard of care (control)

Participants randomised to the control arm will continue to receive standard diabetes and obesity care from their healthcare providers. Providers will receive a letter requesting they continue standard diabetes and obesity care as per current Canadian clinical practice guidelines (with links provided).[42,46] As ~7.5–11% of patients with early (<6 years) T2D and an HbA1c <7.3% experience spontaneous remission at ~1-year,[47–49] the letter will also suggest suitable patients be offered the opportunity to stop antihyperglycemic medications for assessment of remission. Control participants will attend 7 study visits at weeks 0, 12, 28, 40 and 52 and at years 2 and 5 for follow-up. They will receive phone calls from study staff in between visits to provide reminders to attend study visits and follow up with their healthcare providers.

TABLE 1 Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Adults (>18 years) • Diagnosed with type 2 diabetes within the past 6 years • HbA1c between 6.0 and 10.0% • Treated with non-insulin antihyperglycemic therapy • On stable doses (≥3 months) of antihypertensive, antihyperglycemic, or antihyperlipidemic medications, if applicable • Living with significant abdominal adiposity[a] • Has a family physician or healthcare provider who has provided written support for participation • Valid Ontario Health Card	• Type 1 diabetes • HbA1c <6.0% or >10% • Recent weight loss ≥5 kg within past 6 months • Treated with diet alone • Current treatment with insulin, GLP-1/GIP/glucagon receptor agonists or other anti-obesity drugs (naltrexone/bupropion, or Orlistat) • Eating disorders (<12 months) • Substance abuse disorders (<12 months) • Serious depression or psychiatric disorders (diagnosis or hospitalisation) • Allergy or intolerance to soy • Allergy or intolerance to peanuts, tree nuts and seeds (all three) • Pregnancy, intended pregnancy, or currently breastfeeding • Bariatric surgery (ever) or major surgery <6 months • Established chronic kidney disease (CKD) • Atherosclerotic cardiovascular disease (ASCVD) • Heart failure • Active cancer treatment (<12 months) • Major illness with expected death within 12 months • Chronic infections requiring medical treatment (HIV, TB, hepatitis C) • Participation in another trial • Contraindications to safe exercise • Conditions preventing adherence to protocol • Family physician or healthcare provider does not support participation

Abbreviations: ASCVD, atherosclerotic cardiovascular disease; BMI, body mass index; CKD, chronic kidney disease; GIP, glucose dependent insulinotropic polypeptide; GLP-1, glucagon-like peptide 1; HbA1c, haemoglobin A1c; HIV, human immunodeficiency virus; TB, tuberculosis.
[a]Sex and ethnic BMI and waist circumference cut-offs (see Appendix 1).[42,43]

2.7 | Plant-based ILI (intervention)

Figure 3 presents an overview of the plant-based ILI. Participants randomised to the plant-based ILI arm will receive dietary, physical activity, and behavioural support interventions aligning with Diabetes Canada and Canadian Obesity clinical practice guidelines.[13] Intervention participants will attend 22 study visits: weekly until week 2, 2-weekly until week 20, 4-weekly until week 52 and at years 2 and 5 for follow-up. They will receive phone calls at day 3 and week 3 for additional support.

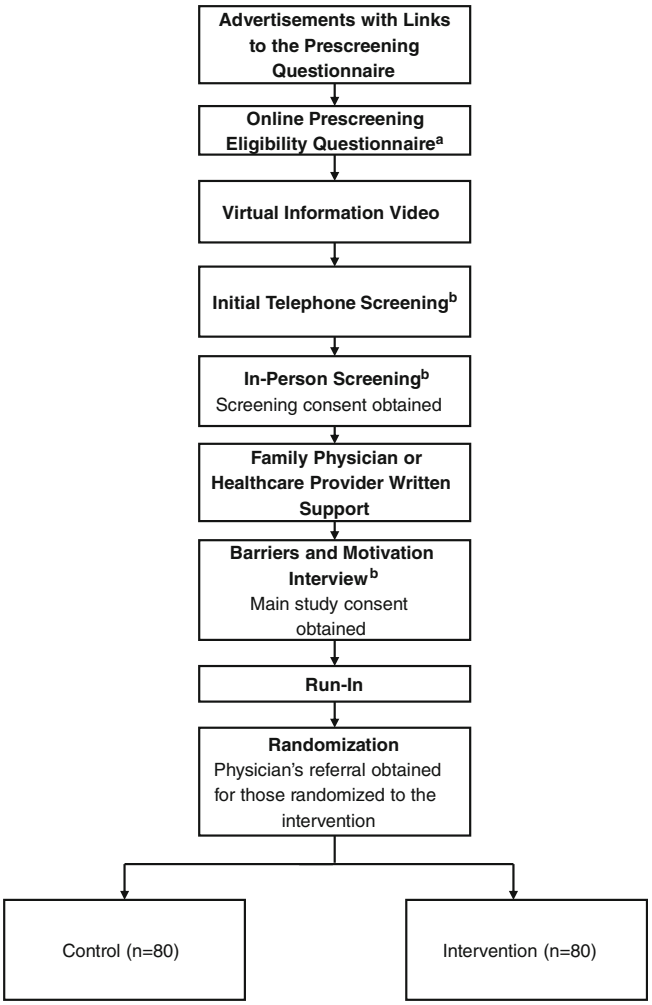

FIGURE 2 Recruitment flow diagram for the REPAIR trial. Participants progress from advertisements and eligibility screening through consent, interviews, and a run-in period before randomisation to the intervention group ($n = 80$) or control group ($n = 80$).[a]Self-administered questionnaire; [b]Questionnaire completed with the help of the study staff.

