

DIABETIC SUPPORT GROUP OR GROUP INTERVENTION FOR ADOLESCENCE WITH
TYPE 1 DIABETES

A Research Grant Proposal

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in

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by

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Preface

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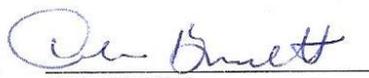
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Abstract
of
DIABETIC SUPPORT GROUP OR GROUP INTERVENTION FOR ADOLESCENCE WITH
TYPE 1 DIABETES

by

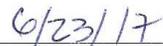
Lorraine Assumma

Type 1 diabetes (T1D) is a chronic condition that is increasing worldwide and it accounts for five to ten percent of all diagnosed cases in the U.S. (NIDDK, 2013). Living with a severe chronic disease such as T1D requires continuous maintenance of the disease to prevent associated complications. Diabetes affects quality of life (QOL) and as QOL diminishes, so does adherence. Adolescents and especially early adolescence are vulnerable during this stage of development. During this difficult time metabolic controls and self-management decline significantly impacting QOL. Everyday management is intensive and can be a very complex and challenging for most adolescence, as they often are not ready to handle the demands to self-manage diabetes on their own. There is limited support outside the hospital and clinical area for youths with T1D and their caregiver. Support groups with group interventions focusing on psychosocial issues and diabetic management can provide support to adolescents and their caregivers during this vulnerable time. Research has identified that providing continued support to adolescents with T1D and their families can improve quality of life.

Sources of Data

The pilot study research design will be a single group pre-test/post-test descriptive design to compare metabolic controls (HbA1c) and PedsQL Diabetes, pre and post support group or group intervention for adolescence with T1D.


_____, Committee Chair
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Date

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Table of Contents

Preface	iii
Abstract.....	v
Acknowledgements.....	vi
List of Tables	ix
List of Figures.....	x
1. INTRODUCTION	1
Background and Significance.....	1
The Problem	4
Purpose of the Research	5
Implications for Nursing Practice/Policy/Research.....	5
Research Variables	6
Theoretical Framework.....	6
2. LITERATURE REVIEW	8
Introduction	8
Major Variables Defined	14
Summary.....	15
3. METHODOLOGY	17
Introduction	17
Research Question	18
Hypothesis	18
Identification of Setting	18
Research Design	19
Population, Sample Method and Sample Size.....	19
Measurement Methods	21
Data Collection Process.....	23
Coding and Scoring	24
Data Analysis.....	24
Bias	24
Ethical Considerations	25
Summary.....	25
4. GRANT ELEMENTS.....	26
Potential grants (feasibility of each).....	26
Selected Grant.....	26
Budget.....	30
Timeline.....	33
Plan for dissemination of findings.....	34
References.....	36

Appendix A: Example Curriculum.....	40
Appendix B: Informed Assent.....	41
Appendix C: Informed Consent.....	42
Appendix D: PedsQL questionnaire (Sample)	43
Appendix E: Detailed Budget (PHS 398).....	45
Appendix F: IRB Application.....	47

List of Tables

Table 1: <i>Complications associated with diabetes</i>	26
Table 2: <i>Two-year timeline</i>	33

List of Figures

Figure 1: *Self-Efficacy Framework*..... 7

CHAPTER ONE: INTRODUCTION

Background and Significance

Type 1 diabetes (T1D) is one of the most prevalent chronic diseases and the incidence is on the rise. It is estimated in the United States (U.S.) that there are up to three million individuals diagnosed with T1D (Chiang, J., Kirkman, M., Laffel, L., & Peters, A., 2014; Juvenile Diabetes Research Foundation, 2014). The incidence of T1D has been increasing by two to five percent worldwide, and it is estimated that T1D accounts for five to ten percent of all diagnosed cases in the U.S. (National Institute of Diabetes and Digestive and Kidney Disease, 2013). The incidence of newly diagnosed T1D, in those under the age of 20 was estimated to be 18,436 in 2009, in the United States (CDC, National Diabetes Statistical Report 2014). Type 1 diabetes is more common in non-Hispanic whites 1.5-2 times compared with other groups, and sixty percent are under the age of eighteen when diagnosed (CDC, 2014; Golden, A., Thomas, D., & Porter, B. 2015, p.876).

