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Stress and Coping in Adults with Type 2 Diabetes Who Initiate Insulin Therapy

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Graduate Program in Nursing
A thesis submitted in partial fulfillment of the requirements for the degree in Doctor of Philosophy
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STRESS AND COPING IN ADULTS WITH TYPE 2 DIABETES WHO INITIATE
INSULIN THERAPY

Thesis format: Integrated Article

by

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Graduate Program Arthur Labatt Family School of Nursing

A thesis submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy

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Abstract

Type 2 diabetes affects 90% of people who live with this chronic disease. A primary goal of healthcare professionals is to assist patients with Type 2 diabetes to achieve optimal glycemic control to prevent the devastating complications of this disease. Research has demonstrated that optimal glycemic control can minimize or prevent macrovascular complications such as heart attack or stroke and the microvascular complications of retinopathy, nephropathy, and neuropathy. Historically insulin has been one of the last agents to be added in type 2 diabetes despite its efficacy and long term treatment data. Reluctance by both patients and clinicians to add insulin to treatment regimens, a phenomenon known as psychological insulin resistance, remains an issue. The perception of stress and ways of coping in participants who were initiating insulin therapy were examined in this research. The relationship between participants' stress and the education they received was also examined. The education provided was based upon a Registered Nurses Association of Ontario (RNAO) Best Practice Guideline (BPG).

In a pretest / posttest design, participants (N = 105) who were seen at a Diabetes Education Centre for initiation of insulin therapy were surveyed prior to receiving insulin initiation education and six weeks following the initiation of their insulin therapy. Three surveys were completed, the Perceived Stress Scale, Ways of Coping Questionnaire, and The Confidence in Administering Insulin and Managing Diet Scale at the pre/post timepoints. A BPG evaluation tool was also completed during the posttest appointment. A mediated regression analysis demonstrated coping to be a mediator of the relationship between stress and insulin self-efficacy. There was a statistically significant decrease in participants' stress and a statistically significant increase in insulin self-efficacy. Analysis of the BPG evaluation tool demonstrated that 80% of the BPG content was recalled by participants. This study provided evidence that the needs of these patients can be met with structured education through the use of a Best Practice Guideline and the assessment of patient stress and coping can improve patient self-efficacy with insulin therapy and decrease their stress burden.

Keywords

Type 2 diabetes, insulin initiation, stress, coping, best practice guidelines, Registered Nurses Association of Ontario, psychological insulin resistance, education

Co-Authorship Statement

The integrity of this dissertation as one completed document was the responsibility of Maureen Loft. She was the primary researcher and completed initial analysis and drafting of the articles. The following co-authors provided substantial intellectual contributions to the study design, interpretation, analysis, and drafting of the 3 articles for publications. Each co-author critiqued and provided revisions prior to final approval of each article.

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Dedication

This dissertation is in loving memory of my grandfather, Ronald Leslie Lee and my parents-in-law, Betty and Arthur Loft, who I think would have been proud of my accomplishment.

I also dedicate this work in memory of Dr. Susan L. Ray from the School of Nursing, who began this journey with me and whose spirit I feel is with me as I complete the work that she helped me to begin.

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Chapter 1

1. Introduction

This chapter provides the foundation for the development of the research presented in this dissertation. It begins with the research questions that were examined, articulates the elements of this integrated thesis, and concludes with an executive summary of the dissertation.

1.1 Background

Evidence regarding the earliest awareness of diabetes dates back to 1552 BC with the description by an Egyptian physician of the “passing of too much urine” (Canadian Diabetes Association, 2013c). Today as diabetes continues to increase throughout the world, particularly Type 2 diabetes, a person dies every 6 seconds from this chronic disease (International Diabetes Federation, 2013). In Canada, approximately 2.6 million Canadians are living with diabetes (Public Health Agency of Canada, 2011). Although diabetes care continues to evolve and the number of pharmacologic agents used to treat diabetes has expanded greatly, the reality is that approximately half of Canadians living with type 2 diabetes do not achieve the recommended clinical practice guideline targets for glycemic control (Harris, Kapor, Lank, Willan, & Houston, 2010a; Leiter et al., 2013a).

Achieving optimal blood glucose control is critical in diabetes to minimize the devastating complications of this disease. Persons living with diabetes have mortality rates at least two times higher than those without diabetes (Public Health Agency of Canada, 2011a). The risk of macrovascular complications such as heart attack, stroke or microvascular complications such as renal failure, retinopathy, and neuropathy are all increased in the presence of diabetes. The importance of glycemic control was demonstrated in the landmark research of the United Kingdom Prospective Diabetes Study (UKPDS) which examined and established the standards for blood glucose control in Type 2 diabetes (1998). Study findings revealed a 12% lower risk of developing any diabetes-related endpoints with substantial risk-reduction in microvascular complications for patients in the intensive glucose group compared to patients in the control group. The findings became the foundation for developing the standard of care for diabetes clinical management.

The reasons for not achieving target blood glucose control are complex, multifactorial, and must take into consideration both the pathophysiologic and psychological elements of living with diabetes. As a nurse practitioner, my clinical practice has included many patients who have struggled with their diabetes self-management. The need to add insulin to a therapeutic regimen has often resulted in anxiety for patients and has frequently been met with resistance or refusal. This study was an important way for me to fulfill my professional commitment as a researcher and educator to add to the diabetes research findings. The results provide new knowledge regarding the education and initiation of insulin therapy in adult patients with Type 2 diabetes.

1.2 Significance

As members of the interprofessional diabetes team, nurses play a key role in the education of people living with diabetes. The majority of diabetes care originates in the primary care setting with the focus on enhancing diabetes self-management skills (Clement, Harvey, Rabi, Roscoe, & Sherifali, 2013). The role of the nurse in out-patient diabetes care has a strong focus on education and assisting patients to develop effective self-management behaviours. In a meta-analysis of the effectiveness of structured care to improve the management of patients with diabetes, Renders (2001) found that enhancing the role of the nurse led to improvements in patient outcomes and process of care. Nurses are frequently involved with medication management and have been shown to assist with improving glycemic control (Barr-Taylor et al., 2003; Hearnshaw et al., 2006; The California Medi-Cal Type 2 Diabetes Study., 2004; Wens et al., 2008). With the recognition that nursing care must be evidenced-based, the use of best practice guidelines (BPG) provides the synthesis of research and clinical expertise required to support the highest caliber of nursing care. Utilizing and evaluating BPGs are integral to effective and efficient nursing care.

1.3 Research Purpose and Questions

The purpose of this research was to examine the relationships between perceived stress and ways of coping of patients with Type 2 diabetes who began insulin therapy and received diabetes education guided by the Registered Nurses Association of Ontario (RNAO) Best Practice Guideline (BPG) for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes (2009). The research questions were:

1. What is the relationship between perceived stress and diabetes education guided by the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes who initiate insulin therapy?
2. What is the relationship between perceived stress, ways of coping in adult patients and the initiation of insulin therapy in adults with Type 2 diabetes?
3. What is the level of participant recall of diabetes education using the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes as evaluated by a novel BPG evaluation tool?
4. What is the patient experience of initiating insulin therapy when receiving structured Best Practice Guideline diabetes education?"

The research findings for question #1 and question #2 are discussed in chapter 3, "Coping as a Mediator of Stress with the Initiation of Insulin in Type 2 Diabetes". Chapter 4, "Evaluating the Use of a Best Practice Guideline with Insulin Initiation in Type 2 Diabetes" presents findings for questions #3 and #4.

1.4 Research Approach

The theory to frame this study was Lazarus and Folkman's (1984) cognitive theory of stress and coping. The theory provides a framework for examining psychological stress and holds that stress is contextual, an interaction between the person and his/her environment. Folkman (1997) further revised the model to include positive psychological states. As defined by Lazarus and Folkman, stress is "a relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being" (Lazarus & Folkman, 1984, p. 21). Stress is not considered to be static and is purported to change over time as a result of interaction between the individual and their environment.

The definition of coping depends on the theoretical framework or context in which coping is identified. Coping is described as a dynamic system which is highly interactive (Folkman, 2010). Coping varies amongst individuals based on the "intensity of their emotion response and their ability to regulate it, the opportunities inherent in the situation for problem solving, and changes in the person-environment relationship as the situation unfolds" (Folkman & Greer, 2000, p. 13). This statement regarding coping is consistent with Bandura's conceptualization of

coping, his view being that a person's beliefs in their coping capabilities can affect the level of stress experienced in threatening or difficult situations (1994).

The hypothesized relationships between the study variables: RNAO BPG education, stress, coping, and self-efficacy with initiation of insulin therapy are illustrated in Figure 1.

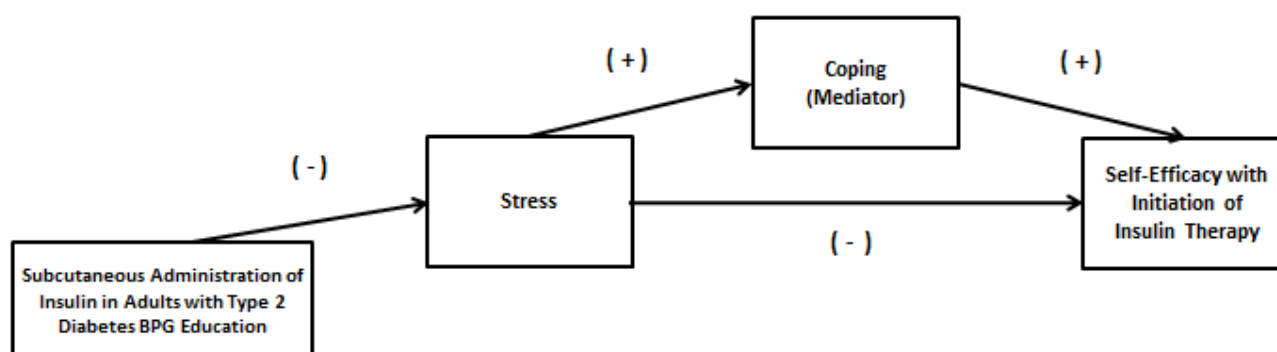


Figure 1 Hypothesized model of the relationships between RNAO BPG education, stress, and self-efficacy with initiation of insulin therapy
 Negative relationship (-) Positive relationship (+)

1.5 Method

A pretest / posttest, non-experimental design was undertaken using one group of participants. Participants were insulin and injection therapy naïve. Convenience sampling was used to obtain a final sample size of 105, calculated to provide a medium effect size of 0.15, an alpha error probability of 0.05 and a power calculation of 0.80 assuming a 10% withdrawal or failure to complete study rate. Participants' stress scores were measured with the following validated tools: Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983). Coping (ways of coping) was measured with the WAYS questionnaire (Folkman & Lazarus, 1988). The Confidence in Administering Insulin-Managing Diet Scale questionnaire developed specifically for use with the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes was utilized to measure participants' insulin therapy self-efficacy (B. Davies et al., 2006). A BPG evaluation tool developed by the author for this study measured participants' recall of the BPG contents. Participants were surveyed just prior to beginning insulin therapy and then approximately six weeks following initiation of insulin therapy at scheduled appointments at a Diabetes Education Centre (DEC).

Descriptive and inferential analyses were performed using the IBM SPSS Statistics v. 22 (IBM., 2013). Paired-samples t-tests and a mediated regression analysis were undertaken to answer the research questions. Content analysis was utilized to examine qualitative data obtained from the BGP evaluation tool.

1.6 Integrated Thesis Article Format

This dissertation is structured in the integrated article format as regulated by the School of Graduate and Postdoctoral Studies at Western University, London, Ontario. Chapter 1 provides an introduction of the foundations for the dissertation research. Chapters 2, 3, and 4 are independent, original articles submitted for publication in peer-reviewed journals relevant to the content of each article. Chapter 5 provides an integrated summary of the dissertation work.

Chapter 2, ‘Stress and Coping in Patients with Type 2 Diabetes Initiating Insulin: A Scoping Review’

This is the first of three articles for publication. This scoping review was undertaken to map the literature, sources of evidence, and gaps in the published research related to stress and coping when patients initiate insulin therapy. Literature between 2001 and 2013 was reviewed. Policy mapping was included within the scoping review to identify documents and statements from professional bodies that influence the nature of practice within the speciality of diabetes. Additionally policy mapping was done to identify educational strategies currently in place and offer direction for future educational strategies. The selection process of identifying relevant studies resulted in nine items that most closely aligned with the research questions and nine documents that related to the policy mapping.

Two themes emerged from the scoping review (a) insulin initiation barriers and (b) coping. The findings reinforced the importance of the psychological aspect of diabetes care which can be critical for successful self-management of diabetes especially for patients requiring insulin therapy. The policy mapping identified comprehensive evidence-based clinical practice guidelines and policy frameworks available as resources for diabetes care. More importantly, there was increasing evidence of integration and recognition of the psychological elements of diabetes care into these resources.

Chapter 3, 'Coping as a Mediator of Stress with the Initiation of Insulin in Type 2 Diabetes'

The second article presents the results of the data analysis of the study variables perceived stress, ways of coping, and insulin initiation self-efficacy. A final sample was obtained from three independent Diabetes Education Centres (N = 105). For research question #1, What is the relationship between perceived stress and education guided by the RNAO BPG for Subcutaneous Administration of Insulin in Adult Patients with Type 2 Diabetes?, there was a statistically significant ($p < 0.05$) decrease in the pretest to posttest scores for perceived stress and increase in scores for insulin self-efficacy. Results showed that patient stress decreased and insulin self-efficacy increased after receiving the RNAO BPG insulin initiation education.

Question #2, What is the relationship between perceived stress, ways of coping and the initiation of insulin therapy in adults with type 2 diabetes? This question was analyzed using mediated regression and correlations. The correlational analysis revealed a moderately positive correlation between stress and coping and a weak, inverse correlation between stress and insulin initiation self-efficacy. The relationship between coping and insulin initiation self-efficacy was non-significant.

The mediated regression analysis examined the relationship between perceived stress and insulin initiation self-efficacy with coping as a mediator. A bias-corrected bootstrap estimate of the 95% confidence interval for the indirect effect of coping indicated that coping was a mediator of the relationship between perceived stress and insulin initiation self-efficacy.

The results of this study suggested assessment of stress and coping would be beneficial for patients initiating insulin therapy. The RNAO BPG can be used by diabetes clinicians to initiate insulin therapy with structured education assisting patients to attain self-efficacy with insulin therapy with a decrease in their stress levels.

Chapter 4, 'Evaluating the Use of a Best Practice Guideline with Insulin Initiation in Type 2 Diabetes'

The third article of this dissertation discusses patient recall of diabetes education with the use of the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes

and an evaluation tool that was developed for use with this BPG. Best Practice Guidelines are becoming increasingly integrated into nursing care and provide a synthesis of research and clinical expertise. Results are presented for Question #3, What is the level of participant recall of diabetes education using the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes as evaluated by a novel BPG evaluation tool? and Question #4, What is the patient experience of initiating insulin therapy when receiving structured Best Practice Guideline diabetes education?

The results of this study demonstrated effective provision of the RNAO BPG with participants recalling 80% of the BPG content. Sick day management items, however, had a noticeably lower rate of recall at 27% – 62%. This is an area for further research as the potential for significant patient harm can result during illness, for example, with poorly managed insulin dosing or if patients become severely dehydrated. Lack of knowledge to self-manage routine illnesses may require patients to seek intervention from their primary care provider or in severe cases patients may need to access urgent care or emergency room assessment which has implications within the context of today's fiscally challenged healthcare environment.

