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Original Research

## The Diabetes Health Coaching Randomized Controlled Trial: Rationale, Design and Baseline Characteristics of Adults Living With Type 2 Diabetes



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### Key Messages

- Diabetes health coaching is a promising low-cost intervention to support individuals living with type 2 diabetes, but it needs to be further evaluated.
- Recruitment and the baseline characteristics of participants in a novel coaching-intervention clinical trial at the community level are representative of Canadians living with type 2 diabetes.

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### ABSTRACT

**Objectives:** The Diabetes Health Coaching Trial was a single-blind, randomized controlled trial designed to evaluate the effect of a 1-year telephone-based diabetes health-coaching intervention for community-dwelling adults living with type 2 diabetes mellitus. It concerned glycosylated hemoglobin levels, self-care behaviours and cost-effectiveness. The purpose of this article is to describe the rationale, design and participants' characteristics.

**Methods:** The eligibility criteria were: 1) adults  $\geq 18$  years of age; 2) a diagnosis of type 2 diabetes; 3) glycosylated hemoglobin levels of  $\geq 7.5\%$  6 months before randomization; 4) the ability to read, write and understand English; and 5) having telephone access. Participants were randomized to either usual diabetes education or diabetes education plus diabetes health coaching.

**Results:** From May 2016 to December 2017, 365 participants were randomized into the trial. At baseline, the mean age was 57.9 (11.78) years, the mean duration of diabetes was 8.69 (8.54) years, the mean glycosylated hemoglobin level was 8.98 (1.58) %, and the mean body mass index was 35.03 (8.07) kg/m<sup>2</sup>.

**Conclusions:** The baseline characteristics of the participants were equally distributed across the intervention and control groups. The Diabetes Health Coaching Trial is in a position to evaluate a potential treatment alternative and approach for type 2 diabetes and examined the effect of the intervention on clinical outcomes, self-care behaviours and cost-effectiveness.

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## R É S U M É

**Objectifs :** L'étude sur l'accompagnement en santé de la personne diabétique constituait un essai clinique à répartition aléatoire et à simple insu conçu pour évaluer les effets d'une intervention d'accompagnement en santé de la personne diabétique par téléphone durant 1 an chez les adultes atteints du diabète sucré de type 2 qui demeurent dans la communauté. Il porte sur les concentrations de l'hémoglobine glyquée, les comportements d'autosoins et l'efficacité de l'intervention. L'objectif du présent article est de décrire la raison d'être et la conception de l'essai clinique, et les caractéristiques des patients.

**Méthodes :** Les critères d'admissibilité étaient les suivants: 1) les adultes  $\geq 18$  ans; 2) un diagnostic de diabète de type 2; 3) des concentrations d'hémoglobine glyquée  $\geq 7,5$  % 6 mois avant la répartition aléatoire; 4) la capacité de lire, d'écrire et de comprendre l'anglais; 5) l'accès à un téléphone. Les participants étaient répartis de manière aléatoire soit à l'enseignement usuel sur le diabète, soit à l'enseignement sur le diabète et à l'accompagnement en santé de la personne diabétique.

**Résultats :** De mai 2016 à décembre 2017, 365 participants étaient répartis de manière aléatoire à l'essai. Au début, l'âge moyen était de 57,9 (11,78) ans, la durée moyenne du diabète était de 8,69 (8,54) ans, la concentration d'hémoglobine glyquée était de 8,98 (1,58) % et l'indice de masse corporelle moyen était de 35,03 (8,07) kg/m<sup>2</sup>.

**Conclusions :** Les participants étaient répartis au groupe d'intervention et au groupe témoin de manière à ce que les caractéristiques initiales s'y trouvent de manière égale. L'étude sur l'accompagnement en santé de la personne diabétique est en mesure d'évaluer une solution et une approche de traitement potentiel du diabète de type 2 et d'examiner les effets de l'intervention sur les résultats cliniques, les comportements d'autosoins et l'efficacité de l'intervention.

