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Supporting self-management in women with pre-existing diabetes in pregnancy: a protocol for a mixed-methods sequential comparative case study

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ABSTRACT

Introduction For women with pre-existing type 1 and type 2 diabetes, glycaemic targets are narrow during the preconception and prenatal periods to optimise pregnancy outcomes. Women aim to achieve glycaemic targets during pregnancy through the daily tasks of diabetes self-management. Diabetes self-management during pregnancy involves frequent self-monitoring of blood glucose and titration of insulin based on glucose measures and carbohydrate intake. Our objective is to explore how self-management and support experiences help explain glycaemic control among women with pre-existing diabetes in pregnancy.

Methods and analysis We will conduct a four-phased mixed-methods sequential comparative case study. Phase I will analyse the data from a prospective cohort study to determine the predictors of glycaemic control during pregnancy related to diabetes self-management among women with pre-existing diabetes. In phase II, we will use the results of the cohort analysis to develop data collection tools for phase III. Phase III will be a qualitative description study to understand women's diabetes education and support needs during pregnancy. In phase IV, we will integrate the results of phases I and III to generate unique cases representing the ways in which self-management and support experiences explain glycaemic control in pregnancy.

Ethics and dissemination The phase I cohort study received approval from our local ethics review board, the Hamilton Integrated Ethics Review Board. We will seek ethics approval for the phase III qualitative study prior to its commencement. Participants will provide informed consent before study enrolment. We plan to publish our results in peer-reviewed journals and present our findings to stakeholders at relevant conferences/symposia.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Mixed-methods sequential comparative case study designs facilitate the development of detailed and nuanced information.
⇒ However, the single-centre design of the cohort study will limit the generalisability of our findings.
⇒ The use of qualitative methods may further limit study generalisability.

INTRODUCTION

Pre-existing diabetes in pregnancy

There has been a rise over the past 20 years in the prevalence of pre-existing diabetes (type 1 or type 2 diabetes) in pregnancy. Currently, pre-existing diabetes affects approximately 1% or 4 000 000 pregnancies in the USA annually[1 2] Worldwide, other countries are also experiencing a similar phenomenon, contributing to what has been called the 'diabetes pandemic.'[3–8]

The increased occurrence of pre-existing diabetes in pregnancy presents a clear threat to maternal–child health. Compared with women without diabetes, infants of women with pre-existing diabetes have an increased risk of experiencing congenital anomalies and stillbirths, and infant death—relative risk (RR) 1.86 (95% CI 1.49 to 2.33) and RR 2.33 (95% CI 1.59 to 3.43), respectively.[3] Infants born to mothers with diabetes also experience increased postbirth complications, including macrosomia, respiratory distress and hypoglycaemia. For example, up to 60% of infants born to mothers with type 1 or type 2 diabetes may be macrocosmic[9]; respiratory distress syndrome is approximately twofold higher (OR 2.66 (95% CI 2.06 to 3.44)) among infants of mothers with pre-existing diabetes compared with infants of non-diabetic mothers[10]; and the occurrence of neonatal hypoglycaemia is approximately 27% among infants born to mothers with diabetes, compared with 3% in the background population.[11]

Role of diabetes self-management education and support

Research suggests that glycaemic management is associated with perinatal complications.[12] Thus, glycaemic targets are narrow

during the preconception and prenatal periods to optimise pregnancy outcomes.[13] Women with pre-existing diabetes in pregnancy achieve glycaemic targets through the daily tasks of diabetes self-management, which includes frequent self-monitoring of blood glucose and accurate titration of insulin doses to blood glucose measures and carbohydrate intake.[13] However, the evidence suggests that expectant mothers often struggle to meet recommended glycaemic targets. A large cohort study in the UK that followed women from conception to delivery found that only 14.3% of those with type 1 diabetes and 37.0% of those with type 2 diabetes met recommended glycaemic targets during early pregnancy (less than 13 weeks gestation).[14] Therefore, recent attention has focused on promoting diabetes self-management education and diabetes self-management support during pregnancy.