The RNAO BPG evaluation tool developed for this study required the deletion of one item to yield a measurement scale with an acceptable internal consistency i.e. a Cronbach's alpha of greater than or equal to 0.70.

Content analysis performed on participant responses to three open-ended questions: 1. "Please describe how you felt when you were asked to start using insulin", 2. "What was the most challenging thing about starting insulin?", and 3. "What made it easier to start using insulin?" revealed three distinct categories of responses. Consistent with the literature were responses related to the first category labeled as Psychological Insulin Resistance (PIR). Participant responses identified the emotional elements related to insulin initiation such as fear of needles or injection, anxiety, or a belief that their diabetes is worsening. The second category was labeled Knowledge Deficit and reflected participants' misconceptions of current diabetes management. This has also been identified in the literature. The last category was labeled Education Impact. Responses in this category supported the positive impact of the education they received which was guided by the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes.

1.7 Summary

The final chapter presented in the thesis is an integrated summary of the research findings as identified in the three articles included in this dissertation. The examination of the relationship between perceived stress and education guided by the RNAO BPG is reviewed. The need for further research into the psychological assessment of patients initiating insulin therapy is discussed. The development and utilization of the RNAO BPG evaluation tool are examined to assist with further revision of the tool for future use. The results of the examination of the relationship between perceived stress, ways of coping and insulin initiation self-efficacy provide a foundation for continuing research to explore coping and stress in patients initiating insulin therapy. The discussion includes patient focused assessment and exploration of educational strategies that best meet the needs of this unique patient population. Implications for nursing and future research are reviewed.

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Chapter 2

2 Stress and Coping in Patients with Type 2 Diabetes

Initiating Insulin: A scoping review

2.1 Introduction

The global burden and incidence of type 2 diabetes is increasing precipitously in countries all over the world (International Diabetes Federation, 2013). In 2013, approximately 2.6 million Canadians were living with diabetes (type 1 or type 2). The majority of people, 90 to 95% have type 2 diabetes which is a combination of insufficient insulin production and impaired response to insulin's effects (insulin resistance) (Public Health Agency of Canada, 2011a). (Despite healthcare provider efforts and the integration of clinical practice guidelines, approximately half of the Canadians living with type 2 diabetes do not achieve the glycemic target of hemoglobin A1C < 7.0% (Harris, Ekoe, Zdanowicz, & Webster-Bogaert, 2005; Harris, Kapor, Lank, Willan, & Houston, 2010b; Leiter et al., 2013b). Optimal glycemic control is critical for the prevention or minimization of diabetes-related complications as demonstrated by the landmark United Kingdom Prospective Diabetes Study (United Kingdom Prospective Diabetes Strategy (UKPDS) Group, 1998). Diabetes self-management education (SME) has been shown to provide clinically important benefits for patients with type 2 diabetes including hemoglobin A1C reductions (Jones, Berard, MacNeill, Whitham, & Yu, 2013). With the number of people living with diabetes projected to rise significantly in the next 20 years, educating patients regarding self-management is critical to ensure their quality of life and avoidance of complications. This is particularly relevant in a healthcare system where fiscal pressures are evident and economic burden of diabetes in Ontario in 2010 was 4.9 billion dollars (Canadian Diabetes Association, 2013b).

In order to achieve optimal glycemic control, many patients with type 2 diabetes will require insulin. The use of insulin, which historically was often the last agent to be added to a patient's treatment, is now considered at any stage of the diabetes continuum according to the Canadian Diabetes Association (CDA) Clinical Practice Guidelines based on the patient's clinical presentation. Barriers to insulin therapy such as psychological insulin resistance (PIR), diabetes

distress, and clinical inertia are well documented in the literature (Brod, Kongso, Lessard, & Christensen, 2009; Brown, Nichols, & Perry, 2004; Fisher et al., 2009; Gherman et al., 2011; Harris, et al., 2010a; Harris, Yale, Dempsey, & Gerstein, 2008; Paddison, Alpass, & Stephens, 2007; Peyrot et al., 2005; Polonsky, 2007). This presents a challenge for healthcare providers working with patients to help them to achieve optimal glycemic control and enhanced quality of life. Recognizing that self-management education needs to be tailored to meet individual needs, it is imperative that healthcare providers have an understanding of patients' perspectives of their diabetes and the factors influencing their abilities for diabetes self-management. Only then can educational strategies and clinical practice guidelines fully reflect the holistic needs of patients and appropriately inform the healthcare providers working with these patients. The purpose of this scoping review is to provide a descriptive account of available research and non-research material centring on the research gap associated with patients starting insulin therapy with type 2 diabetes. A scoping review was chosen for the ability to map the literature, sources of evidence, and gaps in the research particularly when "there is suspicion that not enough literature exists" and "further primary research is necessary" (CIHR, 2009).

2.1 Method

A scoping review based on the framework proposed by Arksey and O'Malley (2005) was chosen for this article. The framework identifies five stages with an optional consultation exercise:

- (1) Identifying the research question.
- (2) Identifying relevant studies.
- (3) Study selection.
- (4) Charting the data.
- (5) Collating, summarizing and reporting the results.
- (6) Optional consultation exercise

Arksey and O'Malley suggest a common reason for the use of a scoping review includes identifying research gaps in the current literature which aligns well with this review. Anderson, Allen, Peckham, and Goodwin (2008) suggest policy mapping as a scoping review can identify main documents and statements from professional bodies that influence the nature of practice in that area. This element was included in this scoping review to assist with guiding future educational strategies.

The research question for this review was “What is known about the relationship between perceived stress, ways of coping and the initiation of insulin therapy in adults with type 2 diabetes?” A policy mapping was also included as part of this review to examine the main documents and statements available that relate to the nature of practice in this area of diabetes.

In order to identify relevant literature, electronic database searches were performed in CINAHL, PubMed, PsycINFO, and ProQuest. The main subject areas searched were diabetes, stress, coping, and diabetes health policy. Websites for organizations known to have a strong focus in diabetes care were searched directly for any policy or guideline statements. As there is no worldwide common database for grey literature, the search strategy included primarily North American literature. The focus of the search was based on type 2 diabetes particularly in relation to the initiation and the use of insulin. For this review, stress was defined as the relationship between a person and the environment which affects the person’s well-being. The definition of coping used for this review was the thoughts and behaviours used by a person to manage stress. Search terms used independently and then in combination included: diabetes mellitus, type 2 diabetes, diabetes self care, coping, ways of coping, stress, distress, psychological distress, insulin, initiating insulin, starting insulin, psychological insulin resistance. Inclusion criteria for this scoping review were: (a) English language, (b) primary research, meta-analysis, literature review, and (c) published between 2001 and 2013. Reference lists of selected items were hand searched for additional items eligible for inclusion in the review. To complete the policy mapping review, a grey literature search of North American diabetes professional organizations and governmental bodies focused on diabetes clinical practice documents.

The selection process resulted in nine relevant items that most closely aligned with the research question and nine documents related to policy mapping. It is important to remember that, unlike a systematic review, a scoping review can include a range of different methods and study designs and does not assess the quality of evidence, rather it provides a descriptive account of available research (Arksey & O'Malley, 2005). Although there was an abundance of literature on the separate elements of the research question, stress or coping with type 2 diabetes or guidelines detailing suggested processes for initiating insulin, more difficult to find were articles which included all of the elements of the research question. Few items were focused specifically on stress and ways coping at initiation of insulin therapy. Charting the data for a scoping review involves extracting data using a “narrative review” method which presents contextual or process

oriented information from each item included in the review (Arksey & O'Malley, 2005; Levac, Colquhoun, & O'Brien, 2010). The data from this review were organized along two thematic categories (a) Insulin initiation barriers and (b) Coping (Table 1). The data from the policy mapping were charted according to the regional level of policy influence (Table 2).

Table 1 Selected Scoping Review Items

Author/Date/Country	Method / Aim	Sample	Important Results
Insulin Initiation Barriers			
Bogaten & Hancu 2001 Romania	Qualitative semi-structured interviews with phenomenologic and content analysis Aims: (1) Identify representations of insulin therapy, (2) study the factors influencing the representations, (3) study factors that might influence decision to accept/refuse treatment	n = 18 people at the moment of initiating insulin therapy	Psychological Insulin Resistance (PIR) influenced by the perceived reasons for the need to start insulin therapy and the perceived consequences of insulin therapy Patient attitudes regarding insulin therapy influenced by family, healthcare providers, others on insulin Physical discomfort is a determinant factor in acceptance/refusal of insulin therapy
Gherman et al., 2011 Romania	Critical Literature Review Aim: Answer the questions: How is PIR measured? With	n = 60 varied articles	PIR consistent among insulin naïve patients with ~ 27% refusing to initiate insulin

	<p>what instruments? Predictive factors? Interventions proposed to reduce PIR?</p>		<p>Emotional state, lack of knowledge, low self-efficacy predictors of PIR</p> <p>Relationship with healthcare providers influences PIR</p>
<p>Polonsky, Hajos, Dain, Snoek 2011 U.S.A.</p>	<p>Internet survey Aim: Assess willingness to start insulin, insulin beliefs, current medications, diabetes distress</p>	<p>n = 1400 insulin-naïve patients with type 2 diabetes in 8 Western nations</p>	<p>Presence of PIR common across the 8 Western nations with 17.2% unwilling to and 34.7% ambivalent about starting insulin</p> <p>Patients unwilling or ambivalent to start insulin reported more diabetes-related emotional distress</p> <p>Authors suggest most effective approach to PIR involves addressing patients' emotional distress</p>
<p>Rubin, Peyrot, Kruger, Travis 2009 U.S.A.</p>	<p>Internet surveys Provider survey (physicians, diabetes educators) Patient self-report Aim: Compare patients' perceptions of injection-related</p>	<p>Provider sample n = 301 Patient sample n = 501 with 77% of patients having type 2 diabetes</p>	<p>Reported several findings related to the burden of insulin injections e.g. 46% patients have changed their life to avoid extra injections</p> <p>Moderate or major impact of insulin injections on quality of</p>

	problems with clinicians' estimates of those problems		life reported by 14% of patients Healthcare providers report highest impact of problems for adherence to injections related to anxiety
Wang & Yeh 2012 Taiwan	Mixed-methods systematic review Aim: Describe the phenomenon of PIR from the perspective of adults with type 2 diabetes	n = 16 studies with 7961 total participants	15 descriptive themes – 3 of which focused on participants' choices of how to cope 5 main theme categories with two levels – cognitive appraisal and emotional responses
Coping			
Gafvels & Wandell 2005 Sweden	Cross sectional design – self-report coping questionnaire; chart review Aim: Assess and compare coping strategies in patients with type 2 diabetes	n = 232 patients ~ 30% on insulin	Coping strategies clearly associated with metabolic control. Variations in coping strategies between men and women. Coping a good predictor for HbA1C and microangiopathy.
Karlsen, Oftedal, Bru 2012 Norway	Cross sectional design - questionnaires Aim: Describe diabetes-related distress, coping styles, perceptions of social support among adults	n = 378 adults with 28.6% on insulin	One fifth of participants experienced relatively high levels of diabetes-related distress Greater variance in emotional distress accounted for by coping styles and perceived

	with type 2 diabetes		support versus clinical indicators
			Healthcare providers should develop methods to decrease diabetes-related distress that prevent the use of negative coping styles
Macrodimitis & Endler 2001 Canada	Cross-sectional design - 4 measures Aim: determine relationships among coping, illness control, psychological adjustment	n = 115 adults with 18.3% on insulin	Problem-focused coping related to better psychological adjustment Emotional preoccupied coping and avoidance coping related to poor psychological adjustment
Shah et al. 2012 U.S.A.	Cross-sectional design using cognitive and behavioural coping strategy instrument and a screening tool for depression Aim: Examine the relationship among diabetes-related distress, appraisal, coping and depressive symptoms	n = 201 adults with 35.3% on insulin	Patients who experienced greater diabetes-related stress had a negative appraisal of their diabetes and were less likely to use problem-focused coping Emotions and coping play a central role in the diabetes/depressive symptom relationship

2.2 Results

Arksey and O'Malley (2005) describe the fifth stage of the scoping framework as collating, summarizing and reporting the results. The following overview describes the two themes identified within this scoping review and the results of the policy mapping. The results are divided into three subsections. The two themes identified were (1) insulin initiation barriers, and (2) coping. The final subsection describes the results from (3) policy mapping.

2.2.1 Insulin Initiation Barriers

Five of the articles selected for this scoping review reflected the theme identified as “insulin initiation barriers”, given that the majority of literature examines issues that impede insulin initiation. Psychological insulin resistance (PIR) is the dominant concept throughout this area of the literature and is most often defined as a psychological (cognitive, emotional, relational, and cultural) barrier or opposition to the initiation of insulin (Brod, et al., 2009). Diabetes-related distress is also found within this theme and is defined as the disease specific stress related to the burden of self-care management of diabetes. The articles selected included one qualitative study, one literature review, two internet surveys and a mixed-methods systematic review.

Bogatean and Hancu (2001) conducted a qualitative study using semi-structured interviews with 18 participants (11 men, 7 women) at the moment of initiating insulin. A phenomenologic analysis and content analysis revealed that psychological insulin resistance is influenced by the perceived reasons of the need to start insulin and the perceived consequences of insulin therapy. Findings also revealed that attitudes regarding insulin therapy are influenced by family, other people on insulin, and the healthcare team.

Gherman et al. (2011) performed a critical literature review of psychological insulin resistance (PIR) and the strategies to reduce it. Databases were searched ultimately yielding 60 articles of varying types (reviews, editorials, cross-sectional studies, instrument validation) that were summarized in the meta-analysis. Six instruments were found that investigated the emotional distress related to insulin, positive/negative insulin expectations, or satisfaction with consequences on daily activities. The authors found that the number of patients with PIR in research settings versus community settings is consistent at approximately 27%. Themes revealed emotional states influenced PIR, as well as, cognitive predictors, e.g., lack of

knowledge. Healthcare providers were found to have an influence on a patient's perception of requiring insulin.

In a multi-national study to examine the perceptions of insulin-naïve type 2 diabetes patients, Polonsky, Hajos, Dain and Snoek (2011) found the presence of psychological insulin resistance (PIR) to be common. Participants originated from France, Germany, the United Kingdom, Italy, the Netherlands, Spain, Sweden, and the U.S.A. with a sample size of 1400. Qualitative interviews were conducted to develop survey tools assessing beliefs about insulin, beliefs about current oral medications, and diabetes-related distress. Findings showed patients unwilling or ambivalent to start insulin reported more diabetes-related emotional distress replicating results from previous studies (Makine et al., 2009; Snoeks, Skovlund, & Pouwer, 2007). The authors suggest the most effective approach overall to overcoming or preventing PIR includes addressing emotional distress about living with diabetes, worries about diabetes medicines and patients' specific beliefs about insulin.

Barriers to injection therapy were compared in a study by Rubin, Peyrot, Kruger, and Luther (2009). They described the (1) burden of insulin injections, (2) impact of injections on quality of life, (3) impact of injection therapy on treatment adherence, (4) injection-related patient/provider communication, and (5) tools to ease burden of insulin injections. Overall, a substantial majority of patients wanted to reduce the number of injections they took on a daily basis. More than half of the patients indicated that they were more likely to take their insulin injections if a product was available to ease the pain of injection.

