Contemporary Clinical Trials 79 (2019) 104–110

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Study protocol and baseline sample characteristics: From clinic to community: Using peer support as a transition model for improving long-term diabetes-related health outcomes

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ARTICLE INFO

Keywords:
T2DM
Peer support
Diabetes self-management

ABSTRACT

Background: The objective of this randomized controlled trial is to examine the effects of a 12-month telephone-based peer-led diabetes self-management support (DSMS) intervention on long-term diabetes-related health outcomes.

Methods: In total, 197 participants with type 2 diabetes were recruited from specialty care settings (diabetes and endocrinology clinics). They were randomly assigned to 1) a 12-month Peer-Led, Empowerment-based Approach to Self-management Efforts in Diabetes (PLEASED) program where they received 12 weekly contacts from their peer supporter (PS) in the first 3 months, followed by 18 biweekly telephone support contacts over the last 9 months, or 2) usual care. The primary clinical and psychosocial outcomes were HbA1c and diabetes distress (DD), respectively. Secondary outcomes were cardiovascular risk factors. Assessments were conducted at baseline, 3 months, and 12 months.

Result: Of 197 recruited participants, 49.7% were female. The majority of participants were married/partnered, well-educated, employed, and Caucasian, with a mean HbA1c of 8.09 ± 1.7. Forty-two percent of participants reported little or no distress. There was no significant difference between the two groups.

Discussion: Despite evidence showing that individuals with poor glycemic control benefit the most from peer support interventions, the majority of such interventions have been designed for and implemented in community and primary care-based settings. The present study investigates a 12-month peer support model to help patients initiate and sustain effective self-management behaviors while transitioning from specialty care to a community setting. The study was completed in November 2018. The outcome data analyses are currently underway.

Trial registration: The study was registered on clinicaltrials.gov (NT02804620).

Protocol version: The protocol version is 3.5.

1. Introduction

1.1. Background and rationale

Based on 2015 statistics, the estimated prevalence of diabetes in Canada is 9.3% and is projected to increase by 44% by 2025 [1]. Effective diabetes self-management requires diabetes self-management education (DSME), followed by diabetes self-management support (DSMS) [2]. Although DSME is associated with improved clinical and psychosocial outcomes, these short-term gains diminish in < 6 months without ongoing support [3,4].

Considering the growing burden of diabetes and the time constraints on physician visits, our current health care system may not be equipped to provide the ongoing support that patients need [5]. To respond to these limitations, peer support, in which individuals with diabetes receive support from others with the same condition, is a promising approach [6–8].

A systematic review of 14 peer support trials in diabetes reported positive changes in patients' clinical and psychosocial outcomes [9]. While peer support interventions in general have been conducted in a

Abbreviations: PS, Peer Supporter; PST, Peer Supporter Training Program; Peer-Led, Empowerment-based Approach to Self-management Efforts in Diabetes (PLEASED)

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https://doi.org/10.1016/j.cct.2019.02.002
Received 22 October 2018; Received in revised form 1 February 2019; Accepted 6 February 2019
Available online 07 February 2019
1551-7144/

wide variety of locations, interventions within the health care system have predominantly targeted primary care settings [7,8,10]. Although the results from primary care–based peer support interventions are encouraging, individuals who present to primary care do not represent the patient population with the highest risk or greatest need. Rather, patients who present to specialty care clinics such as diabetes education centers are most likely to be newly diagnosed, in especially poor control, or have multiple and complex chronic conditions.

To our knowledge, three randomized controlled trials have investigated a peer support intervention in patients with type 2 diabetes recruited from specialty care settings [11–13], and none were in North America or Europe. To address this gap in the literature, our study investigates a peer support model for DSMS designed specifically to help patients initiate and sustain effective self-management behaviors while transitioning from a specialty care to a community setting.

1.2. Objectives

Objective 1: To examine the effect of a peer support intervention on improving glycemic control and diabetes distress at 3 months compared to usual care. Secondary outcomes include changes in blood pressure, apoB, self-care behaviors, dietary patterns, perceived social support, and depressive symptoms.