Diabetes self-management education focuses on individual goal setting, problem-solving and patient empowerment strategies. The intent is to ensure that patients have knowledge regarding their condition to sufficiently collaborate in decision-making with their healthcare providers and receive tailored care.[15 16] Clinical practice guidelines suggest that self-management support should augment education. Self-management support may include activities that reinforce and enhance education and behaviours. Support strategies include text messages, email reminders, automatic phone reminders, peer support and mobile health interventions, among others.[16] Specifically, such strategies aim to improve patient self-efficacy, confidence and one's ability to optimally self-manage diabetes. Among non-pregnant adults with diabetes, systematic reviews and meta-analyses indicate that self-management education and support interventions improve clinically important outcomes,[16] including improved glycaemic control and reduced diabetes complications, such as foot amputations.[17] Thus, diabetes self-management education and support may improve glycaemic control and other clinically important outcomes among women with diabetes in pregnancy. However, the existing research on diabetes self-management education and support in pregnancy is limited and primarily focused on gestational diabetes mellitus.[18]

Objective

Our objective is to explore how self-management and support experiences help explain glycaemic control among women with pre-existing diabetes in pregnancy.

METHODS AND ANALYSIS

Study design overview

We will conduct a four-phased mixed-methods sequential comparative case study. This mixed-methods design will begin with the analysis of collected quantitative data. A phase of qualitative data collection and analysis will follow the quantitative phase. The study will conclude by integrating the quantitative and qualitative findings to generate unique cases. The mixed-methods sequential comparative case design is ideal because we aim to develop detailed information about diabetes self-management among women with pre-existing diabetes during pregnancy. Furthermore, diabetes self-management during pregnancy varies based on diabetes type (type 1 or type 2). Thus, the mixed-methods sequential comparative case design will portray this variation in self-management in the form of constructed cases that can be compared and contrasted. Ultimately, it is our goal that the information from the generated cases will guide subsequent research in designing, evaluating and implementing self-management education and support interventions for women with pre-existing diabetes in pregnancy.

The research questions are threefold, as we will integrate the quantitative and qualitative data within the overall mixed-methods design.

1. Quantitative research question.
   a. What are the predictors of glycaemic control during pregnancy among women with pre-existing diabetes?
2. Qualitative research question
   a. What is the experience of managing diabetes during pregnancy?
   b. What are the diabetes self-management education and support needs during pregnancy among women with pre-existing diabetes?
3. Mixed-methods research question
   a. How do the self-management and support experiences of women with pre-existing diabetes in pregnancy help explain their glycaemic control?

Figure 1 provides a diagram depicting the study flow. Phase I will involve the analysis of data from a prospective cohort study to determine the predictors of glycaemic control during pregnancy related to diabetes self-management (eg, the level of self-efficacy) among women with pre-existing diabetes. Phase II will use the results of the cohort data analysis to inform the interview guide for phase III. Phase III will be a qualitative descriptive study to understand the diabetes education and support needs during pregnancy among women with pre-existing diabetes. Phase IV will integrate the results of phases I and III to generate unique cases representing the various ways in which self-management and support experiences explain glycaemic control in pregnancy.

Study phases I, II, III and IV

Study phase I: prospective cohort

Study design and setting

Phase I will involve the analysis of quantitative data collected as part of the 'Assessing the Determinants of Pregestational Diabetes in Pregnancy: A Prospective Cohort Study.' This study took place at the Maternal-Fetal Medicine clinic at McMaster University Medical Center in Ontario, Canada. Ethics approval was granted by the Hamilton Integrated Research Ethics Board (REB #14-222).

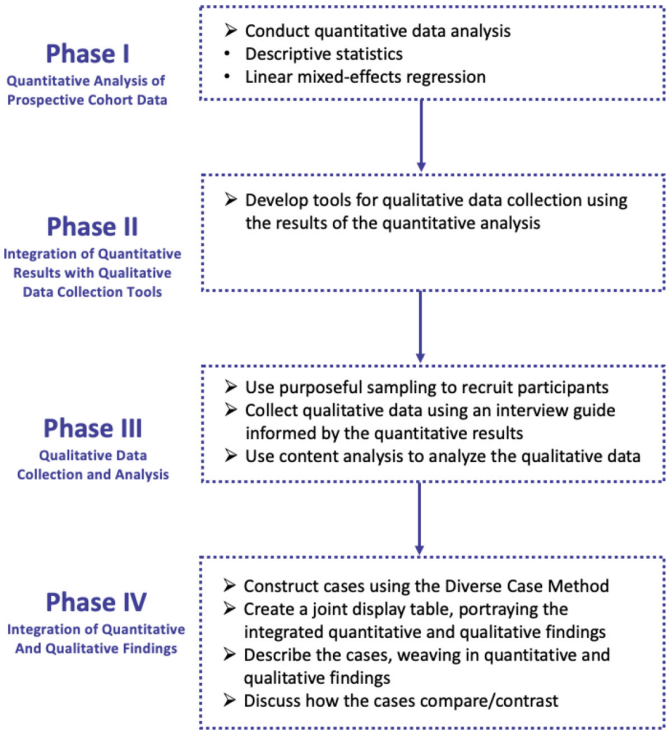

Figure 1 Provides a diagram depicting the study flow.