In a mixed-method systematic review of psychological insulin resistance (PIR) in adults with type 2 diabetes the authors concluded that there is impact from a range of cognitive and/or emotional reaction personal viewpoints (Wang & Yeh, 2012). The review question was "What is known about the psychological barriers to starting insulin therapy among adults with T2DM when or if their physicians recommend they use insulin therapy?" The sixteen articles reviewed originated from sixteen developed countries with participants from Europe, Asia, Australia, and North America. Seven of the studies were interview models, five were descriptive studies and four performed psychometric analyses of data related barriers to insulin initiation. The five main themes reported that people with type 2 diabetes (1) do not see the necessity for insulin and actively seek ways to control blood sugars without insulin, (2) have a holistic view of the

consequences of insulin, (3) see insulin therapy as less feasible, (4) see insulin as a source of fear/anxiety, and (5) feel the necessity to start insulin therapy has a very negative connotation and is associated with dysfunctional emotions. The authors concluded that psychological resistance to insulin therapy involved cognitive appraisal and emotional reaction requiring assessment of an individual's psychosocial barriers to insulin therapy.

2.2.2 Coping

Four cross-sectional studies were identified in the second theme identified as coping. Gafvels and Wandell (2006) conducted a cross-sectional study assessing coping strategies with a Swedish, non-illness specific, self-report questionnaire measuring cognitive, emotional, and action-orient coping efforts. Demographic data was collected from medical records and data on social and psycho-social background were taken from a previous study. Main study findings reported a clear association between coping strategies and metabolic processes. Differences in coping strategies found women using negative coping methods (resignation, protest, isolation) more often than men. Coping was found to be a good predictor for hemoglobin A1C and microangiopathy in insulin treated patients.

The study that most reflected the research question of this scoping review was conducted by Karlsen, Oftedal and Bru (2012). The cross-sectional design employed questionnaires to investigate clinical indicators (hemoglobin A1C, complications, BMI, disease duration), coping styles, and perceived support from healthcare professionals and family related to diabetes-related distress. Of 689 participants invited to participate, a final sample size of 378 was obtained. The Problem Areas in Diabetes (PAID) instrument was utilized to assess diabetes emotional distress, sub-scales from the COPE Inventory and Ways of Coping Questionnaire assessed coping styles. The Patient Questionnaire on Empowerment assessed support from healthcare providers, while the Diabetes Family Behaviour Checklist assessed family behaviours. The authors reported that one-fifth of the participants reported severe diabetes-related distress which was consistent with previous research (Fisher, et al., 2009). Also consistent with previous research, was the finding that showed greater use of task-oriented coping more than emotion-focused coping. Participants felt they received constructive support to a much greater degree from healthcare providers (76%) than their families (11%). The regression analysis showed a substantially greater variance in emotional distress accounted for by coping styles and perceived support versus clinical

indicators. The authors suggested that healthcare providers should develop methods to decrease diabetes-related distress that prevent the use of negative coping styles.

The only Canadian study selected for this scoping review was a cross-sectional design investigating the relationships of coping strategies and perceived control to psychological and physiological adjustment in adults with type 2 diabetes (Macrodimitris & Endler, 2001). Separate instruments were used to assess the following variables (1) coping, (2) perceived control, (3) anxiety, (4) depression, and (5) hemoglobin A1C. Findings indicated that problem-focused coping strategies were related to better psychological adjustment, while in contrast, emotional coping and avoidance coping were related to higher depression and state anxiety. Perceived control was determined to have a direct negative relationship to depression, state anxiety and hemoglobin A1C. The authors suggested that high levels of perceived control have a favourable effect on adjustment in people with type 2 diabetes.

The relationship between diabetes-related distress, appraisal, coping and depressive symptoms in adults with type 2 diabetes was examined in the context of the transactional model of stress and coping by Shah, Gupchup, Borrego, Raisch, and Knapp (2012). A sample of 201 participants completed the cross-sectional study which utilized surveys and a medical records chart review. Findings revealed that participants with depressive symptoms reported significantly higher levels of diabetes-related stress than patients without depressive symptoms. Findings also suggested that appraisal was a mediator in the relationship between stress and coping. Appraisal also mediated the relationship between depressive symptoms and the coping measures of avoidance, passive resignation, and diabetes integration. The authors suggest emotions and coping play a central role in the relationship between diabetes and depressive symptoms and that interventions that promote stress management and healthy coping may assist patients to adapt to living with diabetes.

2.3 Policy Mapping

The policy mapping element of this scoping review focused on the main documents and statements from professional bodies that influence the nature of clinical practice in diabetes. The nine documents published in English selected for this scoping review originated from developed countries that possess the resources and expertise to provide diabetes care at a similar level. The

countries represented within this policy mapping review are congruent with the sources of items selected for the previous section related to the research question scoping review. Six of the documents are directed at healthcare providers with evidence-based clinical practice guidelines to direct care of individuals with type 2 diabetes (American Diabetes Association, 2014; Canadian Diabetes Association, 2013a; International Diabetes Federation, 2012; National Collaborating Centre for Chronic Conditions, 2008; Registered Nurses Association of Ontario, 2009; Ryden et al., 2013). Practice guidelines directed at diabetes educators provide guidance for the training of diabetes educators and diabetes educational practice in the United States (American Association of Diabetes Educators, 2011) The National Service Framework for Diabetes (Department of Health (United Kingdom), 2001) was developed to provide direction for diabetes care in health sector service planning in the United Kingdom. Similarly, The Diabetes in Canada (2011) document is a statistical resource to support public health professionals and organizations in the development of evidence-based public health policies and programs in the prevention and management of diabetes. The policy mapping documents are summarized in Table 2.

Table 2 Policy Mapping Results

Source/Year	Policy Influence Level	Document	Summary
American Association of Diabetes Educators (AADE) 2011	National	Guidelines for the Practice of Diabetes Self-Management Education and Training	Clarifies the roles and responsibilities of all persons facilitating diabetes education
American Diabetes Association (ADA) 2014	National	Clinical Practice Recommendations	Evidence-based clinical practice recommendations to be interpreted on an individual basis

Canadian Diabetes Association (CDA) 2013	National / International	Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada Chapters 1, 7 , 9, 13	Provides evidence-based recommendations on screening, prevention, diagnosis, education, care and management of diabetes.
Department of Health (United Kingdom) 2001	National	National Service Framework for Diabetes: Standards	Standards, rationales, key interventions, implications for planning services
European Association for the Study of Diabetes (EASD) in collaboration with European Society of Cardiology (ESC) 2013	International	ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD	Guidelines provide educational tool with evidence-based approaches and algorithms for achieving best care in managing the combination of diabetes and cardiovascular disease
International Diabetes Federation (IDF) 2012	International	Global Guideline for Type 2 Diabetes	Clinical practice guideline sensitive to resource and cost-effectiveness issues for countries with limited resources (expertise, financially)
National Institute for	National	Type 2 Diabetes	Clinical, evidence-

Health and Clinical Excellence (NICE) (England and Wales) 2008		National clinical guideline for management in primary and secondary care	based guidelines intended for healthcare professionals, people with type 2 diabetes and their support systems
Registered Nurses Association of Ontario (RNAO) 2007-2013	Provincial / National	Best Practice Guidelines directed at diabetes (a) Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes 2009 (b) Assessment and Management of Foot Ulcers for People with Diabetes 2013 (c) Reducing Foot Complications for People with Diabetes 2007	Provides resources necessary for the support of evidence-based nursing practice in the provision of individualized care. Provides overview of structures and supports necessary for provision of best possible evidence-based care
Public Health Agency of Canada 2011	National	Diabetes in Canada: Facts and figures from a public health perspective 2011	Provides most recent diabetes statistics in Canada. Offers risk factors for developing diabetes

2.4 Discussion

The findings from this scoping review reinforce the need for continued research exploring the psychological aspects of diabetes care which is integral to helping patients improve their diabetes

self-management and ultimately their glycemic control. Despite the availability of extensive clinical practice resources, new pharmacologic agents, and an increased awareness of the psychosocial needs of patients with diabetes, the majority of patients do not reach target glycemic control (Nam, Chesla, Stotts, Kroon, & Janson, 2011; Nicolucci et al., 2013a; Piya, Tahrani, & Barnett, 2010). In a recent follow-up to a major research study exploring the Diabetes Attitudes, Wishes, and Needs (DAWN) of people with diabetes, the need for psychosocial support and individualized education was once again reinforced (Holt et al., 2013; Nicolucci et al., 2013b; Peyrot, et al., 2005). The two themes identified in this scoping review: (a) insulin initiation barriers and (b) coping, elucidate the importance of examining these concepts from the individual's perspective. It is critical that healthcare providers design and deliver educational supports that will meet the needs of the individual.

Foundational research exists which examines the barriers to insulin initiation. Numerous factors have been identified from both the patient and healthcare provider perspectives. These factors include psychological insulin resistance, diabetes distress, fear of injection therapy, and clinical inertia. As Wang and Yeh (2012) suggest, technique-oriented skills training or endeavouring to convince individuals to initiate insulin therapy, may meet the needs of the healthcare provider but not those of the individual. They further suggest, "It is essential to have knowledge of how people arrive at medical decisions in relation to their perception of the illness, before we can guide people's awareness of the need for insulin therapy" (p. 754). Previous research (Bogatean & Hancu, 2001) reported patient attitudes regarding insulin are influenced by their family, others on insulin, and healthcare providers which means that the opportunity to educate and influence patients exists. The key is for healthcare providers to use their opportunity to educate in a way that is meaningful for the patient. With the research by Polonsky, Hajos, Dain and Snoek (2011) demonstrating that psychological insulin resistance (PIR) is a common phenomenon, both researchers and educators should heed the authors' suggestion that the most effective approach to decrease PIR is by addressing patients' emotional distress.

Mirroring the need for further research regarding stress and distress, the concept of coping continues to receive increasing focus. The findings of Gafvels and Wandell(2006) linking coping strategies to glycemic control reiterated the link between the psychological and biophysical aspects of diabetes. Shah et al. (2012) concluded that the knowledge that patients with high stress levels are likely to develop a negative appraisal of their diabetes, should assist educators to

develop programs for those at high risk. They also assert that stress management training could be incorporated in diabetes education programs. This reinforces the need for individualized patient assessment with a goal of comprehensive, holistic care.

Research has established that patients employ varying coping styles. Coping styles such as behavioural disengagement and self-blaming are linked significantly with emotional distress (Karlsen, et al., 2012) (Canadian Diabetes Association, 2013c). For those patients who have difficulty with their diabetes self-management, an understanding of their coping styles could assist healthcare providers when choosing educational strategies and processes for providing care.

Comprehensive practice guidelines and policy frameworks are available as evidence-based resources in diabetes. As the research evidence continues to accumulate regarding the importance of the psychological aspects of diabetes care, it is encouraging that diabetes professional organizations and makers of health policy are integrating these elements into the practice guidelines and frameworks that guide diabetes care. Chapters addressing the psychological care of individuals with diabetes can be found in the clinical practice guidelines from Canada, United States, United Kingdom, Europe and the International Diabetes Federation. The documents selected within the policy mapping for this scoping review, consistently identified the need to provide comprehensive diabetes care while acknowledging that continued research is required. Although the need for psychological support is articulated in practice guidelines, knowledge translation is sub-optimal as gaps persist in our understanding of patient perceptions of diabetes and their ways of coping.

2.5 Conclusion

This scoping review highlights the paucity of knowledge available to inform healthcare providers of the patient's perception of stress and coping with the initiation of insulin therapy and therefore a gap in research knowledge. (Figure 2) Evidence continues to mount highlighting the importance of addressing these psychological aspects of diabetes care. The challenge to researchers and healthcare providers is to identify these influencing factors and incorporate educational strategies that acknowledge these factors. Patient-specific education strategies

recognizes the unique challenges that each patient faces and may assist patients to meet their goals of self-care with the hopes of improving glycemic control and enhancing quality of life.

Figure 2

Research Question

What is known about the relationship between perceived stress, ways of coping, and the initiation of insulin in patients with type 2 diabetes?

Insulin Initiation Barriers

Psychological insulin resistance, found in both patients and health care providers

Large body of research exists elucidating this concept with calls to further explore the emotional elements for patients

Coping

Coping strategies are associated with metabolic control and can be influenced by stress

Paucity of research looking at a link between stress and coping when initiating insulin therapy in type 2 diabetes and the implications for patient education

Themes Identified and Research Implications

Policy Mapping Results

Majority of agencies provide evidence-based clinical practice guidelines to guide health care providers identifying the importance of patient-focused care

Results demonstrate a common theme of patient-centred care and education

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Chapter 3

3. Coping as a Mediator of Stress with the Initiation of Insulin in Type 2 Diabetes

3.1 Introduction

Type 2 diabetes affects approximately 90% of those who live with diabetes (Centre for Disease Control and Prevention, 2014; Government of Canada, 2013). In Canada, an estimated 2.6 million people live with this disease and in every age group, individuals with diabetes have mortality rates at least two times higher than those without diabetes (Public Health Agency of Canada, 2011b). For a chronic, progressive disease, the focus of diabetes patient education is to provide the knowledge and skills that will allow patients to self-manage their condition and minimize the potentially devastating complications of diabetes. People living with diabetes are at increased risk for macrovascular complications (myocardial infarction and stroke) and microvascular complications (retinopathy, nephropathy, neuropathy) (Chalmers & Cooper, 2008; Lasker, 1993; United Kingdom Prospective Diabetes Strategy (UKPDS) Group, 1998). Glycemic targets and clinical practice guidelines for the management of diabetes continue to evolve as research demonstrates the importance of optimal glycemic control (Chalmers & Cooper, 2008; Holman, Paul, Bethel, Matthews, & Neil, 2008; United Kingdom Prospective Diabetes Strategy (UKPDS) Group, 1998). The 2013 Canadian Diabetes Association Clinical Practice Guidelines emphasized the importance of achieving optimal glycemic control within 3 to 6 months once pharmacologic therapy has been initiated. The guidelines also suggest that patients with marked hyperglycemia may benefit from the initiation of insulin as a first line intervention in addition to oral agents (Harper et al., 2013).

Clinical practice has historically reserved the use insulin as one of the final agents to be added to a patient's pharmacologic regimen. This hesitation may be in part related to the phenomenon known as psychological insulin resistance (PIR). Psychological insulin resistance is most often defined as a psychological barrier or opposition to the initiation of insulin (Brod, et al., 2009; Gherman, et al., 2011; Polonsky, 2007). PIR is well documented in the literature and is found within both patients and healthcare providers. Patients are reluctant to start or fear beginning

insulin therapy and clinicians are reluctant to initiate insulin therapy. The reluctance by clinicians to initiate insulin therapy is more specifically termed “clinical inertia” (Brown, et al., 2004; Harris, et al., 2010b; Harris, et al., 2008; Phillips et al., 2001). Unfortunately, delaying the introduction of insulin has sometimes been leveraged by healthcare providers as a motivator for patients to improve their adherence to lifestyle and dietary changes reinforcing the idea that insulin should be left as the last resort. This “treatment to failure” approach – adding multiple oral agents with insulin as the final option- is challenged in the literature as unnecessarily prolonging an uncontrolled hyperglycemic state in patients predisposing them to the microvascular and macrovascular complications of diabetes (DeFronzo, Eldor, & Abdul-Ghani, 2013; Lingvay et al., 2009).