Hypothesis: Participants assigned to the 12-month peer support intervention will demonstrate significant improvements in glycemic control and diabetes distress at 3 months compared to participants assigned to usual care.

Objective 2: To examine the effect of a peer support intervention on sustaining at 12 months, improvements in glycemic control and diabetes distress achieved at 3 months compared to usual care. Secondary outcomes include changes in blood pressure, apoB, self-care behaviors, dietary patterns, perceived social support, and depression.

Hypothesis: Participants assigned to the 12-month peer support intervention will sustain, at 12 months, improvements in glycemic control and diabetes distress achieved at 3 compared to participants assigned to usual care.

Objective 3: To conduct a qualitative process evaluation identifying barriers and facilitators to intervention implementation as well as participants' perception, experience of, and satisfaction with the intervention.

1.3. Trial design

This two-phase study is a randomized controlled trial (RCT) comparing usual care to a 12-month peer-led DSMS intervention designed to improve long-term diabetes-related health outcomes.

2. Methods: participants, intervention, and outcomes

2.1. Study setting

The research study was conducted in a speciality setting.

2.2. Eligibility criteria

2.2.1. Peer supporters

To be eligible for the study, candidates had to [1] have diabetes, [2] be ≥21 years of age, [3] speak English, [4] have transportation to attend training, [5] be willing to commit to a 30-h training program, [6] have a landline telephone or mobile phone, and [7] have a self-reported HbA1c ≤ 8.0%.

2.2.2. Participants

To be eligible for the study, potential participants had to [1] have type 2 diabetes, [2] be ≥21 years of age, [3] speak English or any other languages spoken by his/her peer supporter, [4] be willing to be matched with a peer supporter, and [5] have a personal landline telephone or mobile phone.

2.3. Interventions

This study consisted of two phases. In Phase 1, we recruited adults with type 2 diabetes and implemented a 30-h peer supporter training (PST) program to equip trainees with the diabetes knowledge, facilitation strategies, behavior modification techniques, and communication skills to deliver a DSMS intervention. In Phase 2, we conducted a peer support intervention based on the Peer-Led, Empowerment-based Approach to Self-management Efforts in Diabetes (PLEASED) study [14]. Participants randomized to the PLEASED arm were paired with a peer supporter and received 12 weekly contacts (face-to-face and telephone support) from their peer supporter (PS) in the first 3 months, followed by 18 biweekly telephone support contacts over the last 9 months.

2.3.1. Study population and sites

This study was conducted at the Diabetes Education Centers (DECs) affiliated with Vancouver General Hospital, St. Paul's Hospital, Richmond Hospital, and Vancouver Coastal Health/North Shore Chronic Disease Services.

2.3.2. Peer supporter training and support

The PST, a 30-h peer supporter training program adapted from Tang et al.'s original 46-h PLEASED PST program [15], was designed to equip peer supporters with the knowledge, skills, and strategies to address 3 key components of peer support: [1] assistance in daily self-management, [2] social and emotional support, and [3] linkage to clinical care. PS candidates were trained to motivate participants to make positive lifestyle changes, use active listening skills, apply empowerment-based facilitation strategies, set goals, develop action plans, and solve problems. We employed formative (i.e., during the training) and summative (i.e., end of training) assessment approaches. To graduate, candidates had to achieve the pre-established competency criteria in five domains: [1] diabetes-related knowledge, [2] empowerment-based facilitation, [3] active listening, [4] goal setting and action planning, and [5] perceived self-efficacy. Upon successful graduation, peer supporters received a stipend of $400 to compensate for their time investment and parking fees.

2.3.3. Support

To ensure intervention fidelity, the research team followed up with the peer supporters periodically to address any issues they might have.

2.3.4. Intervention condition

Individuals randomized to the 12-month PLEASED intervention arm were matched with a PS. PSs and participants were paired on two major characteristics: gender and geographic proximity. In the first 3 months of PLEASED, the PSs made 12 weekly contacts with their “partner.” The first contact was face-to-face in the health care center, participant's home or at an agreed-upon community-based location (geographic proximity factor).