2.7.1 | Study physician review

At baseline, the study physician meets with the intervention participants to discuss stopping antihyperglycemic and/or antihypertensive medication due to the immediate lowering of glucose and blood pressure with the ILI. At each visit, body weight, capillary blood glucose and HbA1c, and blood pressure will be assessed for monitoring the response to the ILI, and study physicians will review to determine the need for introduction/reintroduction of medications following established protocols (Appendix 2).

2.7.2 | Dietary intervention

The ILI will consist of a 12-week weight loss phase using a plant-based TDR, followed by a 40-week weight loss maintenance phase beginning with an 8-week stepped-food reintroduction on a plant-based diet. Plant-based diets can encompass a spectrum of dietary patterns[50] where foods of animal origin are completely or mostly excluded.[51] For this study, the plant-based intervention will be based on the Portfolio Diet as it provides a quantitative framework for the intake of plant-based foods, particularly for protein. The core pillars of the Portfolio Diet are plant protein (50 g/day from soy and/or dietary pulses), nuts and seeds (45 g/day), viscous fibre (20 g/day), plant sterols (2 g/day), and monounsaturated fatty acids (45 g/day). The Portfolio Diet is recommended in diabetes and cardiovascular clinical practice guidelines in Canada and internationally[13,43] and has been shown to lower low-density lipoprotein-cholesterol (LDL-C) by up to 30%[52] among other cardiometabolic benefits independent of weight loss.[32] The weight loss phase will include the plant protein, viscous fibre and plant sterol pillars, and the weight maintenance phase will include all 5 pillars and leverage the digital Portfolio Diet Program to support sustainable behaviour change.[53] Both traditional (e.g., dietary pulses, soy) and innovative/processed plant-based foods (e.g., dairy and meat alternatives) will be permitted as part of the weight maintenance phase.

Weight-loss phase: Total diet replacement: (weeks 0–12)

During the first 12 weeks, participants will be instructed by study dietitians to consume 4 plant-based calorie-restricted TDR products per day using either Optifast (Nestlé), Ensure® Plant-Based Protein Nutrition Shake (Abbott, Columbus, OH), or Vega (Vega) products. Nestle and Abbott TDR products are not available in Canada, and a Temporary Marketing Approval will be obtained from Health Canada. A psyllium-based fibre (Metamucil, Procter & Gamble) and plant sterol supplement (Cardiosmile, Mantra Pharma Inc) will be provided, as well as a flax oil and complete multivitamin to ensure nutrient adequacy. This will provide participants with approximately 830–920 kcal/day (~36–40% energy protein, 39–47% energy carbohydrate, 30 g/d dietary fibre, 22–28% energy fat). Participants will be advised to drink at least 2 L (8 cups) of calorie-free fluid daily. All TDR products and supplements will be delivered to participants every 4 weeks. Participants will be monitored by study registered dietitians (with review of food records and checklists) and physicians and attend on-site clinic visits every 2 weeks. All participants will have the option to continue with the TDR for up to 20 weeks.

Weight maintenance phase: (weeks 12–52)

Stepped-food Reintroduction: (Weeks 12–20). During the first 8 weeks of the weight loss maintenance phase, participants will start stepped-food reintroduction. Participants will meet with study dietitians every 2 weeks to replace 1 of their daily TDR products with a heart-healthy plant-based meal or snack providing an additional ~300 kcal that aligns with the pillars of the Portfolio Diet. Participants will be supported to reach their individualised weight maintenance calorie goals calculated using the Mifflin St. Jeor equation based on age, sex, weight and height with adjustment for physical activity.[54,55] Participants will have the option to remain on 1 TDR product per day for the remainder of the trial. Participants will begin the Portfolio Diet