3.1.2 Stress and Diabetes

The psychosocial aspects of living with diabetes are well recognized (Clement, et al., 2013; Jones, et al., 2013; Nicolucci, et al., 2013b; Peyrot, et al., 2005; Skovlund & Peyrot, 2005). Managing diet and exercise, self-monitoring of blood glucose, and adhering to medication regimens on a daily basis often create a heavy burden for those living with diabetes. Diabetes distress describes the disease-specific stress related to this burden of diabetes self-care management. The challenges with the identification and treatment of diabetes distress are also well described in the literature (Fisher, et al., 2009; Paddison, et al., 2007; Peyrot, Rubin, & Siminerio, 2006). Research also points to the reduction of general life stress and consideration of broader life contextual factors as influential elements of diabetes management (Albright, Parchman, & Burge, 2001; Fisher, et al., 2009). It is important to remember that 95% of diabetes care is done by the individual themselves (Funnell & Anderson, 2000). Given the small percentage of time interacting directly with health care providers, it is important to ensure that educational opportunities meet the needs of the individual and support behavioural change, as well as, knowledge transfer. When designing healthcare education or directly providing patient-focused education, health care providers need to be sensitive to individual differences in how patients appraise, explain, and cope with stressors which are likely to influence a patient’s ability to comprehend and retain new knowledge (Roesch, Weiner, & Vaughn, 2002).

3.1.3 Coping and Diabetes

The need to behaviourally regulate metabolic processes that are normally controlled by autonomic physiologic functioning makes coping with diabetes different from other chronic illness (Karlsen & Bru, 2002). People living with diabetes must control the timing, quality and quantity of their nutritional intake and optimize their activity and exercise levels to achieve the targets set for optimal metabolic glycaemic control. Coping with diabetes is a lifelong necessity and impacts on the health outcomes achieved by self-management. Gafvels and Wandell (2006) assessed coping strategies in adults with type 2 diabetes and found a clear association between coping and metabolic control. Research examining psychosocial factors predictive of relationships with self-care behaviour found coping efficacy uniquely accounted for 9% of the variance in self-care behaviour (Hart & Grindel, 2010). Bandura notes that a person's beliefs in personal self-efficacy or coping can affect life choices, vulnerability to stress and their quality of life functioning (1994). For health care providers caring for patients with diabetes it is essential to have an understanding of the patient's perception of their stress and their ways of coping with it. Rubin and Peyrot (1999) suggested that with training, effective coping skills for diabetes self-management can be developed and enhanced.

3.1.4 Education Strategies

The use of interprofessional team-based diabetes care, which includes diabetes nurse educators, is well documented in the literature and promoted as the standard of care (Bodenheimer, Wagner, & Grumbach, 2002; Grimmer-Somers, Dolejs, Atkinson, & Worley, 2008; Phelps et al., 2009; Ritholz et al., 2011; Zwar et al., 2007). This type of care has also been shown to improve glycaemic control (Earles et al., 2001; Polonsky, 2003). Effective diabetes education is therefore a key element of living well with diabetes. The Canadian Diabetes Association (CDA) defines diabetes self-management education as “a systematic intervention that involves active patient participation in the self-monitoring (physiological processes) and/or decision making (managing)” (Jones, et al., 2013, p. 26). The majority of diabetes management (~80%) occurs in the primary care setting which may influence the resources available to provide diabetes education (Borgermans et al., 2009). In order for patients to fully participate in their educational opportunities, assessment of their stress levels and coping processes provides educators with

understandings to meet the individual needs of patients. It has also been shown that behavioural interventions enhance education knowledge achieving longer term change in self-care behaviour (M. J. Davies et al., 2008; Kulzer, Hermanns, Reinhecker, & Haak, 2007; Minet, Moller, Vach, Wagner, & Henriksen, 2010).

3.2 Registered Nurses Association of Ontario Best Practice Guidelines (RNAO BPG)

The RNAO BPG development is a rigorous process which includes a systematic literature review and expert clinician and stakeholder consultation to provide evidenced-based recommendations in four areas consisting of (a) practice, (b) education, (c) organization and policy, and (d) evaluation and monitoring. The RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes provides nine specific recommendations that focus on the essential knowledge that a person requires to safely self-administer insulin (Appendix B). The RNAO BPG is designed to assist nurses and allied health professionals who are not specialists in diabetes care to assist clients to safely initiate and administer insulin (Registered Nurses Association of Ontario, 2009).

3.3 Research Purpose

The purpose of this research was to examine the relationships between perceived stress and ways of coping in patients with type 2 diabetes who initiated insulin therapy and received education guided by the Registered Nurses Association of Ontario (RNAO) Best Practice Guideline (BPG) for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes. The two research questions were:

1. What is the relationship between perceived stress and education guided by the RNAO BPG for Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes?
2. What is the relationship between perceived stress, ways of coping and the initiation of insulin therapy in adults with Type 2 diabetes?

3.4 Theory to Frame this Study

Lazarus and Folkman (1984) presented the cognitive theory of stress and coping, a framework for examining psychological stress. The theory holds that stress is contextual, an interaction between the person and his/her environment. Folkman (1997) further revised the model to include positive psychological states. Stress, as defined by Lazarus and Folkman and the definition used for this study, is “a relationship between the person and the environment that is appraised by the person as taxing or exceeding his or her resources and endangering his or her well-being” (1984, p. 21). Two concepts are central to the theory (a) appraisal and (b) coping. Both appraisal and coping are influenced by an individual’s personal characteristics and the environment and are therefore considered to have stable and variable aspects. Appraisal relates to a person’s “evaluation of the personal significance of a given event and the adequacy of the individual’s resources for coping” (Folkman & Greer, 2000, p. 12). Coping is described as a dynamic system which is highly interactive (Folkman, 2010). Coping refers to the thoughts and behaviors used by an individual and is subdivided into three types (a) emotion-focused coping centered on regulating distress, (b) problem-based coping centered on managing the problem causing distress and (c) meaning-based coping centered on the ability to maintain positive well-being. In this study, coping was proposed as a mediator of perceived stress and the patient’s self-efficacy with the initiation of insulin. Lazarus and Folkman suggest that coping is a mediator that changes the relationship between the antecedent variable (perceived stress) and the outcome variable (insulin self-efficacy) transforming the original appraisal and attendant emotion. According to Lazarus, “coping and the appraisals that influence it mediate any emotions that are generated by the emotions process” (2006, p. 10).

Based on the theoretical model and examination of the literature, the following hypotheses for this study were developed (Figure 3):

- (1) Effective provision of RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes will assist with decreasing patients’ perceived stress.
- (2) Patients with higher levels of perceived stress will have lower confidence in administering insulin and managing diet (insulin initiation self-efficacy).
- (3) Patients with higher perceived stress will engage more frequently in ways of coping.

- (4) Patients with effective ways of coping will have higher confidence in administering insulin and managing diet (insulin initiation self-efficacy).
- (5) Coping (ways of coping) is a mediating variable of the perceived stress and initiation of insulin relationship.

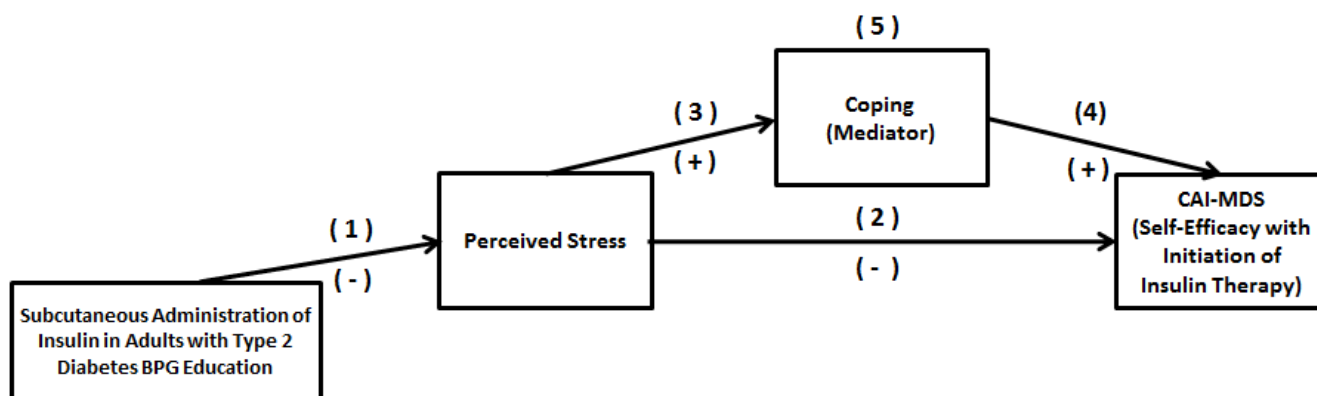


Figure 3 Hypothesized model of the relationships between RNAO BPG education, stress, and self-efficacy with initiation of insulin therapy
Hypotheses (#)
Negative relationship (-) Positive relationship (+)

3.5 Methods

3.5.1 Design and Sample

A one-group, non-experimental pretest / posttest design was undertaken drawing a sample from patients who were seen at a Diabetes Education Centre (DEC) in Southwestern Ontario. Ethics approval was obtained from the Western University Health Science Research Ethics Board and the hospital ethics boards for each of the involved DEC. Participants were surveyed immediately prior to their first visit at a DEC for education prior to starting insulin and once again at their follow-up appointment approximately six weeks later. Appointments in the DEC to start insulin were booked as one to one appointments with a nurse or dietitian and ranged from 45 to 90 minutes. Each participant completed the three survey tools prior to initiating insulin therapy and the same three tools at their follow-up appointment. Additionally, a Best Practice Guideline evaluation tool developed for this study was administered during a brief interview

following the second appointment to evaluate the participants' perceptions of the educational content reviewed during their appointments. In order to be eligible for the study, participants needed to read and speak English, be over 18 years of age and be insulin naïve with no previous injection therapy experience with any type of injectable treatment.

The final sample was obtained from three independent DEC's (n =105). After initially recruiting 113 participants, 4 participants did not return for their second visit and 4 participants were no longer using insulin at their second appointment. The final study sample (Table 3) consisted of 58 men and 47 women with a mean age of 62 years (range 25 – 86 years). The majority of participants were married (68%). The average duration of disease with diabetes ranged from newly diagnosed to 36 years with a mean of 11.6 years. The majority of participants (80%) were started on once daily (basal) injections with the remainder on Multiple Daily Injections (MDI). Seventy per cent of participants had completed high school (42%) or college (28%).

Table 3. Demographics of final sample (n = 105)

Demographic	Frequency	%
Sex		
Female	47	45
Male	58	55
Marital Status		
Single	6	6
Married	71	68
Divorced/Separated	21	20
Widowed	7	7
Education		
Elementary School	11	11
High School	44	42
College	30	28
University	19	18
Insulin Regimen		
Basal (Once daily)	84	80

Multiple Daily Injections	21	20	
	<i>range</i>	<i>mean</i>	<i>SD</i>
Age (yrs)	25-86	62	10.73
Duration with Diabetes (yrs)	0-36	11.6	7.74

3.5.2 Measures

Demographic data collected to describe the study sample included sex, age, duration of diabetes, education level completed, marital status, and type of insulin program initiated.

The Perceived Stress Scale (PSS) was used to measure participants' stress levels (Cohen, et al., 1983). The 10 item PSS is a self-report global stress measure using a 5 point Likert scale ranging from 0 (never) to 4 (Very Often). The total perceived stress score is calculated by summing all 10 items of the scale (items 4, 5, 7, 8 are reversed scored) with a possible range of 0 to 40. Higher scores reflect higher levels of perceived stress. The reported reliabilities of the PSS demonstrate Cronbach's alpha ranges from 0.75 to 0.91 (Reis, Hino, & Rodrigues-Anez, 2010). The Cronbach's alpha reliabilities in this study were 0.83 (pre) and 0.82 (post).

The Ways of Coping Questionnaire (WAYS) was used in this study to measure the theoretically derived coping relationship between stress and the participant's self-efficacy with insulin therapy. It was designed to identify coping processes – thoughts and actions that an individual uses to cope with a specific stressful encounter (Folkman & Lazarus, 1988). The WAYS is a 66 item self-report questionnaire with 8 subscales measuring coping processes. The 8 coping subscales include (a) Confrontive Coping, (b) Distancing, (c) Self-Controlling, (d) Seeking Social Support, (e) Accepting Responsibility, (f) Escape-Avoidance, (g) Planful Problem Solving, and (h) Positive Reappraisal. Items from the 4 point Likert scale were summed, the higher the score the greater use of a particular coping process. The Cronbach's alpha reported for the 8 subscales range from 0.61 to 0.79. In this study, the Cronbach's alphas were consistent with previously reported values for each scale with a range of 0.59 to 0.82 (pre) and 0.67 to 0.77 (post). Raw scoring was used in the final analysis, summing the scores from each of the subscales which provided a total score. The total coping score reflected the extent to which each type of coping was used in each encounter.

The Confidence in Administering Insulin and Managing Diet Scale (CAI-MDS) was developed by the Nursing Best Practice Research Unit in partnership with the Registered Nurses Association of Ontario (RNAO) to evaluate patient outcomes with the use of the RNAO Best Practice Guideline on Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes (Registered Nurses Association of Ontario, 2009). It is a measure of self-efficacy and contains 21 self-report items with 2 subscales: a 12 item insulin administration scale and 9 item managing diet scale. Cronbach's alpha for the insulin administration scale is reported as 0.90 and 0.94 for the diet scale. This study resulted in Cronbach's alpha 0.70 pre and 0.86 post for the insulin administration scale and 0.93 pre and 0.92 post for the diet scale.

3.5.3 Data Analysis

Descriptive and inferential analyses were performed using the IBM SPSS Statistics v. 22 (IBM, 2013). Missing data accounted for less than 5% of the study data acquired therefore imputation was not undertaken (Tabachnick & Fidell, 2001). Bootstrapping for the regression mediation analysis was performed using the PROCESS Macro developed by Hayes (2013).

Paired-samples t-tests were performed to evaluate the impact of BPG education on participants' scores with the variables perceived stress, ways of coping, and insulin self-efficacy from pretest to posttest. Correlation analyses were run between perceived stress and insulin initiation self-efficacy, perceived stress and coping, and coping and insulin initiation self-efficacy to examine the theoretical relationships hypothesized in the study model.

Mediated regression analysis was undertaken using a bootstrapping analysis to examine the relationship between perceived stress and insulin initiation self-efficacy with coping as a mediator. Bootstrapping is a more recent approach to testing mediation hypotheses which has been shown to be superior to earlier methods with regard to power and Type 1 error rates (MacKinnon, Lockwood, & Williams, 2004; Preacher & Hayes, 2008).

3.6.1 Research Question #1

What is the relationship between perceived stress and education guided by the RNAO BPG for Subcutaneous Administration of Insulin in Adult Patients with Type 2 Diabetes?

There were statistically significant differences at the $p < .001$ significance level, in pretest to posttest scores for perceived stress and CAI-MDS (insulin self-efficacy) (Table 4). Results showed that patient stress decreased and insulin self-efficacy increased after receiving the BPG insulin education.