Living with the chronicity of T1D requires continuous maintenance to prevent associated complications. Everyday management of T1D is intensive and demanding, requiring frequent monitoring of blood glucose level, diet control of carbohydrate counting, and multiple daily insulin administration either by injection or infusion pump, depending on individual activity and diet regimes. The fine balance needed to manage diabetes and maintain a near normal glycemic controls can be especially challenging and stressful for an adolescent who is also dealing with multiple psychosocial and physiological developmental issues as well. Diabetes affects QOL; and as QOL diminishes, the risk for psychosocial problems such as depression and anxiety increases, especially in early adolescence (Grey, et al., 2009; Grey et al., 2013). As psychosocial

problems increase, adherence decreases and metabolic controls worsen (Mackey, E., Hilliard, Berger, S., Stresisand, R., Chen, R., & Holmes, C., 2011), impacting quality of life.

The term adolescence describes the teenage years between thirteen and nineteen as the individual is transitioning into adulthood. The obvious differences noted between a thirteen-year-old and a nineteen-year-old have necessitates a further breakdown of adolescence into early (11-15) and late (16-19). Early adolescence with its unique developmental and psychosocial attributes can be an important and difficult period for diabetic care, because metabolic controls and self-management decline significantly during this vulnerable time (Mackey et al., 2011). According to Piaget's theory of cognitive development, early adolescence is the period where youths are developing abstract thinking, or formal operations. As they transition from the concrete operational stage, "concrete thinking," their ability to think about future problems or consequences is still developing. Therefore, early adolescents may not associate out of range metabolic controls with short-term or long-term health complications. At this developmental stage, adolescents may have mastered direct diabetic management skills such as blood glucose monitoring or insulin administration, but they are still dealing with the emotional and social aspects of adolescence; therefore, indirect behavioral skills such as coping skills, stress management or problem solving may benefit them and provide useful tools (Abualula et al., 2016). Additionally, Erikson's developmental stages, defines adolescence as a transition into adulthood. Adolescents are experiencing identity versus role confusion, are becoming more independent and beginning to explore their environment as they seek to form their own identity. During this period, adolescents' have a desire for increased autonomy so they turn away from parental advice and they are highly influenced by their peers. The resistance towards parental

input combined with peer pressure, can negatively influence their decision making; which in turn can affect metabolic controls and overall poor medical adherence (Céspedes-Knadle, Y. M., & Muñoz, C. E., 2011). Lastly, hormonal changes during puberty influence metabolic demands and insulin sensitivity and the intensive and daily management of T1D can be intrusive to an adolescent's schedule and activities of daily living; affecting their sense of control and adherence to diabetic management (Céspedes-Knadle et al., 2011). When the added stress of a chronic disease like T1D is added to the typical challenges faced by adolescents, the culminating result can have a detrimental effect on their psychological wellbeing and sense of control (Sparapani, V., Jacob, E., & Castanheira Nascimento, L., 2015).

The American Diabetic Association (ADA), recommends a glycosylated hemoglobin (HgbA1C) less than 7.5 percent, to be achieved without excessive hypoglycemia, in those 18 years of age or younger with T1D (ADA, 2014). To achieve recommended HgbA1C levels less than 7.5 percent, youths have routine quarterly visits with their medical providers. During the routine visits with their provider, medical adherence includes reviewing and evaluating HgbA1C levels, diabetic management of diet, and insulin needs. The primary focus is on medical adherence or direct interventions, there is little focus or support of psychosocial concern. Psychosocial wellness of the individual is equally important in medical adherence (Abualula, Jacobsen, Milligan, Rodan & Conn, 2016). Abualula et al. (2016) discuss the significant in implementing indirect interventions such as problem solving, coping skills, and conflict resolution in addition to direct interventions (diabetic management) to improve QOL and manage metabolic controls.

Additional factors which may impact support for youth with type 1 diabetes and their caregivers are accessible resource for diabetic management and psychosocial wellness within their community. Many providers are located within the hospital or clinical facility where the individuals obtain quarterly visits, and for many families this involves a lengthy commute up to an hour or greater. Support groups or group interventions such as psychosocial interventions are not available at all provider locations, so depending on the location of the provider, support resources differ. Lastly, support groups or group interventions are lacking within local communities for adolescence with T1D and their caregivers; to assist them in functioning with everyday management and psychosocial issues. Furthermore, research is lacking in the area of diabetic management and psychosocial interventions outside of the hospital or clinical setting for adolescence with T1D. Providing support groups or group interventions for type 1 diabetics within their respective community, is an attempt towards proving interventions locally, to improve QOL and possibly decrease metabolic controls.

The Problem

Adolescence is a time of great physical and psychological changes and is considered to be a transitional stage from childhood to adulthood. Even for the most well-adjusted adolescent, this transitional period can highlight issues of self-identity and independence. Adolescents face increasing academic and social demands and the added complexities of self-management for T1D can be too much to handle without appropriate support. Metabolic control of T1D often worsens as a result of the complexities surrounding the psychosocial and physiologic period of adolescence.