Participants and recruitment

Consecutive convenience sampling was employed to recruit eligible participants who met the following criteria: (1) a diagnosis of type 1 or type 2 diabetes; (2) attending the Maternal-Fetal Medicine clinic at McMaster University Medical Centre clinic for obstetrical care and (3) age 18 years or older.

Sample size calculation

The minimum required sample size was calculated by selecting the following options in G*Power: (1) test family, F tests; (2) statistical test, linear multiple regression: Fixed model, R2 deviation from zero and (3) type of power analysis, a priori: compute required sample size—given α, power and effect size.[19 20] The required sample size varied based on if Cohen's effect size was small, medium or large.[21] In a meta-analysis exploring the effect of nurse-led diabetes self-management education on A1C, Tshiananga *et al*[22] found that nurse-led diabetes self-management education had a medium effect on A1C. Therefore, using an alpha of 0.05, 80% power, a medium effect size of 0.15[21] and accounting for three predictors (self-efficacy, self-care and care satisfaction), the minimum required sample size is 77. A total of 111 women were recruited as part of the 'Assessing the Determinants of Pregestational Diabetes in Pregnancy: A Prospective Cohort Study.'

Data collection

Data collection occurred from April 2014 to November 2019. Data were collected three times during pregnancy, between 0 to 16 weeks (time point 1 (T1)); 17–28 weeks (time point 2 (T2)); and 29–40 weeks (time point 3 (T3)). Participants completed a demographic questionnaire, which inquired about characteristics such as age, ethnicity, marital status, household income, education level, living arrangements and employment status.

Participants also completed a survey to assess the following clinical characteristics:

- Current type of diabetes (type 1 or type 2).
- Gestational diabetes in a previous pregnancy.
- Duration of diabetes.
- Method of diabetes treatment (insulin pump or multiple daily injections).
- Daily frequency of self-monitoring of blood glucose.
- Status of insurance coverage for diabetes supplies.
- Gestational age.
- Gravida.
- Multiple or single gestation.
- Use of assistive reproductive technology.

Glycaemic control was assessed through participant self-report of A1C at each time point. The self-reported values were confirmed with the medical chart.

Self-efficacy was measured using an eight-item Likert scale called the Self-Efficacy for Diabetes scale.[23] Participants rated their confidence in activities, such as knowing what to do when their blood glucose is higher or lower than the target. Responses ranged from 1 to 10 (not at all confident to totally confident). The total score is the mean of the eight-item responses, with a maximum score of 10. A higher score indicates higher self-efficacy in diabetes management.[23]

Self-care was assessed using the Summary of Diabetes Self-Care Activities Measure.[24] Eleven questions over four categories asked participants to indicate how many days in the last week they performed a variety of self-care behaviours. The scale sections included diet, exercise, blood glucose testing and foot care. The scores from each subsection are averaged create a total score, with a maximum score of 7. A greater frequency of performed activities indicates better self-management and adherence to treatment.[24]

Care satisfaction was assessed using the Patient Assessment of Care for Chronic Conditions scale.[25] This scale measured the degree to which a patient perceived that their medical care was congruent with the Chronic Care Model.[25] The Chronic Care Model involves optimising the following components—healthcare organisation, delivery system design, clinical information systems, decision-support, self-management support and community resources.[25] This tool had 20 items that asked participants to quantify the care they received from their healthcare team over the past 6 months. Participants indicated how often they were given choices about treatment or asked to talk about their treatment goals. Responses ranged from none of the time (1 point) to always (five points). There were five subscales: Patient Activation, Delivery System Design/Decision Support, Goal Setting, Problem-Solving/Contextual Counselling and Follow-up/Coordination. The overall score is an average of the combined subscale scores, with a maximum score of five. Higher

scores indicate that the patient is receiving care congruent with the chronic care model.[25]