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## Introduction

Diabetes mellitus is 1 of the most common chronic diseases worldwide, and it continues to be a growing health challenge. Type 2 diabetes mellitus accounts for approximately 90% to 95% of all diabetes diagnoses (1); estimates say that 6.4% (285 million) of the world's adult population is living with type 2 diabetes, and projections point to 553 million by 2030 (2). Similar findings have been found in Canada, where 6.8% of the Canadian population are living with type 2 diabetes, and there is a predicted increase due to the aging population and growing rates of obesity and sedentary lifestyles (3,4). The goals of treatment and management of type 2 diabetes are to achieve optimal glycemic targets, reduce adverse events (i.e. hypoglycemia) and prevent the development of short- and long-term complications (5–9).

Empirical evidence suggests that the best approach to the management of diabetes is self-management (10–29). Diabetes self-management includes self-management education and support for behavioural and lifestyle changes (i.e. healthful eating and engagement in physical activity), glucose monitoring and medication adherence (30). Although diabetes care is centred on individual self-care, it is increasingly supported by multidisciplinary teams. However, due to the complex nature of the disease, coupled with the heterogeneity in management techniques, health-care providers are often challenged to provide long-term diabetes management that is individualized, patient-centred and long term (6–8,31).

In view of such challenges, a growing body of empirical evidence supports the emergence of a new model of care for timely and ongoing diabetes self-management education: health coaching. Health coaching, rooted in behavioural change theory, refers to the delivery of health-related education and the promotion of behaviour changes and psychosocial support by a health-care provider to facilitate the achievement of patients' well-being (enhancing self-efficacy, increasing motivation and promoting problem solving), health-related goals (32–35) and, in turn, the improvement in clinical health outcomes (i.e. glycemic control, reduced health-care use and medication/treatment adherence). Health coaching is emerging as an increasingly effective and efficient model of care to

ensure education, support and feedback that are personalized and convenient for individuals. Although there is increased integration of such interventions to support people living with type 2 diabetes, health coaching interventions have not been adequately assessed in the community health-care setting for people living with type 2 diabetes (36–39). This trial was designed to determine the effect of diabetes health coaching on clinical outcomes and self-care behaviours in community-based adults living with type 2 diabetes. Secondary outcomes measured self-care behaviour, health-related quality of life and cost-effectiveness.

## Methods

The Diabetes Health Coaching Trial is a recently completed recruitment, community-based trial ([clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02128815) identifier: NCT02128815). It was designed to evaluate the impact of having access to diabetes health coaching for 1 year, along with usual diabetes education, compared to usual diabetes education alone, in community-dwelling adults living with uncontrolled type 2 diabetes. The study was approved by the Hamilton Integrated Research Ethics Board, and written informed consent was obtained from all participants. This article follows the reporting of randomized trials of a social and psychological interventions checklist, the CONSORT-SPI 2018 Extension (40).

### Trial population

Based on our sample-size calculation, our goal was to recruit 364 participants from the Waterloo Wellington Region in Ontario, Canada. A total of 3 community health councils (CHCs) (Langs CHC, Kitchener Downtown CHC and Woolwich CHC) and 2 satellite sites (New Hamburg Recreation Centre and Waterloo YMCA) participated as recruitment sites as part of the region's standardized Community Diabetes Program. Collectively, the sites receive approximately 1,400 referrals for individuals with type 2 diabetes in a year, with an average of more than 115 referrals a month. The inclusion criteria for the study were as follows: 1) adults 18 years of age or older; 2) participants having diagnoses of type 2 diabetes; 3) glycated hemoglobin (A1C) levels of  $\geq 7.5$ % prior to randomization;

**Table 1**  
Diabetes health coaching intervention description, using the Template for Intervention Description and Replication (TIDieR)\*