T1D management is complex and can be very challenging for most adolescence, as they often are not ready to handle the demands of self-management on their own, yet they often don't want parental involvement. Typically, during this time of adolescence, there begins a transfer of responsibility from parent to adolescent. However, sometimes this transfer happens prematurely, before the adolescent is ready, and this contributes to poor metabolic controls and self-management. Currently, there is limited support outside the hospital and clinical area for youths with T1D and their caregiver. Therefore, there is a need for a diabetic support group or group interventions outside the hospital and preferably within a community setting. This would be an attempt to bridge the gap between hospital and community, while providing the continuum of support to youth living with T1D and their caregivers. Research has identified that providing continued support to adolescents with T1D and their families can improve quality of life. However, the research for improving glycemic controls has been inconclusive. There has been no published research proving information regarding support group or group interventions for T1D in the community setting, outside of hospital or clinical setting for adolescence.

Purpose of the Research

The purpose of this research is to identify if there is a difference in metabolic controls and quality of life perception for middle school adolescence (ages eleven to fifteen) who have T1D after the exposure to a diabetic support group or group intervention in a community setting.

Implications for Nursing Practice/Policy/Research

The implications for the advanced practice nurse (APRN) extends beyond managing individual glycemic control, APRNs are in a position to facilitate in group interventions, manage metabolic controls through the collaboration with all stakeholders to support optimal diabetic

care. In this role, the APRN has the potential to promote and enhance the quality of life for youths diagnosed with diabetes. Future nursing research examining the impact of support systems in the community setting, affecting QOL and metabolic controls is needed.

Additionally, there is a need for future research in the area of development of ongoing individual and group education supporting and expanding knowledge and expertise on ways to improve QOL in adolescents with T1D.

Research Variables

The dependent variables in this study are the metabolic controls, as calculated by laboratory results and the Pediatric Quality of Life (PedsQL) Inventory Module 3.0 version (for T1D) (Varni, J.W., 1998). The independent variable explored is the diabetic support group or group intervention within a community setting, consisting of ten group meetings. Further described in chapter three.

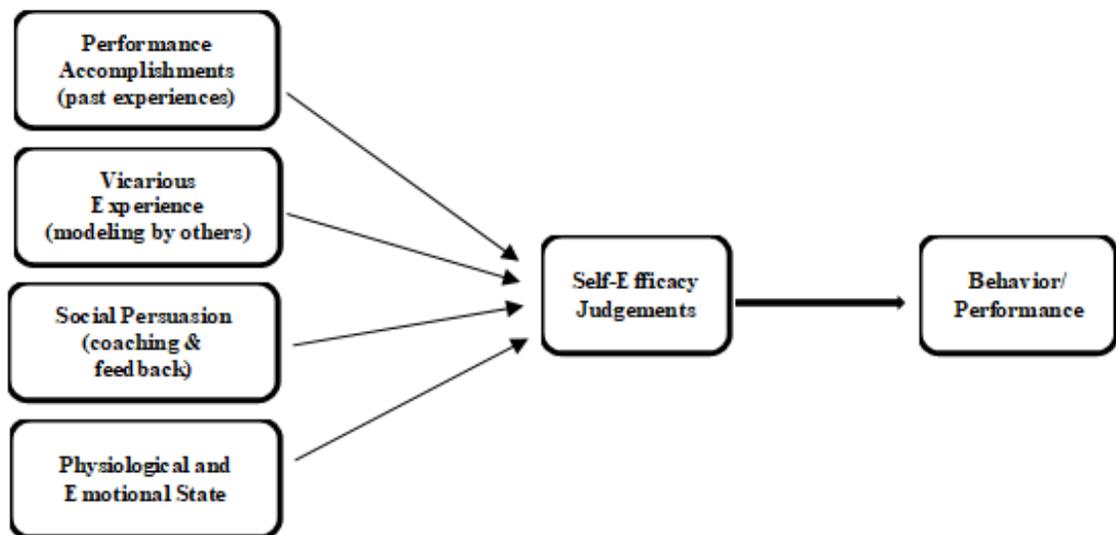
Theoretical Framework

To guide the implementation of a diabetic support group intervention, Bandura's Self-efficacy theoretical framework was chosen for this study. Derived from the social cognitive theory and the triad of person-behavior-environment interaction as a reciprocal in determinism, individual's will choose how to behave. The assumption that individuals have influence over what they do is the core to the self-efficacy theory (Resnick, 2013).