Table 4

Descriptive Statistics and t-test Results for Perceived Stress, Coping, and CAI-MDS (self-efficacy)

Outcome	Pretest		Posttest		n	95%CI for Mean Difference	r	t	df
	M	SD	M	SD					
Perceived Stress	16.61	7.27	14.23	7.02	97	1.07, 3.71	.58*	3.60*	96
Coping	76.38	31.07	73.51	31.22	97	-2.00, 7.756	.70	1.17	96
CAI-MDS (self-efficacy)	76.71	14.23	86.93	10.85	98	-12.90, -7.52	.45*	-7.54*	97

* $p < .001$

3.6.2 Research Question #2

What is the relationship between perceived stress, ways of coping and the initiation of insulin therapy in adults with type 2 diabetes?

The correlation analyses indicated perceived stress had a moderately positive correlation with coping and a weak, inverse correlation with insulin initiation self-efficacy. There was a non-significant relationship between coping and insulin initiation self-efficacy (See Table 5).

Table 5

Bivariate Correlations Among Perceived Stress, Coping, and CAI-MDS (self-efficacy)

Variable	1	2	3
1 Perceived Stress	-	.39**	-.21*
2 Coping		-	.10
3 CAI-MDS (self-efficacy)			-

* $p \leq .05$ ** $p \leq .01$

The paired t-test scores of pretest and posttest for coping suggested fewer coping processes were employed posttest, however, this result was not statistically significant (Table 4).

Table 6 presents the bivariate correlations between perceived stress, the 8 subscales of coping and the 2 subscales of the CAI-MDS (insulin initiation self-efficacy). The 8 coping subscales include (a) Confrontive Coping, (b) Distancing, (c) Self-Controlling, (d) Seeking Social Support, (e) Accepting Responsibility, (f) Escape-Avoidance, (g) Planful Problem Solving, and (h) Positive Reappraisal. The 2 subscales of the CAI-MDS are (a) insulin self-efficacy and (b) diet self-efficacy.

Table 6

Posttest Bivariate Correlations Among Perceived Stress, Coping (subscales), and CAI-MDS (insulin initiation self-efficacy subscales)

Variable	1	2	3	4	5	6	7	8	9	10	11
1 Perceived Stress	-	.22*	.25*	.34*	.17	.37*	.44*	.16	.09	-.17	-.19
2 Confrontive Coping		-	.34*	.60*	.46*	.46*	.35*	.54*	.33*	-.01	.03
3 Distancing			-	.55*	.37*	.59*	.38*	.37*	.40*	.13	.05
4 Self-Controlling				-	.40*	.61*	.47*	.57*	.41*	.10	-.01
5 Seeking Social Support					-	.31*	.26*	.50*	.47*	.07	.17
6 Accepting Responsibility						-	.53*	.39*	.44*	.03	-.01
7 Escape-Avoidance							-	.03	.19*	-.11	-.17
8 Planful Problem Solving								-	.49*	.22	.22*
9 Positive Reappraisal									-	.01	.08
10 Insulin Self-Efficacy										-	.55*
11 Diet Self-Efficacy											-

*p = < .05

The mediated regression analysis examined the relationship between perceived stress and CAI-MDS (insulin initiation self-efficacy) with coping as a mediator. Regression analyses demonstrated statistically significant relationships between perceived stress and insulin initiation self-efficacy ($\beta = -0.208, p < .05$), perceived stress and coping ($\beta = 0.390, p < .001$) and perceived stress and coping predicting insulin initiation self-efficacy (see Figure 4). A bias-corrected bootstrap 95% estimate of the confidence interval for the indirect effect of coping (.153) based on 5000 bootstrap samples was entirely above zero (0.023 to 0.281). Since the confidence interval did not include zero, the indirect effect of coping was shown to be a mediator of the relationship between perceived stress and insulin initiation self-efficacy.

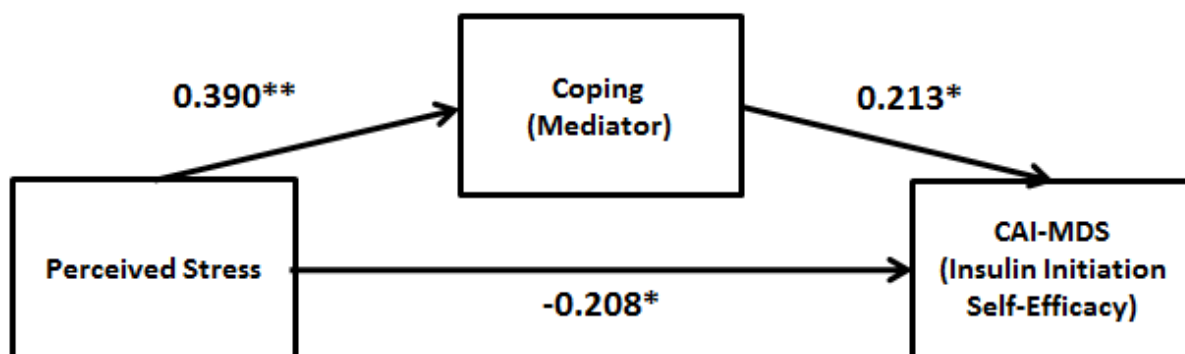


Figure 4 Standardized regression coefficients for the relationship between perceived stress and insulin initiation self-efficacy as mediated by coping.
* $p < .05$ ** $p < .001$

3.6.3 Hypotheses Results

(1) *Effective provision of the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes will assist with decreasing patients' perceived stress.*

Pretest to posttest scores for perceived stress demonstrated a statistically significant decrease therefore this hypothesis was supported.

(2) *Patients with higher levels of perceived stress will have lower confidence in administering insulin and managing diet (insulin initiation self-efficacy).*

The study findings of an inverse, although weak correlation between perceived stress and CAI-MDS (insulin self-efficacy) supported this hypothesis.

(3) *Patients with higher perceived stress will engage more frequently in ways of coping.*

There was a moderately positive correlation between perceived stress and coping which supported this hypothesis.

(4) *Patients with effective ways of coping will have higher confidence in administering insulin and managing diet (insulin initiation self-efficacy).*

The correlation between coping and insulin self-efficacy was non-significant therefore this hypothesis was not supported.

(5) *Coping (ways of coping) is a mediating variable of the perceived stress and initiation of insulin relationship.*

The results of the mediated regression analysis supported this hypothesis.

3.7 Discussion

The first study aim was to examine the relationship between perceived stress and the influence of education guided by the RNAO BPG for the administration of insulin in adults with type 2 diabetes. The findings supported the hypothesis that there would be a significant decrease in participants' stress scores following their two appointments for insulin initiation education at the diabetes education centre (DEC). Perceived stress was inversely related to a participant's insulin initiation self-efficacy i.e. as stress decreased the participant's insulin self-efficacy increased. The improvement in insulin initiation self-efficacy scores was also significant. Researchers have suggested that determining a patient's overall general stress response, as done in this study, may be more beneficial in determining strategies to assist with self-management versus focusing on diabetes distress (Albright, et al., 2001). These findings highlight the need to assess patients individually to determine how stress may impact their learning ability and affect their ability to acquire the skills needed to self-administer insulin effectively.

The second aim of this study was to examine the relationships between perceived stress, ways of coping, and insulin initiation self-efficacy and determine whether coping mediated the relationship between perceived stress and insulin initiation self-efficacy. Findings supported that

perceived stress and coping were significant predictors of insulin initiation self-efficacy which is consistent with the Lazarus and Folkman theoretical framework in this study. Coping was shown to be a mediator of the relationship between stress and insulin initiation self-efficacy. This is consistent with the findings of Lazarus and Folkman who have emphasized that coping mediates any emotions that may be generated during the emotions process (2006). Research in diabetes care has suggested that with training, effective coping skills can be developed and enhanced (Rubin & Peyrot, 1999). Hart and Grindel suggested that coping uniquely accounted for a 9% significant variance in self-care behaviour with higher self-care behaviour resulting in better controlled diabetes (2010). This is an important element of diabetes self-management education as patients need to build a strong foundation of knowledge and skills to carry them over the lifetime of their chronic disease management. Diabetes nurse educators and allied health providers are well positioned to assist patients in the development of coping processes that will result in improved self-care behaviour.

3.7.1 Practical Implications

Research supports the use of a team approach which includes nurse and dietitian diabetes educators. Not all patients will have access to a diabetes education centre as was the situation in this study. With the majority of diabetes management occurring in primary care settings, the integration of a diabetes educator into the primary care team could help to improve patients' ability to self-manage. The results of this study suggest assessment of stress and coping would be beneficial for patients initiating insulin therapy. An awareness of the patient's stress level and coping processes can help tailor the education provided to meet the individual's needs. The use of a short stress survey such as the Perceived Stress Scale can easily and quickly be administered prior to an appointment or education session and can provide useful insight into the patient's stress level. It can also serve to encourage patient self-reflection and dialogue between the patient and educator which allows for exploration of patient questions or concerns. The RAO BPG is an evidence-based guideline that can be applied by healthcare providers with or without speciality knowledge in diabetes. The findings suggest that the use of a best practice guideline can help patients to become self-efficacious with insulin therapy and also help to decrease their stress levels.

3.7.2 Limitations

Convenience sampling limits the generalizability of this study. The use of a control group that did not receive BPG education would have provided a more robust design. The standard of care for diabetes education centres, however, is to provide at least one appointment providing basic education with regard to insulin injection, home glucose monitoring, and potential safety concerns such as hypoglycemia. All of the questionnaires used were self-report which may have influenced participant responses. Patients with diabetes often report self-blame (Karlsen, et al., 2012). If participants struggled with their diabetes self-management, they may have felt the need to provide desirable survey responses.

3.8 Conclusion

The incidence of type 2 diabetes continues to increase exponentially throughout the world (International Diabetes Federation, 2013) and there is strong research evidence for the benefits of glycemic control to minimize the complications of diabetes and improve quality of life (United Kingdom Prospective Diabetes Strategy (UKPDS) Group, 1998). Clinical practice continues to evolve with a move to reduce clinical inertia amongst health care providers regarding the use of insulin therapy. Increasing numbers of patients with diabetes will require insulin therapy to achieve target glycemic control. The holistic approach of nursing lends itself to meeting both the psychological (stress and coping) and physiological (insulin initiation self-efficacy) needs of patients living with diabetes. This study provided evidence that the needs of these patients can be met with structured education through the use of a Best Practice Guideline. Strategies to decrease patient stress and improve coping may help to improve patient self-efficacy with insulin therapy.

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Chapter 4

4 Evaluating the Use of a Best Practice Guideline with Insulin Initiation in Type 2 Diabetes

4.1 Introduction

Providing patient-focused quality care is one of the quintessential tenets of the nursing profession. Nursing practice continues to advance as our knowledge of health and health care provision incorporates new research and enhanced understandings of the needs of those we care for. The movement to evidence-based care gained momentum in the 1990s as clinicians articulated the need for the integration of clinician expertise in combination with systematic clinical research evidence (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). Best practice guidelines (BPGs) are now used in clinical practice to provide healthcare professionals with a synthesis of the research and expert knowledge related to a specific issue or concept. Nelson (2014) examined the concept of best practice in nursing and its increasing presence in the literature noting that the evaluation of best practice guidelines is an area that requires further development. Evaluating best practice guidelines allows healthcare providers to determine the feasibility of implementing the BPG, its potential to influence patient satisfaction, and whether it is cost-effective (Mezey, Fulmer, Abraham, & Zwicker, 2003). In this paper the results are presented of research examining the use of a BPG evaluation tool (Appendix B) with education guided by the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes (Registered Nurses Association of Ontario, 2009).

4.2 Background

The use of evidence-based clinical practice guidelines provides clinicians with tools and resources to assist patients to optimize their health. In 1999, the Registered Nurses Association of Ontario (RNAO) in collaboration with the Ontario Ministry of Health and Long Term Care began a Best Practice Guideline (BPG) development program. To date over 50 BPGs have been developed encompassing a wide variety of clinical subject areas such as diabetes, pain management, and facilitating client-centred learning (Registered Nurses Association of Ontario, 2015). The development of an RNAO BPG is a rigorous process which includes topic selection

by key stakeholders, critical appraisal of the literature by an expert panel, data extraction and draft of BPG recommendations, review of the draft by external stakeholders with subsequent revision of the BPG, and finalization of the BPG and related educational, implementation, and evaluation tools (Virani & Grinspun, 2007). Guidelines are to be reviewed and updated every 3 years or more frequently as necessary. (However, the BPG involved with this study has not been revised since 2009). The final versions of the RNAO BPGs provide recommendations in 4 main areas: clinical practice, aimed at nursing; educational, directed at practice competencies; organizational/policy, directed at the organizational environment to facilitate practice and evaluation/monitoring indicators of the BPG (Registered Nurses Association of Ontario, 2009). Clinical recommendations can be used by nurses and collaboratively with allied health providers to enhance direct patient care.

Numerous organizations such as the AGREE Collaboration, Guidelines International Network, and RNAO champion the evaluation of clinical practice / best practice guidelines (Makarski & Brouwers, 2014; Network., 2002; Registered Nurses Association of Ontario, 2015). The AGREE collaboration, a group of international guideline developers and researchers, developed the AGREE II instrument, to provide a framework to assess clinical practice guideline (CPG) quality (Brouwers et al., 2010). The authors noted that CPGs are relied upon by clinicians to make patient care decisions and can also play an important role in health policy formation and thus must be of high quality to ensure best possible patient care. Uptake of the AGREE instruments has been extensive with translation of the instruments into 33 languages and over 600 article citations which emphasizes the value ascribed to guideline evaluation. Nurse researchers also recognize the critical role guideline evaluation plays and encourage healthcare professionals to carefully consider guideline evaluation in addition to guideline adoption (Graham & Harrison, 2005) .

Type 2 diabetes affects 90% of those people living with diabetes (Centre for Disease Control and Prevention, 2014; Government of Canada, 2013). The challenge for people living with diabetes is to achieve glycemic targets that will help to decrease the probability of developing the devastating complications of the disease. People living with diabetes have a mortality rate of at least twice as high as those without diabetes (Public Health Agency of Canada, 2011a).

Macrovascular complications such as heart attack and stroke and microvascular complications such as retinopathy, nephropathy, and neuropathy can be minimized or avoided with optimal

blood sugar control (Brownrigg et al., 2014; Holman, et al., 2008; Reyden et al., 2013; United Kingdom Prospective Diabetes Strategy (UKPDS) Group, 1998) . Many people, however, have difficulty achieving the recommended glycemic targets. Only 50% of Canadians living with diabetes are reported to have achieved the recommended glycemic targets (Leiter, et al., 2013a). The reasons for this are multifactorial and include psychological aspects, socioeconomic influences, access to care and education, and the progressive nature of diabetes (Canadian Diabetes Association, 2013a).