Item	
Name	Brief name or phrase that describes the intervention. 1. Telephone-based diabetes health coaching
Why	Describe any rationale, theory or goal of the elements essential to the intervention. 2. The goal of this study was to evaluate the effects of an evidence-informed diabetes health-coaching intervention via telephone. The outcomes considered included: A1C, BMI, QoL (generic and diabetes), self-care activities, adherence to the intervention and cost-effectiveness.
What	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in the training of intervention providers. 3. Participants were provided with community-based resources to support diabetes self-care activities such as physical-activity programming. Participants were also provided with personal journals to record ideas, goals and interactions with the coaches. Finally, participants were provided with an outline of coaching sessions (1/week for 6 months and then 1/month for another 6 months). Participants were required to have access to or to have a telephone (land line or cellular). Procedures: Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities. 4. Participants were encouraged to connect with their coaches via telephone and voice-mail messages. If agreed-upon times for telephone interactions were missed, the diabetes health coach left up to 3 messages/phone calls to connect. No further attempts were made.
Who provided	For each category of intervention provider, describe their experiences, backgrounds and any specific training given. 5. The diabetes health coach is a graduation-prepared nurse and a certified diabetes educator trained in the Diabetes Health Coach model, behaviour design and motivational interviewing.
How	Describe the modes of delivery of the intervention and whether it was provided individually or in a group. 6. The intervention was provided exclusively via telephone to individuals.
Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. 7. All coach and participant interactions occurred remotely via telephone.
When and how much	Describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedules and their durations, intensities or dose. 8. The intervention was 1 year in duration, with 1/week telephone interactions for the first 6 months, followed by 1/month in the last 6 months. Each telephone interaction was aimed to be about 15 minutes in length.
Tailoring	If the intervention was planned to be personalized, titrated or adapted, then describe what, why, when and how. 9. Frequency (as identified in #8) was tailored to participants' needs as well as the duration (e.g. $\pm 5$ to 10 min). The topic of discussion for each telephone call was determined by the participant, specifically: 1) case management and monitoring; 2) self-management education; 3) psychosocial support; and 4) behaviour modification.
Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when and how). 10†
How well	Planned: If intervention adherence or fidelity was assessed, describe how and by whom and whether any strategies were used to maintain or improve fidelity; describe them. 11. Operational fidelity, as demonstrated by adherence to the coaching intervention, was defined as the proportion of participants who utilized the coaching as outlined (100% attendance to all sessions). Theoretic fidelity to the Diabetes Health Coach model was assessed through discussions and observations by the research coordinator and principal investigator. Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned. 12†

A1C, Glycated hemoglobin level; BMI, body mass index; QoL, quality of life.

\* See reference (41).

† Unable to complete for the purposes of this protocol paper.

4) ability to read, write and understand English and provide informed consent in English; and 5) have telephone access. A target of A1C levels of 7.5% or above was chosen to demonstrate effectiveness in those most in need of optimizing diabetes management. There was no maximum A1C level or threshold that excluded participants. The exclusion criteria consisted of 1) coaching not being appropriate (e.g. impaired cognition); 2) women who were pregnant at the time of recruitment; 3) people cohabiting with a participant in the study (to reduce contamination); and/or 4) having an underlying medical condition that may provide misleading A1C levels (e.g. hemoglobinopathy or chronic kidney disease).

### Design

The telephone-based diabetes health coaching intervention is outlined in Table 1, as per the Template for Intervention Description and Replication (TIDieR) checklist and guide (41). It was delivered to participants over 1 year, during which participants received access to the intervention once per week in the first 6 months and once per month in the last 6 months. Specifically, the diabetes health coaching intervention comprised an evidence-informed model of care that included: 1) case management and monitoring; 2) diabetes self-management education and support; 3) behaviour modification, goal setting and reinforcement; and 4) general psychosocial support. The diabetes coaching model

philosophy was to provide flexibility and personalization, recognizing that all 4 components are necessary for diabetes self-management and that each component may be required in different amounts and at different times, depending on each participant's circumstances, goals and needs. The diabetes health coach was a certified diabetes educator with training and experience in: 1) motivational interviewing; 2) behaviour modification; and 3) the diabetes coaching model (38). The intervention and control arm received access to usual diabetes education, offered in group and individual sessions at the diabetes education centre. All study participants had access to: 1) community resources for self-management tools (e.g. local physical activity programming); and 2) an accelerometer to monitor activity levels. This report presents the baseline demographic and biomedical characteristics of the study's participants.