According to Bandera (1982), one's self-efficacy judgement is based on four areas: 1) mastery experiences, 2) vicarious experiences, 3) social persuasion, and 4) physiological feedback. The most influential of self-efficacy is the mastery experience. As individuals engage in task or activities they develop beliefs about their capabilities and accomplishments to engage

in subsequent task. The repetitiveness in task or activity accomplishment strengthens the mastery of experiences. The experience of observing another person perform a similar task or activity successfully (modeling) is a form of vicarious experience and promotes self-efficacy. Verbal persuasion from others communicating that a task or activity can be accomplished (feedback) and the individual has the capability to accomplish a given task or activity will develop the individuals' ability to change attitudes. Physiological indicators like stress, anxiety and mood have influence on self-efficacy and are important in relation to coping with stressors, health functioning and physical accomplishments (Resnick, 2013). The four informational sources from Bandera's Self-efficacy will be used to guide the implementation of the diabetic support group or group intervention used for this study.

Figure 1: *Self-Efficacy Framework*



Sources of Self-Efficacy Information

CHAPTER TWO: LITERATURE REVIEW

Introduction

The databases reviewed for this study included CINAHL Plus, PsycINFO, and Google scholar. Literature search terms included for research were support groups, group interventions, quality of life, QOL and diabetes. The search was limited to English, academic journal articles published after 2008. There were 31 articles reviewed for this topic, 19 were relevant, however when the search criteria were further narrowed to adolescent age group and T1D only five journal articles were applicable. The remaining journals focused on information for young adults or older adults, with type 2 diabetes or not related.

This research was focused on journal articles which demonstrated a difference in metabolic controls and/or QOL questionnaires after the implementation of a group intervention or support. Studies in group interventions were sparse, and there were limited studies within an individual's community or home and there was no school-based research for T1D support groups or group interventions outside of the hospital or clinic. This identifies a gap in the literature on continuity of care between hospital or clinic and community for adolescents with T1D.

Abualula et al. (2016), systematic review identified 560 articles of which fourteen were selected based on inclusion criteria: 1) target age group eleven to twenty-one, 2) diagnoses of T1D greater than six months, 3) measurement of QOL, and 4) valid QOL assessment scales. The fourteen articles were dated from 1999 through 2014, and five of the articles were published after 2010. The systematic review identified four studies that rated strong using random control trials, however one was dated 2007. Of the fourteen studies, three had greater than 300 participants while the others ranged between 19 to 116 participants. The population age group varied ranging

from eleven to twenty-one, only one study included 11-14, four studies 11-16, two studies 13-17, the remaining 12-20, 12-18 and 13-17. Six were conducted within the community or in the patients' home, however five of the six studies were dated prior to 2008. Two were conducted in a hospital or outpatient and six did not report the setting. The main purpose of the systematic review was to identify characteristics of effective diabetes self-management education (DSME) interventions and the effects on QOL after an intervention in adolescents with T1D. Six studied used direct and indirect interventions, while eight utilized indirect interventions. Direct behavioral skills focused on specific task including blood glucose monitoring, carbohydrate counting, insulin administration, ketone monitoring, etc.; while indirect interventions concentrated on problem solving, coping skills, stress management and negotiation skills. Four of the fourteen studies had significant QOL outcomes. All studies with improved QOL identified direct and indirect behavior skills. Specifically, within the four studies which had significant QOL outcomes, indirect behavioral skills were composed of at least coping strategies and stress management. However, there was one study which only implemented indirect interventions for social or emotional issues (problem solving, coping skills, conflict resolution) which demonstrated improved QOL. Therefore, implementing both direct and indirect behavior skills would benefit adolescents for improved QOL. Limitations in the systematic review, recognized the difficulty assessing the wide range of interventions and lack of measurement standardization; thus making it difficult to evaluate the impact of interventions when comparing studies. Additionally, age range varied, most studies included subsets of different age groups, and there was a lack of studies within the early adolescent population. Lastly, there was a lack of

diversity, only one study was conducted in a lower socioeconomic area, decreasing generalizability for QOL in ethnic or low socioeconomic groups Abualula et al., (2016).