A challenge for professionals providing diabetes care is to provide patient-focused education within the constraints of a healthcare system that often limits the time available to interact with patients. The psychological aspects of diabetes are well documented and include the phenomena of diabetes distress and psychological insulin resistance. Diabetes distress, disease specific stress related to the burden self-care management of diabetes is established in the literature, as well as the challenges associated with its identification and treatment (Fisher, et al., 2009; Paddison, et al., 2007; Peyrot, et al., 2005; Peyrot, et al., 2006). Psychological insulin resistance is defined as a psychological barrier or opposition to initiation of insulin (Brod, et al., 2009; Gherman, et al., 2011; Polonsky, 2007) and is present in both clinicians and patients. A related concept, clinical inertia is the term used to describe reluctance by healthcare providers to initiate new treatments such as insulin therapy (Brown, et al., 2004; Harris, et al., 2010b; Harris, et al., 2008; Phillips, et al., 2001). Reluctance to initiate insulin often results in prolongation of hyperglycemia which unnecessarily increases the risk of diabetes complications and mortality. Additionally, 95% of diabetes care is self-managed emphasizing the importance of effective, efficient educational interactions (Funnell & Anderson, 2000). The RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes provides an evidence-based, structured resource for nurses caring for patients needing to initiate insulin therapy. This study examines participants' recall of the content of the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes using a BPG evaluation tool developed for this study. This study was derived from a quantitative study examining stress, ways of coping, and insulin initiation self-efficacy (Loft, Forchuk, Kerr, & Harris, 2015).

4.3 Research Purpose

The purpose of this research was to examine participant recall of diabetes education based on the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes when initiating insulin therapy and to examine a BPG evaluation tool developed for this study for use specifically with this RNAO BPG.

The research questions were:

1. “What is the level of participant recall of diabetes education using the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes as evaluated by a novel BPG evaluation tool?”
2. “What is the patient experience of initiating insulin therapy when receiving structured Best Practice Guideline diabetes education?”

The terms recall and retention have similar meanings, however, for this study the term recall was chosen. The term “participant recall” describes more closely the elements of the BPG education that participants remembered. The challenge with using the term retention was the implication that all of the elements of the BPG had been presented by the educators to the participants which might not have occurred.

4.4 Methods

4.4.1 Design and Sample

A pretest / posttest, non-experimental, mixed-methods design utilized one group of participants. A convenience sample was drawn from patients attending one of three independent Diabetes Education Centres in Southwestern Ontario for the initiation of insulin therapy. Participants were adults over the age of 18 with no prior history of injection or insulin therapy. Ethics approval was obtained from the Western University Health Science Research Ethics Board.

Participants were interviewed following two appointments to receive insulin therapy education with the first appointment providing the education to initiate insulin therapy. The second appointment was a follow-up approximately six weeks after the initiation of insulin. During one

to one education sessions, diabetes educators (registered nurses or registered dietitians) provided education which focused on the clinical recommendations of the RNAO BPG. Education sessions ranged from 45 to 90 minutes. Participants were interviewed by a member of the research team in person or by telephone following their six week appointment to complete the RNAO BPG evaluation tool. Three open ended questions were also included during the interview: 1. “Please describe how you felt when you were asked to start using insulin”, 2. “What was the most challenging thing about starting insulin?”, 3. “What made it easier to start using insulin?”. Ethics approval was obtained from the Western University Health Science Research Ethics Board and for each Diabetes Education Centre involved in the research.

4.4.2 Instruments

A Best Practice Guideline evaluation tool was developed for this study to be used with the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes (Registered Nurses Association of Ontario, 2009). Designed to be used during a face to face or telephone interview, it was developed to be consistent with chart audit tools previously developed by the Nursing Best Practice Research Unit (NBPRU) (Edwards et al., 2003). Prior to use in this study, the tool was reviewed and revised by clinical experts working in diabetes. Experts familiar with RNAO BPG development and implementation also reviewed the novel evaluation tool. No changes were recommended by the clinical or BPG experts with respect to the content of the evaluation tool. Revisions were made to ensure clarity of the questions and to ensure each question evaluated a single concept. The tool evaluates participant recall of clinical practice recommendations from the RNAO BPG for the Subcutaneous Administration of Insulin Adults with Type 2 Diabetes, for example, “Did the educator assess stressors about insulin initiation with the patient? Was the patient asked to set a goal for the education session?”. There are 22 items with a yes or no response with yes = 1 point, no = 0 points. Scores can range from 0 to 22. Higher scores reflect higher recall of this study’s RNAO BPG content by the participant.

4.4.3 Analysis

Descriptive statistics and the reliability score of the BPG evaluation tool were obtained using the IBM SPSS Statistics v. 22 (IBM., 2013). The level of participant recall of the content of the BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes was

evaluated by determining participants' total score obtained with the evaluation tool developed for this study.

Qualitative data from the open-ended questions included on the BPG evaluation tool were transcribed verbatim during the interview. Using the approach described by Hsieh and Shannon (2005) a conventional content analysis approach was undertaken. Content analysis offers a flexible approach to extend knowledge of the human health experience. Participant responses were analyzed and coded to enable a deductive analysis and determine categories of participant responses. Exemplars from each category were selected to provide further insight into participant experience with insulin initiation and BPG education.

4.5 Results

A final sample size of $n = 105$ was obtained from participants who completed the two DEC appointments and the BPG evaluation interview. (Table 1)

Demographics

Table 1: Demographics of final sample ($n = 105$) (Loft, et al., 2015)

Demographic	Frequency	%
Sex		
Female	47	45
Male	58	55
Marital Status		
Single	6	6
Married	71	68
Divorced/Separated	21	20
Widowed	7	7
Education		
Elementary School	11	11
High School	44	42

College	30		28
University	19		18
Insulin Regimen			
Basal (Once daily)	84		80
Multiple Daily Injections	21		20
	<i>range</i>	<i>mean</i>	<i>SD</i>
Age (yrs)	25-86	62	10.73
Duration with Diabetes (yrs)	0-36	11.6	7.74

4.5.1 BPG Evaluation Tool

The Cronbach's alpha an estimate of the internal consistency for the BPG evaluation tool was calculated to be 0.57. Removing the first item of the tool, "Did the educator ask you about your beliefs about insulin therapy?" increased the Cronbach's alpha to 0.70 which is considered an acceptable internal consistency. Final analysis was therefore done with the first item removed from the original BPG evaluation tool leaving a total of 21 items in the final scale.

The mean score on the Best Practice Evaluation tool to assess participant recall of the BPG content was 16.7 (SD = 2.19) resulting from a possible maximum score of 21. The frequency scores of patient recollection of the BPG content reviewed during their appointments are summarized in Table 6.

Table 6

Best Practice Guideline response frequency

BPG Question Summary	Frequency	%
(N = 105)	(yes)	(yes)
Did your educator		
ask you to set a goal for your education session?	27	26
provide basic nutrition information?	105	100

Insulin preparation and administration

review your type of insulin?	103	98
review the action of your insulin?	101	96
review the stability of your insulin?	101	96
review the storage of your insulin?	102	97
review the compatibility of your insulin?	99	94
review injection technique?	100	100
review sharps disposal?	100	100

Self-monitoring of blood glucose (SMBG)

review the frequency of blood glucose testing?	104	99
review the recommended targets for blood glucose?	104	100
review how to verify meter accuracy?	83	79
review SMBG technique?	104	99

Hypoglycemia education

review how to prevent hypoglycemia?	101	96
review how to recognize hypoglycemia?	102	97
review how to treat hypoglycemia?	102	97
ask if family members were aware of hypoglycemia treatment?	94	90

Sick Day Management

review blood glucose monitoring during periods of illness?	57	54
ask you when you should seek healthcare assistance?	62	59
review use of easily digested carbohydrates?	30	29
review how to prevent dehydration?	27	26

The majority of BPG items were recalled by greater than 90% of the participants. Items related to sick day management, meter accuracy, and patient goal setting were recalled at noticeably lower rates (26-59%).

4.5.2 Participant Interviews

Participants' responses to the open ended questions asked following their second appointment were analyzed. Three distinct categories emerged: 1. Psychological Insulin Resistance, 2. Insulin Therapy Preconceptions, and 3. Educational Impact. Interview lengths ranged between 6 and 16 minutes which included the completion of the BPG Evaluation Tool. In total, 98 participants provided responses to the open-ended questions with 7 participants preferring not to respond.

4.5.3 Psychological Insulin Resistance (PIR)

The majority of patients described some element of PIR - the psychological barrier or opposition to initiation of insulin (Brod, et al., 2009; Gherman, et al., 2011; Polonsky, et al., 2011). Participant responses were consistent with previous research which identified emotional elements such as anxiety, depression, fear of needles or injection pain, and the belief that diabetes is worsening as barriers to insulin initiation (Gherman, et al., 2011).

Describing his reaction to the need to initiate insulin therapy, a 72 year old male who had been living with diabetes for 14 years responded,

“Another step down into the basement. I felt like it was the end of the road. I'm gonna be dead. Sticking a needle into me was the worst fear. But now I realize that I should have gone on insulin years ago. I just didn't think I could do the needle.”

Similarly, a 49 year old male with a 2 year history of diabetes commented,

“I saw it as a "no turning back" kind of thing. Insulin seemed like a death nail, it's for life. This stuff messes with your head. It's like you're going down a path of unhealthiness. Now, injecting the insulin is not a big deal.”

4.5.4 Insulin Therapy Preconceptions

Many patients appeared to have a lack of knowledge related to the current methodologies for insulin therapy. Their understanding of insulin therapy was often based on the experience of others who had started insulin therapy prior to the newer modalities now available.

Misconceptions regarding insulin therapy have been identified in the literature with some patients attributing such things as heart attack, amputation, and blindness as resulting from the use of insulin (Karter et al., 2010).

“It wasn't good. I didn't know about all the new needles. My sister had diabetes and she had long needles and she had to boil them. It was so much work.” (62 year old female with 1 month history of diabetes)

“I was very nervous and unsure about it. The impact is pretty good that it (insulin) is working. I wondered about the needle and how painful it would be. It's kind of mind over matter. It's not anywhere near as bad as when my father was a diabetic - that was why I thought it was so terrible. He had to boil his needles and everything. But once you see that it's just a pen, it's really quite easy.” (66 year old male with 14 year history of diabetes).

4.5.5 Educational Impact

The impact of RNAO BPG education could be seen in comments that expressed a negative response to the need to begin insulin therapy but suggested a positive opinion of the education that was received.

“No way! I hated needles. I've gotten enough control over it now. I realize that I have to be on the insulin. I've been avoiding it for years. I just hated the thoughts of being diabetic and being on insulin made it real that I was a diabetic. The education has helped. I know it's ok to be diabetic.” (56 year old male with 5 year history of diabetes)

“I didn't really want to. At first he kept saying lose some weight but I just couldn't. It came down to the point where he said ‘You better be on insulin’ now I know it's so easy. The needles are so small and they don't even hurt. The needles. I just didn't like the word - needles. The educators were very knowledgeable. That's very good.”(70 year old female with 14 year history of diabetes)

No negative comments regarding the BPG education were expressed by participants in this study. Comments by participants did not identify any specific educational elements of the BPG referring to the education as a more global experience. Participants appeared to value their

interaction with the diabetes healthcare providers, and often contrasted current knowledge with past preconceptions.

“I was diagnosed 28 years ago. My doctor took me aside and said that I would one day need insulin. I was terrified though. I didn't sleep at all before coming in (for this appointment). I feel a lot more secure. The educators 28 years ago put the fear of God in you. You're going to be dead. This time it was all about them listening to me. I felt like I was heard.” (58 year old male with 28 year history diabetes)

“Support from the diabetes education doctors and nurses. They have a very good education program.”(44 year old male with 6 year history of diabetes)

4.6 Discussion

There was effective provision of the RNAO BPG with the average score (16.71 out of 21) from the evaluation tool indicating that 80% of the RNAO BPG content was recalled by participants as having been discussed during their appointments. Previous evaluations of RNAO BPG have included the evaluation levels recommended by Kirkpatrick and Kirkpatrick (2007). Level 1- Reaction, relates to the degree of participant satisfaction with the education, Level 2 – Learning, relates to the degree to which participants gain the intended knowledge, skills, attitudes and confidence, Level 3- Behavior – relates to the degree to which participants and staff apply what has been learned and Level 4 – Results- relates to targeted patient outcomes. This study provided Level 2 results reporting patient knowledge gained through the use of the RNAO BPG. In the related intervention study by Loft et al. (2015) which examined stress and insulin initiation self-efficacy prior to and following the RNAO BPG guided education, there was a statistically significant decrease in participants' stress scores. Additionally, there was a statistically significant increase in participants' insulin therapy self-efficacy scores. Both the BPG evaluation tool findings and participant interview responses support the positive impact of the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes.

The BPG evaluation tool results revealed, however, that items associated with sick day management were not recalled as consistently as other elements of the BPG. Study design did not allow for identification of the cause of this deficit (i.e. not communicated effectively by educators or reduced uptake by participants). This is an important area for further research.

Although sick day management may not occur frequently, it is essential for a patient to have the recall knowledge to manage sick day issues when they arise. If patients are unable to self-adjust insulin dosing or prevent dehydration, medical intervention may be required leading to utilization of their primary care provider or potentially urgent emergency room access.

Participant inclusion in goal setting for the education sessions also demonstrated low recall with only 26% of the participants recalling the opportunity to set a goal for their insulin initiation education. In order to truly provide patient-centred care it is important to fully engage the patient in shared decision-making. Patient-directed goal setting reflects one of the essential elements of motivational interviewing (MI) which is a concept that has become one of the preferred approaches in chronic disease management and is particularly relevant in diabetes (Kalra, Kalra, & Batra, 2010; Levich, 2011). Motivational interviewing, as defined by Rollnick and Miller (1995), is a directive, client-centred counseling style aimed at promoting behavior change in clients as they resolve their ambivalence. Motivational interviewing in Type 2 diabetes has been shown to be a more effective approach for improving patient self-management (Li, Li, Shi, & Gao, 2014), to improve depressive symptoms and time spent exercising in American Indians (Calhoun et al., 2010), and was preferred over standard care in a qualitative study with focus groups in family practice clinics (Dellasega, Tiangco, & Gabbay, 2012). This finding from the BPG evaluation tool highlights a key area for improvement in patient-centred diabetes education, reminding nurses and interprofessional team members to fully engage their patients to increase patient engagement and success.

This was the first use of this newly developed BPG evaluation tool for this RNAO Best Practice Guideline. Three items of the tool showed no variance and could be deleted. These related to whether insulin injection, disposal of needles or syringes, and basic nutrition information were reviewed during the education sessions. Further revision and evaluation of the tool would be beneficial for future research and to compare diverse BPGs.

The participant interview qualitative responses were consistent with the current literature with respect to psychological insulin resistance. Preconceptions and misconceptions regarding insulin are also common in the literature, particularly in patients who are reluctant or refuse to initiate insulin therapy (Polinski et al., 2013). Although PIR is well recognized the challenge has been to find a mechanism to readily identify it and then work to minimize it. It is difficult to

generalize strategies to decrease PIR as strategies need to be tailored to the unique needs of the patient. The participant responses in this study support the findings of Polonski et al. (2013) who suggested that once patients become familiar with insulin therapy it becomes much less of a barrier.

4.7 Limitations

The Canadian Diabetes Association clinical practice guidelines and the RNAO BPG endorse the need for patient education with the initiation of insulin. Given these recommendations, the study design did not include a control group that did not receive insulin initiation education. A control group would have offered a more robust design for this research. Convenience sampling increases the likelihood of participant bias and decreases the generalizability of these findings. Study design did not include an instrument to assess the provision of the BPG by the diabetes educators. The BPG evaluation interview was not an in-depth interview which limited the depth of the qualitative analysis possible. Participant responses to the open-ended questions on the BPG evaluation tool were manually transcribed during the interviews which limited the quantity of data that could be collected. The primary researcher was directly involved with the majority of data collection. The BPG itself has not been revised since 2009 which introduces the risk that clinical best practices have likely evolved since the BPG introduction.