### Randomization and outcomes

Eligible and consenting participants were randomized into 2 arms using a 1:1 ratio: 1) the intervention arm, which consisted of the diabetes health coach intervention along with usual diabetes education; or 2) the control arm, which consisted of usual diabetes education. A block randomization schedule was prepared by an independent statistician using a computer-generated random-number sequence. Randomization to the study groups was

**Table 2**  
Baseline demographic and clinical characteristics

	Entire cohort (N=365)
Age (years)	57.90 (11.78)
≤40	32 (8.77)
41–65	231 (63.29)
>65	102 (27.95)
Gender (female)	183 (50.14)
Race (white)	294 (80.55)
Age at diagnosis (years)	50.85 (12.22)
Diabetes duration (years)	8.69 (8.54)
BMI (kg/m <sup>2</sup> )	35.03 (8.07)
<25	22 (6.03)
25–30	80 (21.92)
>30	263 (72.05)
Weight (kg)	97.14 (22.52)
A1C (%)	8.98 (1.58)
Fasting blood glucose (mmol/L)	10.47 (3.41)
Total cholesterol (mmol/L)	4.40 (1.40)
TC/HDL ratio	4.16 (1.57)
DSCA (range: 0–7 days)	
General diet	4.76 (2.76)
Specific diet	4.97 (1.57)
Exercise	4.25 (2.61)
Blood-glucose testing	5.35 (2.34)
Foot care	2.92 (1.85)
ADDQoL	
Present QoL score (–3 to +3)	1.01 (0.97)
Diabetes-dependent QoL (–3 to +1)	–1.16 (1.07)
Average weighted impact score (19 items)	–1.47 (1.18)
EQ-VAS (range: 0–100)	67.30 (15.92)

ADDQoL, Audit of diabetes-dependent quality of life; A1C, glycated hemoglobin; BMI, body mass index; DSCA, diabetes self-care activities; EQ-VAS, European Quality of Life Visual Analogue Scale; QoL, quality of life; TC/HDL, total cholesterol/high-density lipoproteins.

Note: Data are mean (±SD) or n (%).

completed using sealed opaque envelopes, ensuring concealment of allocation.

All outcome measures were collected at baseline and at 6 and 12 months, and included: 1) A1C levels because they are responsive to changes in diabetes self-management, such as behaviour modification, self-efficacy and support as well as an accurate measure of glucose control; 2) body mass index (BMI); 3) diabetes self-care activities, including eating habits and physical activity; and 3) health-related quality of life. Process outcomes were also assessed. Adherence to the coaching intervention was defined as the proportion of participants who utilized the coaching as outlined (100% attendance at all sessions). Coach utilization was captured at each interaction by the amount of time spent by the diabetes health coach on: 1) case management; 2) self-management education and support; 3) behaviour modification/goal setting; and 4) psychosocial support, per participant, to determine individual component use or dosing of the coaching intervention.

Study assessments were completed by an on-site research assistant. All participants' A1C levels were taken from electronic medical health records or from the most responsible health-care provider as part of routine care and were aligned with study assessment by ±2 weeks. BMIs were determined after a weight assessment at each study visit, using a baseline height. Diabetes self-care behaviours were collected using the Diabetes Self-Care Activities measure, which is a questionnaire that assesses 7 aspects of diabetes self-management: general diet, specific diet, exercise, medication adherence, blood glucose monitoring, foot care and smoking behaviours (42). Disease-specific quality of life was measured using a self-administered, 18-item diabetes-specific Audit of Diabetes-Dependent Quality of Life instrument (43). Generic health-related quality of life was assessed using the European Quality of Life 5 Dimension Scale, which captures 5 domains: mobility, self-care, usual activities, pain/discomfort and anxiety/

depression (44), and the Visual Analogue Scale. All study assessment visits occurred at Langs Farm Village Association in Cambridge, Ontario.

### Statistical analyses

The data analysis of the primary and secondary outcomes used the intent-to-treat approach, in which all participants were included in their randomly assigned treatment groups. All analyses were done after the database was closed and without knowledge of allocated groups. Missing data were calculated using multiple imputations. Descriptive statistics present the data as means, standard deviations, frequencies and percentages, along with 95% confidence intervals. The primary outcome (the difference in the mean A1C level in the diabetes health-coaching program compared to the mean A1C level in the control group at 12 months) was assessed using a t test. Differences between mean baseline and 12-month BMI, DSCA, audit of diabetes-dependent quality of life (ADDQoL) and EuroQoL 5-dimension scale (EQ5D) scores were examined using t tests with 95% confidence intervals. In addition, A1C trends over time (e.g. baseline, 6 and 12 months) were analyzed using repeated measures analysis of covariance. Key covariates included self-reported length of type 2 diabetes diagnosis, age, sex, ethnicity, education, postal code (for socioeconomic status), baseline A1C levels, diabetes medication and coaching use. These data were also explored by calculating and comparing the proportions of people in each group who achieve and maintain A1C falls of 0.5%. Finally, regression methods were also used to explore the impact of explanatory variables (e.g. baseline demographic, participant characteristics and coaching utilization) on the effect of the intervention on A1C levels and secondary outcomes. Quality-adjusted life years for each treatment arm were based on utilities measured over the duration of the trial.