Grey et al. (2009), described the effects of a coping skills training (CST) intervention in school-age children with T1D. Coping skills training is based on the social cognitive theory and the “goal of CST is to increase competence and mastery,” by “practicing and rehearsing new behaviors,” to enhance self-efficacy (p.406). Coping skills training consisted of communication skills, social problem solving, conflict resolution, stress management, and self-talk. “Children with type 1 diabetes are at risk for negative psychosocial and physiological outcomes, particularly as they enter adolescence,” (p.405). In addition, those who have a premature transfer of responsibility for diabetic task from parents to youth have poor adherence to metabolic controls. The purpose of this study was to determine the effects of a group-based CST intervention for school age children nine-twelve years of age with T1D and their parents. The randomized study consisted of a two-group experimental design n=53 CST with general education (GE) group and n=20 GE. General education was the usual clinical intervention. Data was collected at one, three, six and twelve months. Measurements were metabolic controls, quality of life, depressive symptoms, coping, self-efficacy, and family functioning. Psychosocial variables for youths at twelve months changed over time for both groups QOL. Although there was no statistical significance between groups over time, both groups displayed significance over time. Limitations to this study was a lack of variability in socioeconomic status (participants were predominately of middle to upper income), small sample size, baseline metabolic controls and psychosocial adjustment were good at baseline. Therefore, “improvement may be difficult to demonstrate in a population with good physiological and psychosocial adjustment, such as the

current sample, however, equivalence or lack of decline over time may be equally important,” (p. 415). Additionally, this was a study completed with school-age children nine to twelve years old. Previous research has discussed the relationship between age and metabolic controls; younger children generally have more parental involvement, therefore HbA1c levels are within near normal range (Grey et al., 2009).

Further study with CST and internet psycho-education program by Grey, et al., (2013), investigated the efficacy of two groups again with youths transitioning to adolescence. The study was a multisite randomized clinical trial of 320 youths, eleven to fourteen years old, and two internet based interactive interventions (TeenCope and Managing Diabetes). TeenCope consisted of CST (communication skills, social problem solving, stress management, positive self-talk and conflict resolution) and both interventions were for five weeks. In addition, individuals were permitted to accomplish both intervention if interested. Primary outcomes were metabolic controls and QOL data was collected at baseline, three, six, and twelve months with follow-up data at eighteen months. Overall both group results indicated improvement over twelve months, however no significant differences between the two groups with metabolic controls and QOL. There was significance improvement in those who completed both intervention n=128, compared to those only completing one intervention. Completing both interventions lengthened the program from twelve to eighteen months. The results suggested that youths require both sets of skills managing diabetes and CST to successfully transition to adolescence. In addition, the effect of longer contact (more exposure) for longer period of time may also influence transition for better self-management and self-efficacy. The results did not identify if the actual intervention or duration of intervention improved results. Lastly, the

utilization of an internet platform represents an efficient way to reach youths and to standardize program content (p.2475). Limitations to this study involved not having a highly diverse sample with low-income youth, “low-income youths were more likely to passively refuse to participate after consent than those from higher-income families” (p.2481). Their sample was biased towards adolescence with better metabolic controls, as previous studies have indicated a correlation with low-income and higher HbA1c levels (p.2481).

Kichler, Marik, Kaugars, Nabors and Alemzaden (2013), research study evaluated peer and family groups using the Kicking in Diabetes Support (K.I.D.S) Program developed by Opiari-Arriigan and colleagues (2005). Their specific aim was to identify if the K.I.D.S. Project interventions had impact or improvement on psychosocial adjustment and diabetic management among adolescence with T1D and their families. The study included n=30 adolescents, thirteen to seventeen, with T1D and their parents from a large Midwestern hospital, in an outpatient mental health clinic. Standardize measurement tools for psychosocial and diabetes were utilized, specifically the Pediatric QOL for diabetes scale (PedsQL), given at baseline, post treatment and four month’s post treatment. Metabolic controls were obtained from participant’s medical records. The study did not reveal any statistically significant changes in metabolic control values, however levels did remain stable or decreased slightly overtime. There were some improvements over time (four months’ post-treatment) that were significant in parent-reported diabetic-specific QOL and parent/youth-reported increase parent involvement regarding diabetes responsibility. As this study is consistent with existing literature, it demonstrates improvements with other modifiable diabetic related factors for individuals and family. Limitations to this study was its small sample size (pilot study). The changes found overtime cannot be determined

if the intervention influenced the change or the change just coincided with the intervention. Additionally, there was a high attrition in the WLC group compared to the treatment group, impacting generalizability (Kichler et al., 2013).