4.8 Conclusion

The BPG evaluation tool developed for use with the RNAO BPG for the Subcutaneous use of Insulin in Adults with Type 2 Diabetes was effective in this study and requires only a short time to administer. Participants' preconceived ideas or previous exposure to insulin therapy, through that of a friend or relative, identified a knowledge deficit related to the current insulin therapy modalities available today. The participant interview responses reinforce the need for early patient education regarding the pharmacologic agents, including insulin, used to manage diabetes. Ideally, education should begin at the time of a patient's diabetes diagnosis with insulin being presented as just one of the options available and not used as a threat or in a treat to failure approach. Patients need to have a clear understanding of the relative ease with which insulin therapy can be incorporated into an active, healthy lifestyle. Nurses, in collaboration with the interprofessional team, need to ensure that patients do not experience unnecessary

anxiety or stress related to an obsolete understanding of how insulin therapy is provided today. The results from this study provided evidence that the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes can be an effective tool in the provision of insulin initiation education.

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Chapter 5

5. Discussion

This final chapter is a summary of the research findings with a discussion of implications and recommendations for future research. The purpose of this dissertation was to examine perceived stress and coping in adults with Type 2 diabetes who initiated insulin therapy after receiving an education intervention guided by a Best Practice Guideline (BPG). The research questions were: (a) What is the relationship between perceived stress and diabetes education guided by the Registered Nurses Association of Ontario (RNAO) BPG for the Subcutaneous Administration of Insulin in Adult with Type 2 Diabetes who initiate insulin therapy? (b) What is the relationship between perceived stress, ways of coping and the initiation of insulin therapy in adults with Type 2 diabetes? (c) What is the level of participant recall of diabetes education using the RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes as evaluated by a novel BPG evaluation tool? and (d) What is the patient experience of initiating insulin therapy when receiving structured Best Practice Guideline diabetes education?" It was hypothesized that effective provision of the RNAO BPG would reduce patient stress and that patients with higher levels of stress would have lower confidence with insulin therapy self-efficacy. Related to coping, it was hypothesized that patients with higher stress levels would enact ineffective coping and that patients with effective coping would have higher confidence with insulin therapy self-efficacy. Finally, coping was hypothesized to be a mediating variable in the relationship between stress and insulin therapy self-efficacy.

5.1 Key Findings

5.1.1 Stress

The findings demonstrated a statistically and clinically significant decrease in patient stress after receiving the RNAO BPG education. There was a moderate, positive correlation between stress and coping indicating that as stress increased patients needed to enact additional coping processes. There was an inverse correlation between stress and insulin therapy self-efficacy, indicating stress decreased as participants became more self-efficacious with their insulin therapy, however, the correlation was weak ($r = -.21$).

5.1.2 Coping

Although coping scores decreased from pretest to posttest, which would reflect a decreased need to enact coping processes, the decrease was not statistically significant. As well, the correlation between coping and insulin therapy self-efficacy was non-significant. Coping is a multidimensional construct with Lazarus and Folkman identifying eight different types of coping processes (Lazarus & Folkman, 1984). The coping processes are categorized as either problem-focused or emotion-focused coping. It is important to note that Lazarus stresses that neither type of coping process is inherently better than the other and that the environmental context will influence the coping processes used (Lazarus, 2006). Problem-focused processes include positive reappraisal, planful problem solving, accepting responsibility, and seeking social support. Emotion-focused coping strategies include distancing, self-controlling, confrontive-coping, and escape-avoidance (Lazarus & Folkman, 1984). The complexity and multidimensionality of coping may have made it difficult to demonstrate a difference between pretest and posttest scores.

Of interest, however, is the finding that coping did mediate the relationship between stress and insulin therapy self-efficacy. How an individual chooses to cope in a given situation is fluid and changes with a person's appraisal of the situation and the environmental context. Lindley and Noble-Walker (1993) noted that a mediator variable often represents a process that is intrinsic to an individual. Lazarus and Folkman suggested that coping is a mediator and emphasized that coping mediates any emotions that are generated by the emotions process (Folkman & Lazarus, 1988; Lazarus, 2006). The addition of an instrument to further assess a participant's emotional state would have provided data for a more thorough statistical analysis of correlations and analysis of variance between the study variables of coping, stress, and self-efficacy.

5.1.3 Best Practice Guidelines

The BPG evaluation tool indicated the participants recalled the majority of the RNAO BPG content that was presented to them. Asked to describe their feelings when initiating insulin therapy, the majority of participant responses reflected the findings in the literature seen with psychological insulin resistance such as fear, reluctance, disappointment and self-blame (Krall et al., 2015; Peyrot, et al., 2005). It was encouraging that after receiving the RNAO BPG education

that participant responses indicated satisfaction with the education process and that insulin self-efficacy scores also increased.

Two areas that were not recalled adequately by participants included BPG content related to sick day management and patient-directed goal setting. Sick day management is an essential element of diabetes self-care management. Although patients may not experience illness with a high frequency, having the knowledge to effectively manage insulin dosing, prevent dehydration, and knowing how to modify dietary intake could prevent the need to access higher acuity healthcare services. Therefore it is important that patients have a strategy in place to access sick day management information when necessary. Healthcare providers should provide patients with resources in the form of printed materials or web-based information to access should they become ill. Patients should also be encouraged to speak with their pharmacist about their medications. Having patients provide a verbal confirmation to the question, “What would you do if you were sick and couldn’t take your insulin?” will allow care providers to assess if patients have a good understanding of what they need to do should they become ill.

The low rate of participant recall of being asked to set a goal for their education session is cause for concern. Critical for engaging patients in their diabetes self-management is the need to employ counseling approaches, such as motivational interviewing, which encourages patients to self-direct their care. Motivational interviewing has been shown to be a more effective approach for improving self-management in patients with Type 2 diabetes than traditional educational approaches (Li, et al., 2014). To ensure patients feel engaged in the education process, putting their education goals in writing or perhaps having them verify their goal as it is entered into their health record can be of benefit. For healthcare providers using electronic health records, the use of mandatory reporting fields that call for patient-driven goals to be entered can prompt providers to ensure goal-setting is reviewed.

5.2 Implications and Future Research

The findings of this study provided clear evidence that there is more work that needs to be done to improve the patient experience for adults with Type 2 diabetes initiating insulin therapy. The use of a Best Practice Guideline that can assist with structured education has been shown in this study to decrease patient stress and improve insulin initiation self-efficacy. The task now is to

integrate the use of a BPG into primary care practice settings where the majority of diabetes clinical management occurs. In Canada, patients with diabetes have 1.42 times as many visits to primary care than patients without diabetes (Greiver et al., 2013). Improvements into the provision of insulin initiation education will require changes on several levels.

At the macro level, funding for primary care must be sufficient to allow family practice settings to have access to adequate human resources such as nurses with diabetes expertise. Adequate clinic time must also be available to provide diabetes education, particularly for patients needing to initiate insulin. As the prevalence of diabetes continues to grow, the numbers of patients requiring insulin therapy will also continue to grow. The healthcare system must be able to accommodate the needs of patients initiating insulin therapy to ensure that they feel confident to effectively manage their insulin therapy which should lead to improved glycemic control and the minimization of diabetes complications.

At the healthcare provider level, psychological insulin resistance (PIR) is well recognized in the literature in the form of clinical inertia. Some clinicians do not feel confident that their patient will be able to cope emotionally with insulin therapy or be able to acquire the skills necessary to safely manage insulin therapy. Others cite lack of time and resources to teach insulin therapy. Despite educational efforts to assist healthcare providers to confidently prescribe and initiate insulin, it is evident that some reluctance remains (Krall, et al., 2015). Unfortunately, the paradigm of using patients' fear of insulin as a leveraging agent to target weight loss and dietary compliance also continues to be an issue. As clinicians become more confident with initiating insulin therapy and motivational interviewing becomes a standard approach for patient counselling, it is hopeful that using the "threat" of insulin will no longer be an issue.

It is possible that the elevated stress level that participants experienced prior to initiating insulin therapy included some element of self-blame or feelings of failure when insulin became necessary to control their diabetes. It will require continued reinforcement, by providers with insulin therapy expertise, to promote the need for insulin therapy education at the outset of a patient's journey with diabetes and that insulin is presented in a positive light.

At the patient level, the presence of psychological insulin resistance (PIR) has also been well researched. The majority of participants in this study described some element of PIR during the short interview component including such emotional elements as anxiety, depression, and fear of

needles. Further research is necessary, however, to explore specific strategies and educational modalities to decrease PIR concepts such as injection phobia, needle phobia, fear of weight gain, hypoglycemia, and lifestyle accommodations (Larkin et al., 2008; Nam, et al., 2011).

Misconceptions and preconceptions regarding insulin therapy were clearly demonstrated in this study. Many researchers have recommended introducing the concept of insulin therapy at the outset or early into a patient's journey with diabetes. Reluctance to the early introduction of the concept of insulin therapy is found both in clinician and patient populations who would benefit from further research to provide evidence of its benefit and promote adoption of early insulin education as the norm in diabetes education and practice.

The ubiquitous nature of diabetes provides a strong case for increasing the awareness of diabetes management including insulin therapy to a broader audience than just those living with diabetes. As evidenced in this study, patients clearly listen to the narratives of their friends and family. Indeed, research has shown that it is the information received from family and friends that is often valued more highly than that received from healthcare professionals. Educating the general public about the advances in diabetes management and insulin therapy at health fairs, in print media such as popular magazines, electronic media, or social media may help to dispel some of the misconceptions present today.

Future research to extend upon the findings of this study should be done in primary care settings such as family health teams or Nurse-Practitioner Led clinics where the majority of diabetes management actually occurs versus the specialized environment of the Diabetes Education Centres. This would also allow for further exploration of the impact of the Best Practice Guideline when utilized by providers not specialized in diabetes care. Further study needs to be undertaken exploring coping processes in patients on insulin therapy, examining the relationship between coping and glycemic control. Is there a difference in glycemic control between patients who enact effective coping processes versus patients who do not? A qualitative study that provides a more in-depth examination of the patient experience of the education process during transition to insulin therapy would illuminate our understanding of the patient experience identifying possible gaps education or clinical care. An intervention study that provided alternative methods for decreasing stress when initiating insulin therapy such as guided meditation, peer to peer support, or use of technology such as smartphone application may help to identify which strategies are more effective in reducing diabetes-related stress.

5.2.1 Implications for Nursing

Nurses are ideally positioned to advocate for, educate, and assist patients transitioning to insulin therapy. With a presence in primary care, ambulatory care, acute care, and long term care nurses have multiple contact points with patients and their families to dispel misconceptions of insulin therapy. As direct care providers, nurses can advocate for the use of best practice guidelines and the use of assessment tools to ensure patients receive patient-focused education. The use of a brief stress screening tool or coping tool can help to tailor the diabetes education patients require and ease the transition to insulin therapy. Nurse researchers should continue to explore opportunities to improve the patient experience of transitioning to insulin therapy including the influences of stress and coping as patients work to achieve insulin self-management.

5.3 Conclusions

Much has changed in the 94 years since the discovery of insulin. From purified beef and pork insulin to human insulin analogs, from long, thick gauged needles to tiny, thin-walled pen tip needles, the physical aspects of insulin therapy have advanced to the point where insulin pumps can now deliver subcutaneous insulin in a pattern that mimics the normal human pancreas. It is the psychological aspect of insulin therapy, however, that often prevent patients from achieving optimal glycemic control. Stress and coping can be improved with structured Best Practice Guideline education as evidenced by the findings of this study. For adults with Type 2 diabetes, initiating insulin therapy can be a stressful experience but as Lazarus (2006) noted, from such an experience can come reorganization of life in ways that leave a person more productive, engaged and satisfied. Nurses and healthcare professionals have an important role in helping patients to achieve such a result.

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Appendix A



**Western
Research**

Research Ethics

Use of Human Participants - Ethics Approval Notice

Principal Investigator: Dr. Cheryl Forchuk
File Number: 103640
Review Level: Delegated
Approved Local Adult Participants: 113
Approved Local Minor Participants: 0
Protocol Title: An Examination of Perceived Stress and Ways of Coping in Adults with Type 2 Diabetes Who Initiate Insulin Therapy
Department & Institution: Health Sciences\Nursing, Western University
Sponsor:
Ethics Approval Date: April 19, 2013 **Expiry Date:** November 30, 2014
Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Instruments	Best Practice Guideline Evaluation Tool	2013/02/13
Instruments	The Confidence in Administering Insulin and Managing Diet Scale (CAI MDS)	2013/02/13
Instruments	Ways of Coping Questionnaire	2013/02/13
	Consent	2013/02/10
Western University Protocol		2013/03/11
Letter of Information	LOI revised as requested and version date added	2013/04/11
Instruments	PSS revised to remove NAME	2013/04/11

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Ethics Officer to Contact for Further Information

Janice Sutherland	Grace Kelly	Shantel Walcott
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Western University, Research, Support Services Bldg., Rm. 5150
 London, ON, Canada N6A 3K7 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/services/ethics



**Western
Research**

Research Ethics

Use of Human Participants - Revision Ethics Approval Notice

Principal Investigator: Dr. Cheryl Forchuk
 File Number: 103640
 Review Level: Delegated
 Protocol Title: An Examination of Perceived Stress and Ways of Coping in Adults with Type 2 Diabetes Who Initiate Insulin Therapy
 Department & Institution: Health Sciences \ Nursing, Western University
 Sponsor:
 Ethics Approval Date: January 27, 2014 Expiry Date: November 30, 2014
 Documents Reviewed & Approved & Documents Received for Information:

Document Name	Comments	Version Date
Instruments	Nursing BPG Evaluation tool revised to add 3 qualitative questions	2013/06/03
Revised Letter of Information & Consent		2013/12/16
Revised Western University Protocol	(received Jan.26/14) Addition of Chatham-Kent Health Alliance Diabetes Education Centre and Middlesex Health Alliance Diabetes Education Centre	

This is to notify you that The University of Western Ontario Research Ethics Board for Health Sciences Research Involving Human Subjects (HSREB) which is organized and operates according to the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans and the Health Canada/ICH Good Clinical Practice Practices: Consolidated Guidelines; and the applicable laws and regulations of Ontario has reviewed and granted approval to the above referenced revision(s) or amendment(s) on the approval date noted above. The membership of this REB also complies with the membership requirements for REB's as defined in Division 5 of the Food and Drug Regulations.

The ethics approval for this study shall remain valid until the expiry date noted above assuming timely and acceptable responses to the HSREB's periodic requests for surveillance and monitoring information. If you require an updated approval notice prior to that time you must request it using the University of Western Ontario Updated Approval Request Form.

Members of the HSREB who are named as investigators in research studies, or declare a conflict of interest, do not participate in discussion related to, nor vote on, such studies when they are presented to the HSREB.

The Chair of the HSREB is Dr. Joseph Gilbert. The HSREB is registered with the U.S. Department of Health & Human Services under the IRR registration number IRB 00000940.

Ethics Officer to Contact for Further Information

<input type="checkbox"/> Erina Baerle	<input type="checkbox"/> Grace Kelly	<input type="checkbox"/> Mina Mekhail	<input checked="" type="checkbox"/> Vikki Tran
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This is an official document. Please retain the original in your files.