Data analysis

We will conduct descriptive statistics to understand the distribution of participant demographic and clinical characteristics, and participant levels of self-efficacy, self-care and care satisfaction. We plan to explore differences in variable distribution, stratified by diabetes type. We will use linear mixed-effects modelling to explore trends in glycaemic control and examine self-efficacy, self-care and care satisfaction as predictors of A1C. To control for potential confounding factors on the relationship between self-efficacy, self-care, care satisfaction and glycaemic control, we will adjust for participant age, diabetes duration, ethnicity, education level, household income and insurance coverage. The decision to control for these factors was based on the knowledge that they may be independently associated with both the proposed independent variables (self-efficacy, self-care and care satisfaction) and dependent variables (A1C), making them potential confounders of any association between the independent and dependent variables. For example, evidence indicates that diabetes duration is associated with self-efficacy[26] and glycaemic control among non-pregnant adults with type 2 diabetes.[27]

Study phase II: planning the qualitative data collection

In phase II, we will use the results of the quantitative data analysis, which aims to determine the predictors of glycaemic control during pregnancy for women with pre-existing diabetes, to develop the interview guide for phase III. Using the quantitative results to inform the qualitative interviews will allow us to focus on areas of the quantitative results that require further exploration.

Study phase III: qualitative description

Study design and setting

We will use a qualitative description design for Phase III. Fundamental qualitative description allows researchers to gather rich narrations from participants regarding the phenomenon of interest.[28] The Consolidated Criteria for Reporting Qualitative Studies will be used to guide the reporting of the phase III.[29]

Albert Bandura's Theory of Self-Efficacy will be used as a framework to guide this study phase. The Theory of Self-Efficacy proposes that individuals can exercise control over their behaviour.[30] Two integral concepts of the Theory of Self-Efficacy include efficacy expectations and outcome expectations. Bandura describes efficacy expectations as a person's judgement in their ability to complete a certain task. On the other hand, outcomes expectations represent what a person thinks will occur as a result of successfully completing a task.[31] Bandura further outlines that personal efficacy is derived from four sources: performance accomplishments, vicarious experiences, verbal persuasion and physiological state.[31] Performance accomplishments represent a person's past experiences, both positive and negative, of performing the targeted behaviour. This is the source that has the most influence on the development of personal efficacy. High or low personal efficacy is also developed vicariously through viewing someone else performing the desired behaviour. Verbal persuasion—encouragement from another person—as well as the physiological state—a person's bodily sensation in response to a stressful situation—also influence a person's confidence in their capabilities. These sources of information come together to shape a person's perceived ability to accomplish a task.[31] Supporting patients to engage in healthy behaviours to the best of one's ability presents a challenge for healthcare providers, even for diseases that can be self-managed, such as diabetes.[32] Therefore, the notion of self-efficacy within an understanding of the impact of the social determinants of health is key, for it strongly influences the initiation and maintenance of behaviour change, a component essential in chronic disease management.[33] Arguably, understanding one's self-efficacy is paramount for women with pre-existing in pregnancy, as there is a limited window of time within which self-management education and support can be provided to optimise diabetes-related and pregnancy-related outcomes.

Participants and recruitment

We will use the principles of purposeful sampling to recruitment women aged 18 years or older, with type 1 and type 2 diabetes, who are currently or who were previously pregnant. These women will participate in individual semi-structured interviews to describe their experience of managing diabetes and determine their needs regarding diabetes self-management education and support during pregnancy. Additional sampling strategies such as snowball sampling and theoretical sampling, in which initial data analysis guides future recruitment to explore emerging themes, will also be used.[34] The guidelines regarding sample sizes in fundamental qualitative description studies focus on recruiting an adequate number of participants to generate descriptions of the phenomenon of interest.[35] Sample sizes are usually small to facilitate in-depth exploration of participant descriptions.[35] For qualitative description studies that employ individual interviews, sample sizes are typically in the range of eight to 20 participants.[35] The sample size for this study will be between 10 and 20 participants. Data saturation will guide the completion of recruitment and data collection.[35]

Data collection

Interviews provide first-hand knowledge regarding participant experiences.[36] As such, individual interviews will be the primary means of data collection. A literature review and the phase I study results will inform the development of the semi-structured interview guide. The interviews will be conducted face to face via videoconferencing (Zoom, WebEx, Skype or Microsoft Teams) or by telephone and will have an approximate duration of 30–60 min. All

interviews will be audiorecorded. The primary researcher (KS) will conduct all interviews to maintain consistency. Several pilot interviews will be completed with the first few recruited participants to evaluate the appropriateness of the interview guide. The interview questions may be modified based on the pilot interviews.[37] Questions may also be added or removed as the number of interviews progresses, depending on emerging themes and content. We will collect baseline demographic and clinical characteristics before the interview and write supplementary field notes immediately after. We will also verbally summarise the interview with the participants and ask them to confirm or expand on the summary as a way of member checking.[38]