According to Hilliard, Holmes, Chen, Maher, Robinson and Streisand (2013), the aim for this research study was to examine the association among glycemic controls, diabetes management, parental monitoring and family conflict. Participants $n=257$, ages eleven to fourteen years of age and their parents (one parent per family). This was a RCT from two mid-Atlantic children's hospitals. The control group received diabetes information and the treatment group received diabetes information and behavioral interventions; both groups received this information in conjunction with their quarterly diabetes clinic visit over the course of one to one and one half years. Data was collected at baseline and during the clinical visits, by chart review and multiple instruments regarding diabetes self-care, parental monitoring, and family conflict. Demographic and medical data was also collected and analyzed. Using descriptive analysis, the conclusion of this study revealed "elevated family conflict and less parental monitoring are risk factors for poorer glycemic controls, and diabetes self-care is one mediator linking these variables," (pg. 1). They suggest interventions promoting parental involvement or parental monitoring of diabetes management during early adolescence may be a beneficial strategy to decrease family conflict (Hilliard et al., 2013).

Cespedes-Knadle et al. (2011), discuss the development of a group intervention for teens with T1D using the Teen Power model developed by Children's Hospital Los Angeles University Center for Excellence in Developmental Disabilities, and a parallel caregiver support group. "The group intervention is designed to improve psychosocial functioning and medical

adherence in teen participants and to reduce diabetes-specific stress in caregivers,” (p.278). The team intervention is a collaboration of psychology, medicine, nursing, social work and nutrition. The curriculum addresses the unique needs of diabetic teens incorporating process and skill based activities, and other components identified which are “linked to positive metabolic outcomes and improved psychosocial adjustment in diabetic teens,” (p.280). The components of the curriculum include peer and family involvement, psychoeducation, stress management, and self-monitoring (Attachment A). The program has been in existence for ten years at Children’s Hospital Los Angeles and many families have benefited from their successful program. However conclusive research has not been provided since the original proposal of the Teen Power model (Cespedes-Knadle, et al., 2011).

Major Variables Defined

Metabolic controls (glycemic controls, HbA1c). Metabolic controls are defined as quantitative analysis to observe a statistical difference between pre-and post-test after the implementation of an intervention. Near-normal glycemic controls can postpone or prevent long-term complications of diabetes. According to research the adolescent period has been associated with poor metabolic control (Abualula et al., 2016; Grey et al., 2009; Grey et al., 2013). Metabolic controls are often used as a measure, however there are other factors that affect HbA1c to include hormones, stress, duration of diabetes, and other medical illnesses (Gaston, A. M., Cottrell, D. J., & Fullen, T., 2012).

Group Intervention. An intervention is any action designed to bring about change in an individual. Group intervention is bringing together several individuals to take part in direct or indirect intervention aimed at helping them adjust or handle long-lasting problem.

Psychosocial. Psychosocial approach looks at the uniqueness of the individuals and the combined influence that psychological factors and surrounding environment have on their mental, socio-emotional, and physical wellness and their ability to function.

Quality of Life. Quality of life encompasses psychosocial, emotional, functional and physical well-being (Abualula et al., 2016). “Quality of life can be defined as to the extent certain desirable factors are attained or retained” (Psychology Dictionary). The enhancement of QOL is important for individuals who suffer from chronic diseases.

Self-management. Management of or by oneself; the taking of responsibility for one’s own behavior and well-being.

Transfer of Responsibility. The optimal transferring of responsibility “is the ongoing process in which the responsibility gradually moves from the parent to the adolescent,” as described by Olinder, Nyhlin, & Smide, (2011), (p.1553). Or as Hanna and Decker (2010) describe it as a process of measuring and assessing the amount of independence.

Family Conflict. Be incompatible or at variance; to clash. Increase family conflict and decrease parental monitoring are risk factors for poor glycemic controls (Hilliard et al., 2013).

Summary

The literature has identified the need to provide youths and caregivers with support interventions during the adolescent time, as metabolic controls deteriorate during this unstable time due to many variables. Common variables discussed above impact self-management. Self-management can be a very complex and challenging undertaking for most adolescence, as they often are not ready or mature to handle the full responsibilities to self-manage their diabetes (Céspedes-Knadle et al., 2011; Grey, et al., 2009). Secondly, the premature transfer of

responsibility from parent to youth and less parental monitoring of adolescents' self-care decreases adherence, causing increase family conflict and poorer diabetes outcome (Hilliard et al., 2013). Additionally, adolescents desire for increase autonomy and peer pressure influence their decision making and affect psychosocial well-being, metabolic controls and overall poor medical adherence (Grey et al, 2009; Céspedes-Knadle et al., 2011), thus impacting QOL.