The remaining support contacts were conducted via telephone. In the last 9 months of PLEASED, PSs made 18 biweekly telephone support contacts to participants. The support contact followed a general structure: discuss recent self-management challenges; share feelings about these challenges; solve problems; address self-management questions; and set self-management goals. PSs helped participants apply the 5-step goal-setting model and develop action plans. PSs were prohibited from answering medical or clinical questions. PSs received a modest stipend

of $20 per participant, per month, over the 12-month period of the study.

2.3.5. Usual care

Individuals randomized to the usual care arm received all services normally available to them at the DECs, including access to an endocrinologis, nurse, dietician.

2.4. Outcomes

2.4.1. Primary outcomes

The change in HbA1c (%) was measured using venous puncture blood draw in the DEC. The change in diabetes distress was measured by the Diabetes Distress Scale (DDS), a 17-item instrument that assesses emotional distress and functioning specific to living with diabetes, with higher scores indicating higher levels of distress [16].

2.4.2. Secondary outcomes

ApoB was collected using venous puncture blood draw in the DEC. Blood Pressure was measured using an Omron® automatic blood pressure monitor (Model HEM-705CP). Height and weight were obtained by Seca stadiometer (Model 217) and digital scale (Model 874). Body mass index (BMI) was calculated as weight in kilograms divided by height in meters squared. Waist circumference was measured using the Seca ergonomic tape (Model 203).

Self-care behaviors were measured by items from the Summary of Diabetes Self-Care Assessment – Revised [17]. Dietary assessment was measured using the Block fruit and vegetable and fat screeners [18]. Perceived social support was measured using the Diabetes-Specific Social Support Scale [19]. Depressive symptom severity was assessed with the Patient Health Questionnaire-9 [20].

2.5. Participant timeline

Study timeline has been visualized in Fig. 1.

2.6. Sample size

In a trial of peer health coaching on glycemic control, Thom et al. observed a 6-month difference in mean HbA1c of 0.77% between the peer coaching and usual care groups [7]. After adjusting for age, marital status, work status, use of insulin, hypertension, and BMI, this difference was estimated to be 0.69%. The standard deviation of the 6-month difference was assumed to be 1.7% and common to both groups, consistent with similar studies [21].

Conservatively, these assumptions were made for the 12-month time point. The null hypothesis of no difference between the two groups in change in HbA1c from baseline to 6 months was tested using a 2-sided *t*-test with a 0.05 significance level. With the assumptions provided above, 190 subjects were necessary to have 80% power to detect a difference between the two groups. Accounting for a 20% attrition rate, the total sample size was calculated to be $n = 228$ participants. The same differences were also assumed for the outcomes at 12 months. Despite efforts to utilize different recruitment strategies across different sites, we were able to recruit 200 participants, of which three were excluded.

2.7. Recruitment

2.7.1. Peer supporter recruitment and selection

Fifty-two PSs were recruited between May 2015 and June 2017. Recruitment strategies included: [1] recommendations from Diabetes Education Center (DEC) staff, [2] flyers posted in the DECs and endocrinologists' offices affiliated with the three hospitals, [3] invitations sent to eligible patients identified from the endocrinologists' electronic medical records (EMR), [4] Vancouver Coastal Health Research Institute e-blast, [5] the Patient Voices Network newsletter, and [6] advertisements in local newspapers.

2.7.2. Participants recruitment and selection

In total, two hundred participants were recruited between August 2015 and September 2017 and three were excluded. Recruitment strategies included: [1] approaching patients who completed any diabetes education, including an 8-h diabetes course taught at a DEC or a 15-min doctor visit, [2] flyers posted in the DECs and endocrinologists' offices affiliated with the three hospitals, [3] referrals from health professionals and medical office assistants, [4] invitations sent to eligible patients identified from the endocrinologists' electronic medical records (EMR), and [5] Vancouver Coastal Health Research Institute newsletter.

3. Methods: assignment of intervention (for controlled trials)

3.1. Allocation

3.1.1. Sequence generation

The research team contacted potential participants via telephone and conducted eligibility screening. Candidates who met the inclusion criteria were invited to attend individual or group orientation sessions, during which details of the study were explained. Interested persons provided informed consent, enrolled into the study, and completed a baseline assessment. Participants were subsequently randomized to either the PLEASED intervention or the usual care arm. Random sequence generation and treatment group assignment were determined centrally following the orientation session.