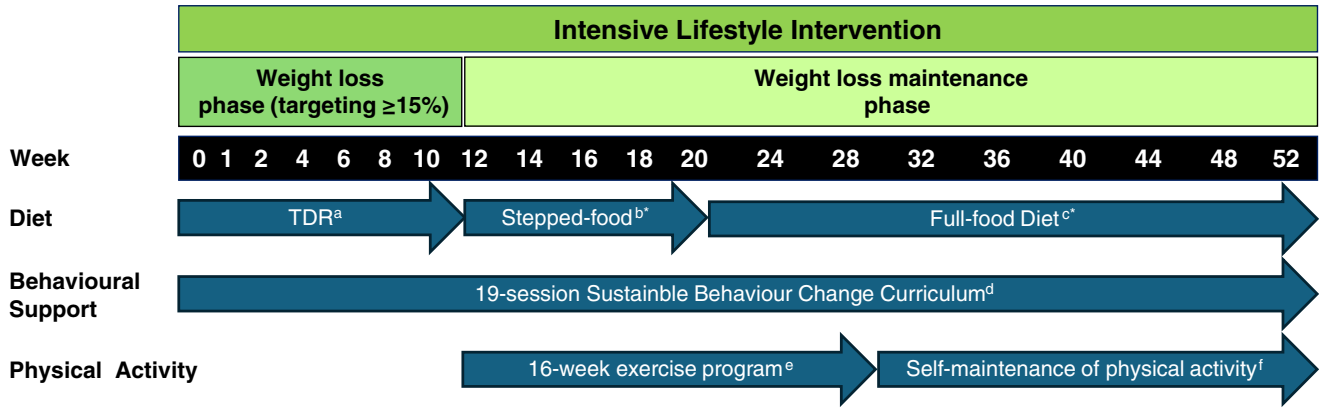

FIGURE 3 Design of the plant-based intensive lifestyle intervention. [a]Total Diet Replacement (TDR) phase: Participants will consume 4 TDR products daily for 12 weeks, with the option to continue up to week 20. [b]Stepped-food reintroduction phase: Over an 8-week period, participants will meet with study dietitians every 2 weeks where they will be advised on replacing 1 of their daily TDR products with a heart-healthy plant-based meal or snack providing an additional ~300 kcal that aligns with the pillars of the Portfolio Diet. Participants will have the option to retain 1 TDR product per day throughout the remainder of the trial. [c]Full-food Diet phase: Participants will follow the Portfolio Diet for weight loss maintenance until the end of the trial. *If a participant regains >2 kg during the weight loss maintenance phase, they will be offered rescue therapy where participants will resume full-TDR (4 TDR products per day) for 4 weeks, followed by a 4-week stepped-food reintroduction where they will be advised to replace 1 of their daily TDR products with a meal each week, and then transition to the full-food diet. [d]Participants will complete 19 interactive behaviour change modules as part of the sustainable behaviour change curriculum, delivered every 2 weeks to week 20 and then monthly to week 52, led by trial dietitians. Beginning at week 12, participants will also initiate the Portfolio Diet Program, including the mobile app, 1-week Kickstart package via emails, and structured behavioural nudges via in-app notifications. [e]Beginning at week 12, participants will engage in a 16-week structured exercise program at the Diabetes, Exercise and Healthy Lifestyle Program, Unity Health Network (UHN) Toronto Rehabilitation Institute. [f]From weeks 28–52, participants will continue their exercise plan using self-monitoring and receive motivational behaviour change counselling phone calls every 2 weeks.

Program to support sustainable dietary changes. They will be instructed to continue taking the psyllium-based fibre and plant sterol supplements, and flax oil and complete multivitamin to maintain nutrition adequacy. Food baskets containing some plant-based foods will be delivered to participants every 4 weeks. Participants will attend on-site clinic visits every 2 weeks and continue to be monitored by study dietitians (with review of food records and checklists) and physicians. Participants who elect to continue the TDR beyond the 12 weeks will initiate the stepped-food reintroduction phase at the end of their TDR (up to week 20).

Full-food Diet (Weeks 20–52). In the full-food diet phase, participants will be advised to continue the Portfolio Diet Program, following the Portfolio Diet, high in plant protein (total protein, ~1.2 g/kg body weight), low glycemic index (GI <55 on a glucose scale), and high in fibre. Participants will have the option to remain on 1 TDR product per day. Participants will continue taking the psyllium-based fibre, plant sterol, and complete multivitamin supplements. Food baskets containing some plant-based foods will continue to be delivered every 4 weeks. Participants will attend on-site clinic visits every 4 weeks, with monitoring by study dietitians (with review of food records and checklists) and physicians.

Rescue therapy

If a participant regains >2 kg during the weight loss maintenance phase, rescue therapy will be initiated. Participants will resume full-TDR (4 products per day) for 4 weeks, followed by a 4-week stepped-food reintroduction where they will be advised to replace 1 TDR product per day with a meal or snack each week, and then transition to the full-food diet.

2.7.3 | Physical activity intervention

The ILI will include a 16-week structured, in-person exercise training program (weeks 12–28), followed by a self-maintenance phase to week 52. Participants will join as cohorts of ~8 individuals in the Diabetes, Exercise and Healthy Lifestyle Program at UHN Toronto Rehabilitation Institute. Each cohort will attend a weekly 90-min group session led by a registered kinesiologist, with physician consultation available as needed. Sessions will include a cardiovascular warm-up and stretching routine, aerobic exercise (walking/jogging, stationary cycling or elliptical machine), resistance training, and 15 interactive educational sessions. Participants will be asked to set a goal of completing their personalised aerobic program 4 more times per week at home (aiming for 150–300 min per week of moderate intensity or 75–150 min per week of vigorous intensity exercise) and resistance training 1 to 2 more times per week, including 8–10 exercises for 1–3 sets of 10–15 repetitions. Intensity of the aerobic training prescription will be determined by cardiopulmonary exercise stress test based on ventilatory thresholds achieved completed 1–2 weeks prior to week 12. Participants will receive a heart rate monitor and/or activity tracker and be asked to maintain an exercise diary. Program goals align with Diabetes Canada

and American College of Sport's Medicine physical activity guidelines.[56,57] After completing the structured program, participants will continue their personalised program at home and receive behaviour change counselling phone calls every 2 weeks until week 52.

2.7.4 | Behavioural support intervention

To support adherence and sustained behaviour changes to the plant-based ILI, participants will receive a digital 19-session educational curriculum over 52 weeks and the digital Portfolio Diet Program (mobile health app, kickstart package, nudges) from weeks 12–52.