Data analysis

Following the completion of the interviews, the recorded audio will be transcribed verbatim and imported into NVivo (NVivo. QSR International ; 2020) for analysis. The goal of data analysis in qualitative description is to elicit the participant's viewpoint regarding the phenomenon of interest and remain close to the surface of the data.[35] Therefore, we will employ conventional content analyses, as described by Hsieh and Shannon.[39] This method of analysis is appropriate for studies with the aim of description because it allows codes and categories to be derived directly from the data rather than from preconceived ideas informed by existing literature or theories.[39] Content analysis in this study will begin with repeated reading of interview transcripts to facilitate immersion in the data. We will then identify codes through a line-by-line review and highlight relevant concepts. Simultaneous note-taking and reflection on initial impressions will allow code labelling derived from the interview text. We will then group related codes into 10–15 categories and develop definitions for each.[39]

Study phase IV: integration of quantitative and qualitative findings and case construction

The purpose of the mixed-methods procedures will be to integrate the quantitative and qualitative data to develop a deep description and analysis of diabetes self-management in women with type 1 and type 2 diabetes during pregnancy. The recommendations by Creswell and Clark for integration procedures will guide our mixing process.[40]

The mixed-methods integration will occur following the completion of the qualitative study when the results of the cohort data analysis and the qualitative interview findings are combined to construct cases. We will integrate the quantitative and qualitative data following their separate analyses through data displays and the development of meta-inferences.[40] The Diverse Case Method[41] will be used to construct cases that describe how diabetes self-management and support experiences explain glycaemic control in pregnancy. For categorical variables, such as diabetes type, we will construct cases for each category. For example, we will select participant groups with type 1 diabetes and good and poor glycaemic control and participant groups with type 2 diabetes and good and poor glycaemic control to assemble cases. For continuous variables, such as self-efficacy score, we will create cases using high compared with low values of the variable. For example, we will choose participant groups with high compared with low levels of self-efficacy and examine differences in their glycaemic control. Supporting data will then be selected from the qualitative interview results to contextualise and complete case construction.

Displaying the data will be done in several ways to link the quantitative and qualitative phases. We will represent the points of integration in two ways. First, we will develop a statistics-by-theme joint-display table to present the cases constructed from the quantitative and qualitative data.[40] The joint display will depict the quantitative results alongside the qualitative themes to portray the results of the mixed-methods integration.[40] Second, we will mix the data in our write-up of the study results by using an approach that weaves together quantitative statistics with narrative themes.

DISCUSSION

This study will use a mixed-methods design to provide a comprehensive understanding of how self-management and support experiences influence glycaemic control for women with diabetes in pregnancy. Specifically, a better understanding will be gained of the following: the prevalence and correlates of self-management support and glycaemic control in women with pre-existing diabetes in pregnancy; and the self-management experience of women with pre-existing diabetes in pregnancy.

This study will also lay the groundwork for future research that could include collecting further quantitative data to confirm the results—locally, regionally, provincially and nationally. The study results also have the potential to inform medical care for high-risk patients with pre-existing diabetes during the critical finite, intensive period of pregnancy. However, this study also has limitations. Specifically, the single-centre design of the cohort study and the use of qualitative methods will limit the generalisability of our findings. In addition, our study is subject to biases inherent in self-report data, such as recall bias. In an attempt to address recall bias, we have made the recall period short (6 months or less), are studying participants with a chronic disease and made the duration of the study relatively short (over the 9 months of pregnancy), all factors known to be related to impact recall bias.[42]

PATIENT AND PUBLIC INVOLVEMENT

Patients and the public were not involved in the protocol design. We plan to make study results available to participants on request. We also plan to use the results of this study to provide the basis for the development, evaluation and implementation of a patient-centred intervention

based on the constructed cases to inform models of self-management education and support including the use of technology, peer support and health coaching interventions, among others.

Contributors The study concept and design and plans for data collection and analysis were conceptualised by KS and DS with support from KN, PHS and MB. The manuscript was drafted by KS and DS, KN, PHS and MB contributed to its critical revision. All authors have reviewed and approved the final manuscript.

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