3.1.2. Allocation concealment mechanism

Sequences were concealed until interventions were assigned. Randomization was conducted after baseline surveys and clinical measures.

3.2. Implementation

Computerized random sequence generation was used for the randomization portion. The randomization was completed by statisticians and enclosed in sealed envelopes based on sites of recruitment.

3.3. Blinding (masking)

The study was unblinded.

4. Methods: data collection, management, and analysis

4.1. Data collection methods

We collected baseline data from all participants immediately before the first PS-participant contact. Data were also collected at 3 and 12 months. The assessment battery included HbA1c, BP, apoB, BMI, diabetes distress, self-care behaviors, dietary patterns, perceived social support, and depressive symptoms. To offset transportation costs to the clinic and aid in retention efforts, we provided a subject incentive of $30 for PLEASED intervention participants and $50 for usual care group participants at each assessment.

Twenty-seven PLEASED intervention participants who completed the study were invited for semi-structured interviews (SSI). SSIs were audio-taped and transcribed verbatim for the purpose of qualitative analysis.

4.2. Data management

The research team periodically checked the collected data for missing information. If any information was missing, the participants

were contacted. We allocated a number to each participant and used their IDs throughout the study and data entry process. REDCap was used for data entry. Double data entry and merging were used to check for any discrepancy. The research coordinator randomly checked the entered data for accuracy.

4.3. Statistical methods

4.3.1. Quantitative analysis

The null hypothesis of no difference in change from baseline to 3- and 12-month HbA1c levels will be tested separately at each time point using a 2-sample, 2-sided *t*-test assuming equal variances. A similar hypothesis for changes in DDS score will be tested using a Mann-Whitney test. As secondary analyses of the primary outcomes, a longitudinal mixed-model will be fit using HbA1c and DDS scores at all time points, and a test for differences between randomized groups will be performed using a Wald test on the time-by-treatment interaction term to determine whether the trajectory of the outcome over time is affected by treatment. Higher-order terms may be included in the model as a simple adjustment for non-linear trajectories. In addition to the formal test, model-based estimates of 95% confidence interval will be calculated. There will be no adjustment made for the analyses at 3 and 12 months, as these will be tested as independent hypotheses.

For the primary analysis, an intent-to-treat framework will be followed; subjects will be analyzed in the arm to which they are randomized, and all randomized subjects will be included in the analysis. Multiple imputation methods will be utilized to enable use of the *t*-test for the primary analysis. A sensitivity analysis will be performed to confirm the result of both the primary analysis and the mixed model, and will include a best-worst case imputation and a complete-case analysis. In addition to the formal testing procedures described above, data visualization techniques will also be implemented, including longitudinal data plots and side-by-side boxplots.

Secondary outcomes will each be analyzed in a similar method to the primary outcomes, but with appropriate transformations to satisfy parametric models or non-parametric analyses. There will be no adjustment for multiple comparisons for secondary objectives. All demographic and baseline clinical characteristics and psychosocial and quality-of-life measures will be compared using *t*-tests or appropriate non-parametric tests.

4.3.2. Qualitative analysis

All semi-structured interviews were recorded and transcribed verbatim. Standard qualitative research analysis techniques will be used to generate themes from these transcripts. An initial list of codes will be generated based on the topics and research questions of interest. All substantive information will be assigned a code(s) as appropriate, and the initial code list will be refined as needed to fit the data. Final codes will be grouped conceptually into themes and subthemes. Qualitative analysis software (NVivo 10) will be used to facilitate this process.

4.4. Methods: monitoring

4.4.1. Data monitoring

We did not have any specific data-monitoring committee. However, the research team members were asked to review the data upon the completion of assessments for quality control purposes.

4.5. Harms

There was no study-related adverse event.

4.6. Auditing

Research team members randomly reviewed participants' folders to check the accuracy and completeness of the collected data.