The 19-session educational curriculum is delivered virtually to the cohorts of ~8 participants (same cohorts as the exercise class) every 2 weeks for the first 20 weeks and every 4 weeks thereafter. The curriculum focuses on self-management strategies for modifying diet, increasing physical activity, and supporting behaviour change. Several modules draw on principles and materials from the PreventT2 Curriculum from the Diabetes Prevention Program (DPP), developed by the Centers for Disease Control and Prevention (CDC).[58] All modules have been designed and mapped with behavioural change theories, including the Capability, Opportunity, and Motivation system of behaviour change (COM-B) and the Theoretical Domain Framework (TDF).[59,60] The curriculum also embeds multiple behavioural change techniques that have been identified based on the Theory and Techniques Tool.[61] The modules will be delivered using Articulate, a software that enables interactive e-learning.[62]

The Portfolio Diet Program is a digital education and engagement tool to support sustained behaviour change to the Portfolio Diet with features mapped to the COM-B and TDF. The Program consists of a mobile app, 1-week Kickstart package received as daily emails, and structured behavioural nudges received as in-app notifications.

3 | OUTCOMES AND MEASUREMENTS

In-person evaluations in both arms occur before randomisation and at weeks 12, 28, 40, and 52 and at years 2 and 5 for follow-up.

3.1 | Primary and key secondary outcome

The primary outcome is the proportion achieving diabetes remission (defined as an HbA1c <6.5% without glucose-lowering medication for ≥3-months) at 52 weeks.[63] HbA1c will be assessed using capillary blood and the Roche Cobas b101 system.

The key secondary outcome is the proportion achieving ≥15% weight loss from baseline at 52 weeks. Body weight will be assessed fasting and by beam scale.

3.2 | Secondary outcomes

Other secondary outcomes include the proportion experiencing relapse (HbA1c ≥6.5% at week 52 as per Diabetes Canada),[13] proportion achieving ≥10% and ≥5% weight loss, and changes in measures of body composition (body weight, BMI, waist circumference, body fat, lean body mass), functional testing (sit-to-stand and hand grip strength tests), glycemic control (HbA1c, fasting plasma glucose), blood pressure (systolic and diastolic), lipids (LDL-C, non-HDL-C, triglycerides, HDL-C, total cholesterol), and inflammation (C-reactive protein [CRP]).

Measurement of secondary outcomes will use standard methods. HbA1c, lipids and CRP will be assessed using capillary blood and the Roche Cobas b101 system. LDL-C will be calculated using the National Institutes of Health (NIH) equation.[64] Fasting blood glucose will be assessed in plasma using the glucose hexokinase method.[65] Height will be measured with a wall-mounted stadiometer (Perspective Enterprises, Portage, MI, USA). Waist circumference will be assessed according to Obesity Canada guidelines. Functional testing will be assessed using the 30-s sit-to-stand test[66] and hand grip strength tests. Blood pressure will be measured oscillometrically (OMRON Intellisense HEM-907) following Hypertension Canada[67] and JNC VII guidelines.[68,69] Body fat and lean body mass will be assessed by bioelectrical impedance analysis (Inbody 970).

3.3 | Implementation outcomes

The trial has been designed to align with the RE-AIM framework (Appendix 3).[70] Health research outcomes aligning with the quadruple aim framework will be assessed from healthcare economic analyses (EQ-5D-5L)[71] and participant and provider experiences through mixed-form questionnaires and participant 60-min virtual focus groups (at weeks 12, 28, and 52). These assessments will be used to understand barriers and facilitators to each phase of the ILI and self-rating of behavioural change in each domain of the TDF.[72] Mental well-being will be assessed (HADS),[73] eating disorders,[44] diabetes distress,[45] and quality of life outcomes (EQ-5D-5L).[71]

3.4 | Adherence outcomes

Adherence will be assessed by visit attendance and adherence to program components, including diet using food records, objective biomarkers of intake [plasma phytosterols,[74] urinary hydroxytyrosols,[75] plasma alpha linoleic acid,[75] plasma N-acetyl-ornithine,[76] urinary isoflavonoid excretion[77]], exercise using the diary and IPAQ, and completion of modules.

3.5 | Exploratory outcomes

Exploratory outcomes include changes in insulin resistance (homeostasis model assessment of insulin resistance [HOMA-IR] from fasting insulin and glucose), renal markers (estimated Glomerular Filtration Rate [eGFR], albumin-to-creatinine ratio [ACR]), metabolic dysfunction-associated steatotic liver disease [MASLD] markers (liver enzymes [ALT, AST, GGT], fatty liver index), urea, vitamin B12, vitamin

D (25-hydroxy vitamin D), ferritin, and iron, medication usage, sleep (PSQI, Insomnia Severity Index, Berlin Sleep Questionnaire, and MEQ), diet quality (Alternative Healthy Eating Index [AHEI] using the food records), gut microbial beta-diversity, gene expression (DNA methylation, telomere length). These outcomes will be assessed using standard techniques.

3.6 | Safety and adverse events

Safety outcomes include symptoms questionnaires and adverse events. Serious adverse events will be reported to all REBs within 7 days.