### Results

From May 2016 to December 2017, a total of 686 people were screened for the study; 365 participants consented and were randomized into the trial. Recruitment strategies that were employed and found to be effective from previous studies (37–39) included: 1) advertisement of the study with the Local Health Integration Network, which provides centralized referrals for diabetes programming in the region; 2) brochures and posters to referring primary care physicians, pharmacies and hospital-based diabetes programs in the region; 3) brochures, posters and presentations at the region's Diabetes Canada office and Diabetes Educator Section chapter meeting; and 4) a study information website.

The demographic and clinical characteristics are presented in Table 2. Participants were primarily female (50.14%) and self-identified as Caucasian (80.55%). At baseline, the mean age was 57.9 (11.78) years; the mean duration of diabetes was 8.69 (8.54) years; the mean A1C level was 8.98 (1.58) %; the mean BMI was 35.03 (8.07) kg/m<sup>2</sup>; and the mean European Quality of Life Visual Analogue Scale (EQ-VAS) score was 67.3 (15.92). In regard to clinical characteristics, participants were 50.85 (SD 12.22) years of age upon receiving type 2 diabetes diagnoses and lived with type 2 diabetes for an average of 8.69 years. Most participants (72.05%) had BMIs >30 kg/m<sup>2</sup>, with the total study sample having a mean BMI of 35.03 (8.07) kg/m<sup>2</sup> and weighing 97.14 (22.52) kg. Participants' mean A1C level was 8.98 (1.58) %; their mean fasting blood glucose level was 10.47 (3.14) mmol/L; their mean total cholesterol level was 4.40 (1.40) mmol/L; and their mean triglyceride/high-density lipoprotein ratio was 4.16 (1.57).

According to the DSCA measure, participants reported being on general and specific diets for 4.76 and 4.97 days, respectively. Further, participants reported exercising an average of 4.25 times in

the past 7 days and checking their blood glucose levels an average of 5.35 days in the past 7 days. For disease-related quality of life (EQ5D range:  $-3$  to  $+1$ ), participants reported their quality of life to be slightly worse; the mean score was  $-1.16$  (1.07) for diabetes-dependent quality of life, and the mean score was  $-1.47$  (1.18) for average weighted impact ADDQoL (19 items).

## Conclusions

The Diabetes Health Coaching study is a recently completed community-based trial examining the effect of telephone-based coaching for adults living with type 2 diabetes. The pragmatic inclusion of community-based adults across a broad geographic region (Waterloo Wellington) ensured diversity in diabetes duration, age, gender, self-management skills, medication/insulin use and race. The study is the first of its kind to assess telephone-based coaching over a 1-year period, using an evidence-informed coaching model.

Overall, the data obtained at baseline from participants randomized into the 2-arm Diabetes Health Coaching intervention trial indicates that the researchers successfully recruited a cohort comprising the target population of adults living with type 2 diabetes in Canada (i.e. adults 40 years of age or older who are overweight and have high cholesterol levels) (45). The Diabetes Health Coaching trial seeks to determine whether a novel health service intervention (i.e. diabetes health coaching) is able to improve A1C levels, BMIs, diabetes self-care activities, diabetes distress and quality of life in individuals living with type 2 diabetes in the community.

In summary, it is expected that the results of the Diabetes Health Coaching study will provide evidence regarding a low-cost intervention to support individuals living with type 2 diabetes and will help to inform future research and diabetes self-management education and support programming for the general population of Canadians with type 2 diabetes.

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## Author Disclosures

Conflicts of interest: None.

## Author Contributions

DS and SI prepared the draft manuscript, RMUA led the analysis. All authors reviewed and edited the manuscript.

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