5. Ethics and dissemination

5.1. Research ethics approval

The study was approved by the Clinical Research Ethics Board at the University of British Columbia (H14-02419).

5.2. Protocol amendments

We made amendments to the study to accelerate the participant-recruitment process. Among other changes, we sent invitation letters to eligible patients identified from the collaborating endocrinologists' electronic medical records, and we removed the HbA1c measure from the participants' eligibility criteria.

5.3. Consent or assent

In the orientation session, consent forms were offered to participants interested in the study. The research team members read the consent form aloud to the participants. Those who agreed to participate in the study were given a copy of the consent form.

5.4. Confidentiality

In order to fully respect participants' confidentiality, we used specific IDs for the purpose of anonymization. All folders are in a locked cabinet in the research team office. Lab results have been kept strictly confidential and are stored in a binder in a locked cabinet at the study site. Participants' folders are stored in a different locked cabinet at the same location. Participants' assessments and face-to-face sessions were held in private rooms to ensure their confidentiality. Only coded data will be shared with statisticians. Participants' identities were not, and will not be, disclosed under any circumstances without the participants' written permission.

5.5. Declaration of interest

There is no conflict of interest to report.

5.6. Access to data

The principle investigator, project coordinator, selected research assistants, and biostatistician have access to de-identified data. The coded data will be used for the purpose of analyses.

5.7. Ancillary and post-trial care

Not applicable.

5.8. Dissemination policy

The data analysis and interpretation, manuscript preparation, and submission of study papers to any journal will be under the supervision of the principal investigator. We expect to publish the primary outcome paper in 8–12 months. All other papers and abstracts will be submitted for publishing upon the approval of principal investigator. The results will also be shared with participants, collaborators, and the medical community, if interested.

6. Results

In total, 200 participants were recruited between August 2015 and September 2017. Three of the 200 were excluded, either for having a chronic condition that would have hindered their participation in the study or for being simultaneously enrolled in a different clinical intervention. One hundred patients and 97 patients were allocated to the

Table 1
Baseline characteristics of participants.

N	197
Age (years), mean ± SD	59.5 ± 11.2
Male/Female, n (%)	99/98 (50.3%/49.7%)
Diabetes duration (years), mean ± SD	11.7 ± 11.3
Marital status, n (%)	
Never married	48 (24.4%)
Married or partnered	98 (49.8%)
Separated/divorced/widowed	49 (24.9%)
Ethnicity, n (%)	
Indigenous	9 (4.6%)
Caucasian	101 (51.3%)
East Asian	30 (15.2%)
South Asian	21 (10.7%)
Southeast Asian	7 (3.6%)
Others	27 (13.8%)
Education, n (%)	
Less than high school	7 (3.6%)
High school degree	19 (9.6%)
University/college graduate	168 (85.3%)
Household income	
< $20,000	30 (15.2%)
$20,000 to $49,999	64 (32.6%)
$50,000 to $69,999	31 (15.7%)
> $70,000	50 (25.4%)
Employment status, n (%)	
Employed	87 (44.2%)
Retired	64 (32.5%)
PHQ-9 score, mean ± SD	6.1 ± 5.5
DDS score, n (%)	
Little or no distress	83 (42.1%)
Moderate distress	63 (32%)
High distress	46 (23.4%)
Anti-hyperglycemic medication, n (%)	
No medication	23 (11.7%)
Oral diabetes medication	153 (77.7%)
Insulin	84 (42.6%)
GLP-1 non-insulin injectable	18 (9.1%)
HbA1c, mean ± SD	8.09 ± 1.7
Apo-B, mean ± SD	0.84 ± 0.2
BMI, mean ± SD (metric)	31.0 ± 6.8
WC, mean ± SD	105.7 ± 15.2
SBP, mean ± SD (metric)	129.6 ± 18.8
DBP, mean ± SD	77.6 ± 12.4

WC: waist circumference (cm), SBP: systolic blood pressure (mmHg), DBP: diastolic blood pressure (mm Hg).

intervention and control groups, respectively.