4 | STATISTICAL ANALYSIS PLAN

Data will be analysed according to the intention-to-treat (ITT) principle. Primary analyses will be based on change from baseline at 52 weeks for all outcomes. Interim analyses will be conducted at 28 weeks for the primary and key secondary outcomes to assess for event rates in the control group given the current changing environment around incretin-based therapies.[78] The primary and key secondary outcomes will be assessed hierarchically. If the primary outcome of proportion achieving remission is significant, the key secondary outcome of the proportion achieving ≥15% weight loss will be assessed without a correction for false discovery. All other outcomes will be treated as exploratory and assessed without correction for false discovery. Missing data for the primary ITT analysis will be imputed using inverse probability weighting. Completers and per-protocol analyses will be undertaken as secondary analyses for all outcomes. Prespecified subgroup analyses will be conducted by age, sex, gender, social determinants of health, ethnicity, duration of diabetes, and by baseline body weight, waist circumference, HbA1c, and diabetes/antihyperglycemic medications. A subgroup analysis will also be conducted by degree of weight loss for the primary outcome of remission. Analyses will be performed using logistic regression models for categorical (odds ratio with 95% CI) data and mixed models for continuous (mean differences with 95% CIs). Models will be adjusted for age, sex, and baseline value, as well as use of diabetes/antihyperglycemic agents that cause weight loss (e.g., GLP-1 therapies and SGLT-2 inhibitors) or weight gain (e.g., sulfonylureas and insulin). Non-parametric tests and data transformations will be applied as necessary. Qualitative data from focus groups will be analysed thematically by at least two trained staff. They will manage data analysis using NVivo software.[79]

5 | SAMPLE SIZE

To preserve the type 1 error, the p-value will be shared between the interim analysis ($p < 0.01$) and final analysis ($p \leq 0.04$) (Table 2). A total sample size of 160 participants will provide ≥80% power to detect a diabetes remission rate of at least 46% in the intervention arm, consistent with the effects observed in DiRECT.[16,80] Given the increasing and high use of incretin therapies, with 25% expected to go on incretin therapies in the control arm,[78] we assume a higher proportion will achieve remission (18% vs. 12%) and 15% weight loss outcome (5% vs. 1%) in the control arm than was seen in the prior remission trial with the highest proportion achieving these outcomes (DIADEM-I).[17,81]

DISCUSSION

With the recognition of remission as a therapeutic goal in diabetes clinical practice guidelines, ILIs targeting ≥15% weight loss have emerged, along with bariatric surgery, as effective strategies to achieve remission.[14] While weight loss has been well established as a key mechanism for remission, as described by the twin-cycle hypothesis through ectopic fat loss in the liver and pancreas restoring hepatic insulin sensitivity and beta cell function,[82] intervention designs that emphasize plant-based dietary patterns, consistent with current clinical practice guidelines for obesity and diabetes, as well as behavioural strategies, can support both weight loss-dependent and weight loss-independent pathways. These approaches can deliver improvements in fibre-related appetite and weight control,[83–85] as well as additional metabolic benefits, including improvements in blood pressure, lipid profiles, inflammation, and long-term cardiovascular outcomes.[25,26] To date, ILIs have only been assessed using diets with considerable amounts of animal protein and in countries outside Canada (e.g., UK,[16] Middle East,[17] South Asia[18]), where health care systems, cultural contexts, and population demographics differ considerably. A critical evidence gap is whether ILIs can leverage plant-based dietary patterns, which are recommended in dietary and clinical practice guidelines[25–27] and have demonstrated cardiometabolic benefits independent of weight loss,[30–33] and be applied in the Canadian context as a successful strategy to address the diabetes burden. The REPAIR trial was designed to address this gap by testing whether a heart-healthy, plant-based ILI combined with exercise and behavioural support can achieve diabetes remission, support sustained weight loss and improve other cardiometabolic factors, in a multi-ethnic Canadian population, as well as demonstrate patient-important quality of life and health service outcomes.

Landmark studies have demonstrated that dietary ILIs produce remission rates through weight loss, with uptake in health services. The DiRECT trial reported 46% remission at 12 months and 36% at 24 months, with remission rates exceeding 80% among those who achieved ≥15 kg weight loss.[15] Similarly, replication studies including DIADEM-I in Qatar achieved remission in 61% of participants at 12 months[17] and the STANDby trial in South Asian populations in the UK reported 39% remission at 12 months.[18] The success of DiRECT has been translated into health policy through the National Health Service Type 2 Diabetes Path to Remission Programme, where those who have completed the 12-month program have demonstrated 32% remission.[86] If the REPAIR trial demonstrates effective and

TABLE 2 Sample size.

Outcome	Timepoint	Alpha	Power	Absolute difference
Primary Outcome: Diabetes remission	28 weeks	0.01	80%	28% (46% vs. 18%)
	52 weeks	0.04	92%	28% (46% vs. 18%)
Key Secondary Outcome: Proportion achieving weight loss ≥15%	28 weeks	0.01	86%	24% (29% vs. 5%)
	52 weeks	0.04	85%	19% (24% vs. 5%)

sustainable remission in the Canadian context, the intervention may be scalable within the publicly funded health care system to reduce the burden of diabetes in Canada.