A review of the literature found several studies which focused on group interventions but did not specify and there is not an identified one approach that is more effective than another. There was a clear distinction that both psychosocial and diabetic skills management interventions are needed to improve QOL and maintain glycemic controls. Standards of care recommended by the ADA, which guide health care professionals to care for Type 1 diabetics and there are National Standards for Diabetes Self-Management Education (DSME) which are designed to support educators to provide evidence-based education and self-management support. This allows providers and health care professionals to develop curriculum based on individual needs and the environment they live in (Haas et al., 2012).

With the recommendations of the ADA and utilizing the DSME national standards health care professionals are able to develop T1D curriculum pertinent to individual needs within their respective community. Since there is no recommended group intervention for adolescence with T1D in the community setting, the development of a curriculum is needed or the use of existing curriculum should be explored. Teen Power group intervention warrants further exploration to see if it is feasible for the implementation as a diabetic group intervention for the proposed research study. Additionally, Teen Power intervention was derived considering needs of the Latino population and its "curriculum includes interventions in Spanish by bilingual/bicultural

leaders to eliminate language barriers, allowing caregivers to openly communicate culturally driven beliefs about chronic illness, diabetes, and parenting in their native language” (Cespedes-Knadle et al., 2011, p.289). Research has identified the need for psychosocial support and diabetic education for youths who have T1D. Together they can provide the needed tools for adolescents to have greater self-efficacy or judgement in making the right choices, especially when posed with difficult situations, thus preventing future complications associated with diabetes (Table 1).

CHAPTER THREE: METHODOLOGY

Introduction

The objective of this pilot study is to illustrate the development of a support group or group intervention for adolescence with T1D and their caregivers. The intention is to develop and implement a similar intervention as Teen Power (prior approval will be obtained prior to use), which was developed to improve medical adherence in adolescents with T1D, by “promoting psychosocial adjustment, eliminating psychological barriers associated with poor diabetes management, and reducing diabetes specific stress in caregivers” (Cespedes-Knadle et al., 2011, p.280). Components of this group intervention will consist of diabetes management, family and youth involvement, self-monitoring, goal setting/problem solving, stress management, nutrition, school and peer issues (see attachment C). The Self-Efficacy Theory will provide the framework for the support group or group intervention. The support group will allow parents and adolescents to meet other families coping with T1D, hopefully develop relationships and learn new skills and coping mechanisms to promote positive health outcomes. This platform will provide the needed parent and peer support for students and families who live

with the chronic disease of T1D or care for an adolescent with T1D. The support group or group intervention is in addition to medical treatment, which youths with T1D attend every three months from their provider. The group will be comprised of an adolescent group and a caregiver group. The group will meet once a week for ten consecutive weeks and will begin with a meal preparation, allowing youths and caregivers to have unstructured time (30 minutes) and engage in diabetes management behaviors together. Following the mealtime, both groups would meet separately (90 minutes) and follow structured curriculum.

Research Question

The research question is “Does a diabetic support group or group intervention for adolescence (eleven to fifteen years of age) with Type 1 Diabetes (T1D) statistically change (decrease) metabolic controls (HbA1c) and improve Quality of Life (QoL) for middle school adolescence?”

Hypothesis

There will be a difference in hemoglobin A1C levels (decrease) and Quality of Life (QoL) (increase) after participation in a diabetic support group or group intervention for middle school adolescence (eleven to fifteen years of age) with T1D.

Identification of Setting

The setting for this pilot study research will be a community-based support group or group intervention, outside of the hospital or clinical setting. All T1D students enrolled in a Riverside County Public School District in Southern California will be invited to attend. There are twenty-four primary and secondary schools within this school district. The support group intervention will be completed within a community setting and after school hours.

Research Design

For this pilot study, the research design will be a single group pre-test/post-test descriptive design to compare metabolic controls (HbA1c) and PedsQL Diabetes Module 3.0 version for adolescence with T1D pre-and post-support group or group intervention. The rationale for the pre-test/post-test descriptive design is to observe if there is a change in QOL after an intervention. Additionally, we would compare HbA1c values to identify if the values maintained (did not get worse) or if they actually decreased, as research has indicated metabolic controls did not consistently decrease (Grey et al., 2009; Grey et al., 2013; Kichler et al., 2013). This will be a two-year pilot study. The two-year study will be needed to obtain the minimum number of participants.

Population, Sample Method and Sample Size

Population. Population demographics for this district includes enrollment of 22,346 for school-year 2015-2016 as of December 4, 2015. Racial demographics included for the 2012-2013, school year identify the largest group as Hispanic or Latino 54% (11,953), White 34.3% (7,598), Black 4.5% (1,001), and Asian 2.1% (462), Pacific Islander 0.5% (116), Filipino 0.6% (135), American Indian 0.6% (123) and other 3.4% (749). The percentage of student on federal reduce and free lunch program for school-year 2015-2016, is 62% (13,762). Additionally, there are sixty-three students documented to have T1D in this district, and most require supervision by a licensed nurse. The demographics display a high Hispanic population and low socioeconomic area; therefore, this population could benefit from a group intervention for T1D and could benefit from a bilingual curriculum and this will be considered when developing and implementing a diabetic support group or group intervention.