Of the included participants, 49.7% were female. A majority were married/partnered, well-educated, employed, and Caucasian. In terms of clinical values and cardiovascular risk factors, 48.7% of participants were classified as obese, with mean HbA1c of 8.09 ± 1.7, mean apoB of 0.84 ± 0.2, and mean BP of 129.6 ± 18.8/77.6 ± 12.4. In the psychosocial measures, the majority of participants had little or no distress, while their mean PHQ-9 score was suggestive of mild depression [20]. There was no significant difference between the two groups at baseline.

The baseline characteristics of our study population are provided in Table 1. Table 2 compares the baseline characteristics of participants in both groups.

7. Discussion

Peer support interventions have been shown to be associated with favourable clinical and psychosocial outcomes. Despite evidence that patients with poor glycemic control benefit the most from peer support interventions, most peer support interventions have been designed for and implemented in community and primary-care settings, where patients tend to be in better control than those presenting to specialty care settings [22–24]. To date, only a few randomized controlled trials have been conducted in tertiary settings, where the patients are at the highest risk [11–13]. Accordingly, the objective of this study is to evaluate the impact of a 12-month telephone-based peer support model for DSMS on patients with T2DM in a tertiary care setting.

Table 2
Comparing the baseline characteristics of participants in the intervention group versus the control group.

	Intervention	Control
N	100	97
Age (years), mean ± SD	60.4 ± 11.4	58.6 ± 10.9
Male/female, n (%)	51/49 (51%/49%)	48/49 (49.5%/50.5%)
Diabetes duration (years), mean ± SD	12.3 ± 11.0	11.1 ± 11.5
Marital status, n (%)		
Never married	23 (23%)	25 (25.8%)
Married or partnered	52 (52%)	46 (47.5%)
Separated/divorced/widowed	24 (24%)	25 (25.7%)
Ethnicity, n (%)		
Indigenous	6 (6%)	3 (3.1%)
Caucasian	49 (49%)	52 (53.6%)
East Asian	10 (10%)	20 (20.6%)
South Asian	10 (10%)	11 (11.3%)
Southeast Asian	3 (3%)	4 (4.1%)
Others	20 (20%)	7 (7.2%)
Education, n (%)		
Less than high school	4 (4%)	3 (3.1%)
High school degree	10 (10%)	9 (9.3%)
University/college graduate	85 (85%)	83 (85.6%)
Household income		
< $20,000	15 (15%)	15 (15.5%)
$20,000 to $49,999	32 (32%)	32 (32.9%)
$50,000 to $69,999	10 (10%)	21 (21.6%)
> $70,000	32 (32%)	18 (18.6%)
Employment status, n (%)		
Employed	45 (45%)	42 (43.3%)
Retired	37 (37%)	27 (27.8%)
PHQ-9 score, mean ± SD	5.5 ± 5.2	6.7 ± 5.8
DDS score, n (%)		
Little or no distress	46 (46%)	37 (38.1%)
Moderate distress	33 (33%)	30 (30.9%)
High distress	17 (17%)	29 (29.9%)
Anti-hyperglycemic medication, n (%)		
No medication	13 (13%)	10 (10.3%)
Oral diabetes medication	75 (75%)	78 (80.4%)
Insulin	46 (46%)	38 (39.2%)
GLP-1 non-insulin injectable	14 (14%)	5 (5.2%)
HbA1c, mean ± SD	8.02 ± 1.81	8.17 ± 1.61
Apo-B, mean ± SD	0.82 ± 0.26	0.85 ± 0.23
BMI, mean ± SD (metric)	31.0 ± 6.7	31.0 ± 6.9
WC, mean ± SD	106.1 ± 16.1	105.2 ± 14.6
SBP, mean ± SD (metric)	133.7 ± 20.4	125.4 ± 15.9
DBP, mean ± SD	78.6 ± 12.4	76.6 ± 12.4

WC: waist circumference (cm), SBP: systolic blood pressure (mmHg), DBP: diastolic blood pressure (mmHg).