Beyond diet, behavioural strategies are essential for sustaining lifestyle changes. The REPAIR trial includes a 19-session educational curriculum modelled on established prevention programs. A notable example is the DPP, which promotes modest weight loss (5–7%) through increased physical activity and a 26-module curriculum focused on behaviour modification and goal setting.[87] This approach contributed to a reduction in the incidence of T2D (58%) after 2.8 years in the DPP[87] and to remission (11%) in LOOKAHEAD after 1 year.[88] Use of specific behavioural change techniques, such as social support, problem-solving, and goal setting, has also shown improvements in glycemic control.[89] Moreover, incorporation of innovative plant-based foods that provide familiar food platforms (e.g., meat and dairy alternatives), in addition to traditional plant-based foods, will help decrease feasibility barriers and cognitive dissonance among participants not as familiar with plant-based dietary patterns.[90,91]

The REPAIR trial was designed with consideration of potential challenges. To mitigate challenges in participant recruitment, recruitment is planned across a broad catchment area and will use multiple platforms to enhance representativeness. To support adherence to the ILI, the intervention includes provision of the TDR and key Portfolio Diet foods with review of food records by dietitians and heart rate/physical activity monitors with review of exercise diaries by kinesiologists, and a structured educational curriculum and digital support tools designed with integration of behaviour change theories to enhance participant retention and success. To address the role of adherence, these measures, enhanced with objective biomarkers of adherence across key dietary components, will be included in analyses. To mitigate bias, outcome assessors and statisticians will be blinded throughout.

The REPAIR trial will generate the first high-quality Canadian evidence on a plant-based ILI for diabetes remission, weight loss and additional cardiometabolic benefits and provide insights into behavioural strategies for sustaining remission. These findings provide Canadian context to inform national nutrition and health policy, clinical guidelines, and provide a readily implementable clinical public health solution using plant-based ILIs to address the burden of obesity and diabetes and downstream complications in Canada and beyond.

AUTHOR CONTRIBUTIONS

Laura Chiavaroli, John L Sievenpiper, Cyril WC Kendall, and David JA Jenkins conceived the trial and obtained funding. All authors provided input on the design and analysis plan. Brighid McKay, Dayana El Chaar, Melanie Paquette, John L Sievenpiper, and Laura Chiavaroli drafted the manuscript. All authors critically revised the manuscript for important intellectual content. Laura Chiavaroli is the guarantor. All authors have given approval for publication.

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FUNDING INFORMATION

The trial is supported by funding from a Government of Canada Global Innovation Cluster, Protein Industries Canada. In-kind donations and unrestricted funding will be provided for the provision of key foods from Abbott, Mantra Pharma Inc. (Cardiosmile), CHO-America (Terra Delyssa olive oil), Danone, WK Kellogg Co, Almond Board of California, Procter & Gamble, and General Mills Inc. The University of Toronto is the sponsor of the study and has the authority over study design; collection, management, analysis and interpretation of data; writing of the report; and the decision to submit the report for publication. Brighid McKay and Dayana El Chaar received Banting and Best Diabetes Centre Graduate Studentships. Brighid McKay received a CANTRAIN Studentship. Laura Chiavaroli received partial salary support from a Toronto 3D New Investigator Award. None of the sponsors had a role in any aspect of the present trial, including the design and conduct of the trial; collection, management, analysis, and interpretation of the data; and the preparation, review and approval of the manuscript or decision to publish.

CONFLICT OF INTEREST STATEMENT

Michael Vallis sits on Advisory Boards and consults to, and receives speaking fees from, Abbott, Abbvie, Bausch Health, Boehringer Ingelheim, Medtronic, Novo Nordisk, Sanofi, and Vivus. He sat on the Executive of the Canadian Clinical Practice Guidelines for Obesity in Canada (Adults) and has been a regular contributor to Diabetes Canada's Clinical Practice Guidelines. Hertzel C. Gerstein holds the McMaster-Sanofi Population Health Institute Chair in Diabetes