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 London, ON, Canada N6A 3K7 t. 519.661.3036 f. 519.850.2466 www.uwo.ca/research/services/ethics

Appendix B

RNAO Nursing Best Practice Guideline for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes Interview Evaluation Tool

Education Audit

Client Eligibility Criteria (all eligibility criteria must be met to proceed)

- Adults over 18 years of age
- Diagnosis of Type 2 diabetes
- Patient has received education by a diabetes educator at an organization that uses RNAO BPG for the Subcutaneous Administration of Insulin in Adults with Type 2 Diabetes

Patient Identification: _____

Date Data Collected: _____

Organization / Site Data Collected from: _____

Data Collector's Initials: _____

Patient Age: _____

Patient highest level of education: _____

Gender: _____

Duration of diabetes: _____

Diabetes regimen: _____

Please describe how you felt when you were asked to start using insulin.

What was the most challenging thing about starting insulin?

What made it easier to start using insulin?

1. Did your educator ask you about your beliefs about insulin therapy?

	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------
2. Did your educator ask you to set a goal for the education session?

	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------
3. Did your educator review:

a. the type(s) of insulin you are taking?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. how the insulin works in your body?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. how long the insulin can be kept at room temperature?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. how to store your insulin?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
e. if your insulin is compatible with other insulins?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
f. how to inject your insulin?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
g. how to safely dispose of your needles or syringes?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Did your educator review these topics related to Self Monitoring of Blood Glucose (SMBG):

a. how often to test your blood sugar?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. what the recommended blood sugar targets are?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. how to ensure your meter is accurate?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. how to apply blood to the test strip?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Did you receive basic nutrition information?

	<input type="checkbox"/> Yes	<input type="checkbox"/> No
--	------------------------------	-----------------------------
6. Did your educator review these topics related to hypoglycemia (low blood sugar):

a. how to prevent low blood sugar?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. the symptoms of low blood sugar?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. how to treat low blood sugar ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. teach your family or support members how to help if you have low blood sugar?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
7. Did your educator review these items related to sick day management:

a. checking your blood sugar every 4 to 8 hours when ill?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. adjusting your insulin dose when you are ill?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. knowing when to be seen by a healthcare provider?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. using easily digested / liquid carbohydrates if can't tolerate solid food?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
e. how to prevent dehydration?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Appendix C

Participant Letter of Information and Consent

Study Title: An Examination of Perceived Stress and Ways of Coping in Adult Patients Who Initiate Insulin Therapy

Principal Investigator: **Maureen Loft, NP, M.Sc.N., CDE** (maloft@uwo.ca)

Faculty Supervisor: **Dr. Cheryl Forchuk, RN, PhD, Associate Director Nursing Research**
Western University, Arthur Labatt Family School of Nursing (cforchuk@uwo.ca)

Introduction:

In order to achieve the best blood sugar control, patients with type 2 diabetes may be started on insulin. Research has previously shown that patients respond differently and have different coping strategies when starting insulin therapy.

The purpose of this letter is to provide you with the information that you require to make an informed decision about participating in this research. This letter contains important information that you should understand about why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is not clear or there are words or phrases that you do not understand.

What is the purpose of the research?

The purpose of this research is to examine the relationships between perceived stress, ways of coping, and education that is guided by a best practice guideline.

What does participation in the survey involve?

If you agree to participate in the study you will be asked to complete 3 questionnaires during your two appointments with the education centre. One questionnaire will ask you questions about your stress level. Another questionnaire will ask you about your ways of coping with different situations. The third questionnaire will ask you about your confidence in giving yourself an injection and managing your diet. The questionnaires will be completed during your regularly scheduled visits to the Diabetes Education Center. The surveys will take approximately 20 minutes to complete. All of your responses and health information will be anonymous and kept confidential.

Who can be in the study?

Patients who are 18 years of age or older, speak and understand English, have type 2 diabetes and are beginning or have recently begun insulin therapy may be asked to participate. Patients cannot participate in the study if they have previously used insulin therapy or are unable to complete the surveys.

If you decide to participate, you will be asked to sign an informed consent form.

What are the possible risks?

There are no known risks involved in participating in this study. There is a small risk that some questions may cause you to experience emotional discomfort or distress. Should you wish to end your participation in the study you may do so without providing a reason and your care will not be affected. Your primary care caregiver or Endocrinologist will continue to be available to assist you.

What are the possible benefits?

Information provided by this study may be used by diabetes healthcare providers to improve education that they provide to people with diabetes. It may assist healthcare providers to help patients develop strategies for coping with their diabetes. You may not benefit directly although completing the questionnaires may provide you with the opportunity to reflect on your personal diabetes self-management and factors that influence it.

What is the cost of participating in the study?

There is no direct cost to you for participating in the study. You will be providing your time to complete the questionnaires.

Will I be reimbursed for participating in the study?

You will not be paid to complete the surveys.

Your rights:

Participation in the study is voluntary. You can refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. You have the right to be given all the important information about the study and what you will be asked to do. You should only agree to participate in the study if you are satisfied and feel comfortable that you know enough about the study. The study investigator may withdraw you from the study if your continued participation could impair your health.

You do not waive any legal rights by signing the consent form.

How will confidentiality be maintained?

This study has been reviewed and approved by the Research Ethics Board for Health Sciences Research involving Human Subjects at the University of Western Ontario. Your research records will be kept confidential and stored in a locked cabinet in a secure office. If the study results are published, your name will not be used and no information that identifies you will be released or published without your explicit consent. Your confidentiality will be respected. However, it is important to note that the original signed research consent form and the data

which will follow will be included in your health record. Representatives of the research team, ethics review board, or regulatory bodies, such as Health Canada, may require access to your records for the purpose of monitoring the research.

All information collected during the study will be stored until the completion of the study and the findings have been released. Your personal information will be destroyed within one year after the study is complete. Electronic data and paper based data sheets and analysis will be kept secured and destroyed through shredding or deletion and file removal ten years after publication of the study results.

Who do I contact if I have a question about the study?

If you have any questions about this research study please feel free to contact:

Maureen Loft, NP, M.Sc.N., PhD student

If you have any questions regarding your rights as a study participant, or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute.

Thank-you for your interest in this study.

Consent form: Study Title: **An Examination of Perceived Stress and Ways of Coping in Adult Patients Who Initiate Insulin Therapy**

I have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction. I have received a copy of the patient information and consent form for this study.

Name of Participant _____

Signature of Participant _____

Name of person obtaining consent _____

Signature of person obtaining consent _____

Date _____

Appendix D

Perceived Stress Scale

The questions in this scale ask you about your feelings and thoughts **during the last month**. In each case, you will be asked to indicate by circling *how often* you felt or thought a certain way.

Name _____ Date _____

Age _____ Gender (Circle): **M** **F** Other _____

0 = Never 1 = Almost Never 2 = Sometimes 3 = Fairly Often 4 = Very Often

- | | | | | | |
|---|---|---|---|---|---|
| 1. In the last month, how often have you been upset because of something that happened unexpectedly?..... | 0 | 1 | 2 | 3 | 4 |
| 2. In the last month, how often have you felt that you were unable to control the important things in your life?..... | 0 | 1 | 2 | 3 | 4 |
| 3. In the last month, how often have you felt nervous and "stressed"? | 0 | 1 | 2 | 3 | 4 |
| 4. In the last month, how often have you felt confident about your ability to handle your personal problems?..... | 0 | 1 | 2 | 3 | 4 |
| 5. In the last month, how often have you felt that things were going your way?..... | 0 | 1 | 2 | 3 | 4 |
| 6. In the last month, how often have you found that you could not cope with all the things that you had to do? | 0 | 1 | 2 | 3 | 4 |
| 7. In the last month, how often have you been able to control irritations in your life?..... | 0 | 1 | 2 | 3 | 4 |
| 8. In the last month, how often have you felt that you were on top of things?..... | 0 | 1 | 2 | 3 | 4 |
| 9. In the last month, how often have you been angered because of things that were outside of your control? | 0 | 1 | 2 | 3 | 4 |
| 10. In the last month, how often have you felt difficulties were piling up so high that you could not overcome them?..... | 0 | 1 | 2 | 3 | 4 |

Please feel free to use the *Perceived Stress Scale* for your research. The PSS Manual is in the process of development, please let us know if you are interested in contributing.

Mind Garden, Inc.

References

The PSS Scale is reprinted with permission of the American Sociological Association, from Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior*, 24, 386-396.

Appendix E

Appendix A: The Confidence in Administering Insulin and Managing Diet Scale (CAI MDS)

Listed on the following two pages are different situations and activities relating to diet and insulin management.

Section A: How confident do you feel with doing these activities related to your insulin treatment?

Please circle only one answer for each question using the following scale:

NA - Not Applicable
 1 - Not at all confident
 2 - Not very confident
 3 - Moderately confident
 4 - Very confident
 5 - Extremely confident

1. Preparing a dose of insulin by myself	NA	1	2	3	4	5
2. Giving myself an insulin injection	NA	1	2	3	4	5
3. Safely disposing of used needles or syringes	NA	1	2	3	4	5
4. Doing a blood sugar test with a meter	NA	1	2	3	4	5
5. Testing my blood sugar as often as recommended by my nurse/doctor	NA	1	2	3	4	5
6. Knowing what to do if my blood sugar is high	NA	1	2	3	4	5
7. Knowing what to do if my blood sugar is low	NA	1	2	3	4	5
8. Monitoring my blood sugar more often when I have a bad cold or flu	NA	1	2	3	4	5
9. Following instructions from my nurse/doctor on caring for myself when I am sick with a bad cold or flu	NA	1	2	3	4	5
10. Preventing low blood sugar (hypo-glycemia)	NA	1	2	3	4	5
11. Recognizing when my blood sugar is low	NA	1	2	3	4	5
12. Knowing when to contact my doctor or health care team for assistance	NA	1	2	3	4	5

Section B: How confident do you feel with doing these activities based on dietary advice given to you by a health professional for your diabetes?

Please circle only one answer for each question using the following scale:

NA - Not Applicable
 1 - Not at all confident
 2 - Not very confident
 3 - Moderately confident
 4 - Very confident
 5 - Extremely confident

13. Making healthy food choices when eating in <u>familiar</u> places	NA	1	2	3	4	5
14. Making healthy food choices when eating in <u>unfamiliar</u> places	NA	1	2	3	4	5
15. Making healthy food choices with people who don't know I have diabetes ³	NA	1	2	3	4	5
16. Choosing from recommended snack foods when I want to have a snack	NA	1	2	3	4	5
17. Choosing foods from different food groups	NA	1	2	3	4	5
18. Spacing meals apart as recommended	NA	1	2	3	4	5
19. Reducing fat content as recommended	NA	1	2	3	4	5
20. Reducing sweets	NA	1	2	3	4	5
21. Eating the recommended amount of starchy foods	NA	1	2	3	4	5

Curriculum Vitae

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**Post-secondary
Education and
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Belleville, Ontario, Canada
1984-1986 Nursing Diploma

The University of Western Ontario
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1996-1999, B.Sc.N.

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London, Ontario, Canada
1999-2001, M.Sc.N.

The University of Toronto,
Toronto, Ontario, Canada
2001-2002, Acute Care Nurse Practitioner Diploma

Western University, Canada
London, Ontario, Canada
2008-2015, Ph.D.

**Honours and
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Best Practice Guideline PhD Fellowship
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Dr. D. and Z. Meltzer Nursing Professional Development Award 2004
Awarded funds based on excellence in support of education

Excellence in Innovation and Evidence-Based Practice 2003
St. Joseph's Health Care London

Dr. Robert Salter Award, 2003
Recognizes research in orthopaedic nursing
Canadian Orthopaedic Nurses Association

Medical Research Council of Canada,
Research Trainee Award, 2000

Board of Governor's Award 1986
Belleville General Hospital

Related Teaching Experience: Adjunct Assistant Professor
Arthur Labatt Family School of Nursing
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Research Mentor
MN/NP student research practicum
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Guest Lecturer for
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Arthur Labatt Family School of Nursing
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Teaching Assistant, 1st year students
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2009

Related Work Experience: April 2015 to present
NP/CNS Medical/ Surgical/Diabetes
Strathroy Hospital

Principle Site Investigator
“A Client-Driven Intervention to Support Self-Management among
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2013 to present
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NP/CNS Diabetes and Endocrinology
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NP/CNS Orthopaedics
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Oral Presentations:**2010-2015****Abstract**

- **Loft, M.,** Forchuk, C., Ray, S., Kerr, M. & Harris, S. *Stress and Coping in Patients with Type 2 Diabetes Starting Insulin*, American Association of Nurse Practitioners National Conference, New Orleans, LA. June 2015.
- **Loft, M.,** Forchuk, C., Ray, S., Kerr, M. & Harris, S. *Perceived Stress and Ways of Coping in Adults with Type 2 Diabetes who Initiate Insulin Therapy*. Iota Omicron Annual Research Conference, London, ON, May 2014
- **Loft, M.** *Tips to Optimize Your Diabetes Self-Management*, Diabetes London Community Presentation, London, ON, April 2012.
- **Loft, M.** *Perceived Stress and Ways of Coping in Patients with Type 2 Diabetes Who Begin Insulin Therapy*, London Regional Advance Practice Nurses 14th Annual Retreat, London, ON, April 2011
- **Loft, M.,** Syrovy, J., Dukes, S., Kidnie, S. *Preadmission Shoulder Education*. International Collaboration of Orthopaedic Nurses Conference, Dublin, Ireland, September 2010

Oral Presentations:**2010-2015****Invited**

- **Loft, M.** Retiring with Strong Minds. Western University Outreach Lecture Series. *Stress and Coping in Patients with Type 2 Diabetes who Start Insulin Therapy*, London, ON, April 2014.
- **Loft, M.** Community Presentation – Riverbend Retirement Community, *Diabetes Self-Management*, London, ON, April 2014
- **Loft, M.** London Regional Advance Practice 15th Annual Conference, *Diabetes Update: Jeopardy*, London, ON, April 2012
- **Loft, M.** Geriatric Interdisciplinary Grand Rounds, SJHC London Region, *Diabetes Update: Considerations in the Elderly Population*, London, ON, February 2012
- **Loft, M.** Best Practice Spotlight Organization SJHC Champion Open House, *The Use of Best Practice Guidelines and Clinical Research*, London, ON, October 2011

Poster Presentations:**2010-2015**

Loft, M., Yakobchuk, H., Hurley, D. *Evaluation of a Best Practice Guideline for Patients with Type 2 Diabetes Using Insulin*. Canadian Diabetes Association / Canadian Society of Endocrinology and Metabolism Conference, Montreal, PQ, October 2013.

Loft, M. *Diabetes Update: Caring For Your Orthopaedic Patient with Diabetes*, National Association of Orthopaedic Nurses Congress, San Antonio, TX, May 2013.

Loft, M., Syrovy, J. *Pre-Admission Total Shoulder Arthroplasty Education Program: Lessons Learned*. J. National Association of Orthopaedic Nurses Congress, San Antonio, TX, May 2013

Loft, M., Forchuk, C. *Perceived Stress and Ways of Coping in Adults with Type 2 Diabetes Receiving Education Guided by a RNAO Best Practice Guideline.* STTI – Iota Omicron 25th Annual Nursing Research Conference, London, ON, May 2012

Publications:

Loft, M. , McWilliam, C., Ward-Griffin, C. 2003. Patient Empowerment after Total Hip and Knee Replacement. *Orthopedic Nursing*, 22 (1), 42 – 47.