A few characteristics distinguish our study population from the populations of the two other tertiary care-based peer support interventions. Our population's mean age (59.5 ± 11.2), and number of years living with diabetes (11.7 ± 11.3) are both higher than in the other two studies [11,13]. Our study population's mean HbA1c (8.09 ± 1.7) is consistent with that of Chan et al.'s population [11]. However, based on the Diabetes Canada 2018 Clinical Practice Guidelines [25], our population's mean blood pressure (SBP: 129.6 ± 18.8; DBP: 77.6 ± 12.4) is within the acceptable range, while that of Chan et al.'s population (SBP: 136 ± 19; DBP: 80 ± 11) is not [11].

This study has a few limitations. First, we were unable to reach our calculated sample size in the recruitment period. This may affect our ability to detect significant differences between the two groups. Second, due to resource constraints, randomization was performed by the same personnel who conducted the assessments. Third, the participants were not allocated equally among peer supporters; the number per peer

supporter varied from 1 to 13. This may have resulted in the peer supporters with more participants allotting less time for each participant. Finally, to monitor intervention fidelity, we periodically conducted follow up contacts with peer supporters but not participants. This omission may have caused us to overestimate intervention dose.

What makes this study unique is that, to our knowledge, it is one of only a few at the international level and the first at the national level to evaluate the impact of peer support on diabetes self-management among patients with T2DM in a tertiary setting.

7.1. Trial status

The last 12-month assessment was conducted in November 2018. The data entry and merging were completed in January 2019. The outcome data and intervention dosage are under analyses. The primary outcomes manuscript is projected to be published by December 2019.

Funding

Diabetes Canada, VGH & UBC Hospital Foundation, and the Azad and Yasmin Shamji Family.

Appendix A. Appendix

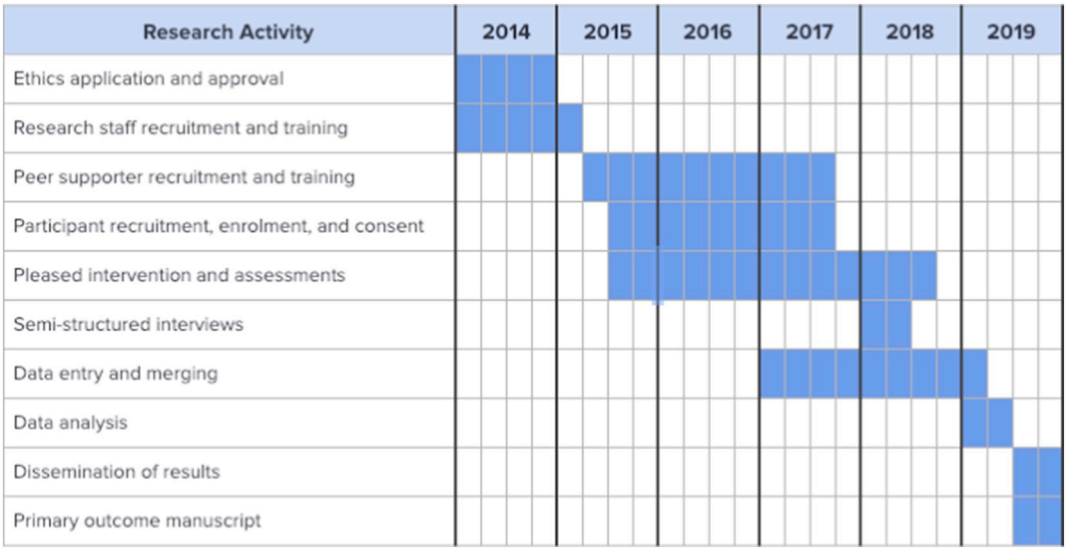

Fig. 1. Study timeline.

Role and responsibilities

T.T. contributed to study conception and design, study implementation, data analysis and interpretation, and manuscript preparation, and is the study guarantor. R.A. contributed to study implementation, data analysis and interpretation, and manuscript preparation. T.E., J.K., and S.G. contributed to study implementation.

Disclaimers

Dr. Tricia S. Tang has designed this existing study entirely based on her own views and is responsible for the content.

Source of support

Diabetes Canada, VGH & UBC Hospital Foundation, and the Azad and Yasmin Shamji Family.

Conflict of interest declaration

There is no conflict of interest to report.

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