Research and Care. He reports research grants from Novo Nordisk; continuing education grants from Eli Lilly, Abbott, Sanofi, Novo Nordisk, and Boehringer Ingelheim; honoraria for speaking from AstraZeneca and Jiangsu Hanson; and consulting fees from Abbott, Bayer, Eli Lilly, Novo Nordisk, Sanofi, and Zealand, and holds a patent for the use of GDF15 as a biomarker for metformin intake. Jordi Salas-Salvadó has received research support from Instituto Carlos III (Spain), the National Institutes of Health (USA), Recercaixa (Spain), Marató TV3, and the European Commission (H2020 grants). He has received grants and support for meeting attendance and travel from the Nut and Dried Fruit Foundation. He is an honorary member of the International Advisory Board for the project "Effect of Cashew Nut Supplementation on Glycemic Status and Lipid Profile in Type 2 Diabetes Subjects" and was a member of the Scientific Committee of the Danone Institute International. He has received personal fees for serving on the Danone Institute Advisory Board. JS-S serves on the Clinical Practice Guidelines Expert Committees of Diabetes Canada and the European Association for the Study of Diabetes (EASD). He has also received free olive oil from the Patronato Communal Olivalero for use in the PREDIMED-Plus trial. Jacqueline L. Beaudry has received research support from the Canadian Foundation for Innovation, Ontario Research Fund, Natural Sciences and Engineering Research Council of Canada (NSERC), Canadian Institutes of health Research (CIHR), Banting and Best Diabetes Centre, and holds a Canada Research Chair in Fat Biology and Nutrition. Christopher P. F. Marinangeli is an employee of Protein Industries Canada (A Government of Canada Global Innovation Cluster) and former employee of Kellogg Canada and Pulse Canada. He has received support from General Mills and Pepsico. He is a member of the IAFNS Protein Committee. Cyril W. C. Kendall has received grants or research support from the Advanced Food Materials Network, Agriculture and Agri-Foods Canada (AAFC), Almond Board of California, Barilla, Canadian Institutes of Health Research (CIHR), Canola Council of Canada, International Nut and Dried Fruit Council, International Tree Nut Council Research and Education Foundation, Loblaw Brands Ltd. He has received in-kind research support from the Almond Board of California, Barilla, California Walnut Commission, Kellogg Canada, Loblaw Companies, Nutrartis, Quaker (PepsiCo), the Peanut Institute, Primo, Unico, Unilever, WhiteWave Foods/Danone. He has received travel support and/or honoraria from Barilla, California Walnut Commission, Canola Council of Canada, General Mills, International Nut and Dried Fruit Council, International Pasta Organization, Lantmannen, Loblaw Brands Ltd., Oldways Preservation Trust. He has served on the scientific advisory board for the International Tree Nut Council, International Pasta Organization, McCormick Science Institute, and Oldways Preservation Trust. He is a founding member of the International Carbohydrate Quality Consortium (ICQC), Past-Chair of the Diabetes and Nutrition Study Group (DNSG) of the European Association for the Study of Diabetes (EASD), is on the Clinical Practice Guidelines Expert Committee for Nutrition Therapy of the DNSG, and is a Director of Glycemia Consulting and the Toronto 3D Knowledge Synthesis and Clinical Trials foundation. David J. A. Jenkins has received research grants from Heart and Stroke Foundation Grant-in-Aid, Soy Nutrition Institute (SNI), Diabetes Canada, the Canadian Institutes of Health Research (CIHR), Saskatchewan & Alberta Pulse Growers Associations, the Agricultural Bioproducts Innovation Program through the Pulse Research Network, the Advanced Foods and Material Network, Loblaw Companies Ltd., Unilever Canada and Netherlands, Barilla, the Almond Board of California, Agriculture and Agri-food Canada, Pulse Canada, Kellogg's Company, Canada, Quaker Oats, Canada, Procter & Gamble Technical Centre Ltd., Bayer Consumer Care, Springfield, NJ, Pepsi/Quaker, International Nut & Dried Fruit Council (INC), Soy Foods Association of North America, the Coca-Cola Company (investigator initiated, unrestricted grant), Solae, Haine Celestial, the Sanitarium Company, Orafti, the International Tree Nut Council Nutrition Research and Education Foundation, the Peanut Institute, the Canola and Flax Councils of Canada, the Calorie Control Council, the Canada Foundation for Innovation (CFI) and the Ontario Research Fund (ORF). He has received in-kind supplies for trials as research support from the Almond Board of California, Walnut Council of California, the Peanut Institute, Barilla, Unilever, Unico, Primo, Loblaw Companies, Quaker (Pepsico), Pristine Gourmet, Bunge Limited, Kellogg Canada, WhiteWave Foods. He has been on the speaker's panel, served on the scientific advisory board and/or received travel support and/or honoraria for lectures/presentations from Diabetes and Nutrition Study Group (DNSG), Lawson Centre Nutrition Digital Series, 19th Annual Stare-Hegsted Lecture, Diabetes Canada, Nutritional Fundamentals for Health (NFH)-Nutramedica, Saint Barnabas Medical Center, The University of Chicago, 2020 China Glycemic Index (GI) International Conference, Atlantic Pain Conference, Academy of Life Long Learning, the Almond Board of California, Canadian Agriculture Policy Institute, Loblaw Companies Ltd., the Griffin Hospital (for the development of the NuVal scoring system), the Coca-Cola Company, Epicure, Danone, Diet Quality Photo Navigation (DQPN), Better Therapeutics (FareWell), Verywell, True Health Initiative (THI), Heali AI Corp, Institute of Food Technologists (IFT), Soy Nutrition Institute (SNI), Herbalife Nutrition Institute (HNI), Saskatchewan & Alberta Pulse Growers Associations, Sanitarium Company, Orafti, the International Tree Nut Council Nutrition Research and Education Foundation, the Peanut Institute, Herbalife International, Pacific Health Laboratories, Barilla, Metagenics, Bayer Consumer Care, Unilever Canada and Netherlands, Solae, Kellogg, Quaker Oats, Procter & Gamble, Abbott Laboratories, Dean Foods, the California Strawberry Commission, Haine Celestial, PepsiCo, the Alpro Foundation, Pioneer Hi-Bred International, DuPont Nutrition and Health, Spherix Consulting and WhiteWave Foods, the Advanced Foods and Material Network, the Canola and Flax Councils of Canada, AgriCulture and Agri-Food Canada, the Canadian Agri-Food Policy Institute, Pulse Canada, the Soy Foods Association of North America, the Nutrition Foundation of Italy (NFI), Nutra-Source Diagnostics, the McDougall Program, the Toronto Knowledge Translation Group (St. Michael's Hospital), the Canadian College of Naturopathic Medicine, The Hospital for Sick Children, the Canadian Nutrition Society (CNS), the American Society of Nutrition (ASN), Arizona State University, Paolo Sorbini Foundation and the Institute of Nutrition,

Metabolism and Diabetes. He received an honorarium from the United States Department of Agriculture to present the 2013 W.O. Atwater Memorial Lecture. He received the 2013 Award for Excellence in Research from the International Nut and Dried Fruit Council. He received funding and travel support from the Canadian Society of Endocrinology and Metabolism to produce mini cases for the Canadian Diabetes Association (CDA). He is a co-chair of the International Carbohydrate Quality Consortium (ICQC). He is invited by International Diabetes Federation (IDF) to join the committee on diabetes treatment and to take the lead in writing the dietary guidelines for the treatment of diabetes. His wife, Alexandra L Jenkins, is a director and partner of INQUIS Clinical Research for the Food Industry, his 2 daughters, Wendy Jenkins and Amy Jenkins, have published a vegetarian book that promotes the use of the foods described here, The Portfolio Diet for Cardiovascular Disease Risk Reduction (Academic Press/Elsevier 2020 ISBN:978–0–12-810 510-8) and his sister, Caroline Brydson, received funding through a grant from the St. Michael's Hospital Foundation to develop a cookbook for one of his studies. He is also a vegan. John L. Sievenpiper has received research support from the Canadian Foundation for Innovation, Ontario Research Fund, Province of Ontario Ministry of Research and Innovation and Science, Canadian Institutes of Health Research (CIHR), Diabetes Canada, American Society for Nutrition (ASN), Institute for the Advancement of Food and Nutrition Sciences (IAFNS), The United Soybean Board (USDA soy "Checkoff" program), Protein Industries Canada (a Government of Canada Global Innovation Cluster), Almond Board of California, European Fruit Juice Association, The Glycemic Control and Cardiovascular Disease in Type 2 Diabetes Fund at the University of Toronto (a fund established by the Alberta Pulse Growers), The Plant Protein Fund at the University of Toronto (a fund which has received contributions from IFF among other donors), The Plant Milk Fund at the University of Toronto (a fund established by the Karuna Foundation through Vegan Grants), and The Nutrition Trialists Network Fund at the University of Toronto (a fund established by donations from the Calorie Control Council, Physicians Committee for Responsible Medicine, and Login5 Foundation). He has received food donations to support randomized controlled trials from the Almond Board of California, California Walnut Commission, Danone, Mantra Pharma, Terra Delyssa, House Foods, General Mills, WK Kellogg Company, Quaker, Procter & Gamble (P&G), Abbott, and Dairy Farmers of Canada. He has received travel support, speaker fees and/or honoraria from Nestlé, Abbott, General Mills, International Food Information Council (IFIC), International Sweeteners Association, Calorie Control Council, International Stevia Council, Mantra Pharma Inc., Chinese Institute of Food Science and Technology (CIFST), and Collaborative CME and Research Network (CCRN). He has or has had ad hoc consulting arrangements with Almond Board of California, Perkins Coie LLP, Tate & Lyle, Ingredion, and Brightseed. He is on the Clinical Practice Guidelines Expert Committees of Diabetes Canada, European Association for the study of Diabetes (EASD), Canadian Cardiovascular Society (CCS), and Obesity Canada/Canadian Association of Bariatric Physicians and Surgeons. He serves as an unpaid member of the Board of Trustees of IAFNS. He is Vice President – Clinical of the Canadian Nutrition Society (CNS), founding member of the International Carbohydrate Quality Consortium (ICQC), Executive Board Member of the Diabetes and Nutrition Study Group (DNSG) of the EASD, and Director of the Toronto 3D Knowledge Synthesis and Clinical Trials foundation. His spouse is an employee of AB InBev. Laura Chiavaroli has received research support from CIHR, Protein Industries Canada (a Government of Canada Global Innovation Cluster), the United Soybean Board (USDA soy "Checkoff" program), and the Alberta Pulse Growers Association and honoraria from the Arkansas Children's Hospital and Physicians Committee for Responsible Medicine. All other authors report no relevant conflicts of interest.

PEER REVIEW

The peer review history for this article is available at https://www.webofscience.com/api/gateway/wos/peer-review/10.1111/dom.70510.

DATA AVAILABILITY STATEMENT

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

ETHICS STATEMENT

This study has been approved by the research ethics board at St. Michael's Hospital and the University of Toronto, and all participants will provide written informed consent. The trial protocol conforms to the ethical guidelines of the Tri-Council Policy Statement 2[92] and the study was conducted in accordance with the Declaration of Helsinki. A qualified and trained staff member has been appointed as the trial monitor to ensure adherence to Good Clinical Practice (GCP) guidelines. The monitor will be well-acquainted with the protocol and trial procedures. Monitoring visits are planned at key time points. During these visits, the monitor will perform statistical sampling of trial charts, identify any missing or inconsistent data across study documents, and prepare detailed reports of their findings to share and discuss in meetings with the PIs and study team. The results of this study will be disseminated through publication in peer-reviewed journals and presented at relevant conferences. Protocol amendments will be disseminated to all primary investigators as soon as they have been approved. The trial is registered on ClinicalTrials.gov (NCT06906172).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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