Sample Method. The sampling method will be a snowball and convenience sample, as participants will be adolescent students (ages eleven to fifteen years of age) with type 1 diabetes and their caregivers from different schools throughout the school district located in Riverside County. District nurses will provide information to all students who have been diagnosed with T1D and their caregivers, regarding a diabetic support group or group intervention which will be available within the community. All T1D will be invited to attend, however only adolescence attending middle school (ages eleven to fifteen years of age) will participate in the study.

Sample Size. The sample size was calculated using G*Power analysis (Faul, Erdfelder, Buchner, & Lang, 2009) to detect differences between two samples based upon an alpha of .10, power of .80 and standard effect size of .30 for the analytic technique means difference between two dependent means (paired t-test). An additional 20 percent was added to account for attrition. The required sample size was determined 51 and adding 20 percent for loss factors the desired sample size is 62 participants.

An alpha of .10 was used as the proposed study in a pilot study. Additionally, the sample is a very narrowed group of individuals (adolescents age eleven to fifteen with T1D, in middle school, diagnosed with T1D for greater than one year, attend group intervention with care giver, speak and read English and no additional major health problems). The proposed pilot study will be required to be conducted over a two-year period in order to obtain a sample size of $n=62$. The effect size was not discussed in the literature research, only one journal article described an effect size of 0.5.

Inclusion and exclusion. To participate in this study inclusion/exclusion criteria includes: participants must be middle school adolescents (ages eleven to fifteen) diagnosed with

T1D for more than one year, attend the diabetic support group or group intervention with caregiver, speak and read English, and no additional major health problems (excluding those with asthma or hypothyroidism).

Measurement Methods

The data analysis will begin with a careful examination of the effects of the intervention by using a single sample paired t-test. Comparison of metabolic controls (HbA1c levels) and PedsQL before and after group intervention will be analyzed to determine if there is a difference.

Tools. For the purpose of this study pre/post levels of HbgA1c levels and PedsQL 3.0 T1D will be collected from student participants.

HbA1c Measurement. Metabolic controls will be obtained from caregiver prior to the start of the intervention (a copy of the lab results within three months). This will be a pretest measurement.

Posttest measurements will be collected after the intervention (within three months after intervention). Hemoglobin A1C is a measurement of glycosylation of the hemoglobin molecule and it reflects the individual's average blood glucose over the past three months (Grey et al. 2009). Standard practice for routine HbA1c is collected every three months. An optimal HbA1c for diabetics is below 7.5% (ADA, 2014).

PedsQL Measurement. Secondly, a PedsQL Diabetes Module 3.0 version for adolescence (thirteen to eighteen) and child (eight to twelve) instrument will be used to explore the difference in quality of life for middle school adolescents (ages eleven to fifteen) with T1D after attending a diabetic support group or group intervention (Attachment D).

The PedsQL 3.0 tool is a modular approach to measure health-related quality of life in children and adolescence with T1D (Varni, James, 1988). Varni, Burkwinkle, Jacobs, Gottschalk, Kaufman, Jones (2003), further describe the PedsQL 3.0 as a multidimensional module consist of five subscales to assess perceptions of impact: 1) diabetes symptoms (11 items), 2) treatment barriers (4 items), 3) treatment adherence (7 items), 4) worry (3 items), and 5) communication (3 items). Items are scored from a 5 point Likert scale, (0 = never, 1 = almost never, 2 = sometimes, 3 = often, 4 = almost always). “Items are reversed-scored and linearly transformed to a 0 - 100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0)” (p. 263), so a higher score indicates fewer symptoms or problems, representing a positive rating of health-related quality of life (Varni et al. 2003). The PedsQL scales has evidence there is adequate construct validity and internal consistency Cronbach alpha (0.63-.81) (Varni et al. 2003). Permission and authorization to utilize this tool has been requested and will be obtained prior to the study.

Demographics. Lastly, demographic data and diabetes information will be obtained from caregivers. Demographic information requested will include age, gender, racial and ethnic identity, family income, and marital status of caregiver (married/cohabitating or single parent), and insurance type. Demographic data is important as previous research has indicated that a decrease metabolic controls (increased HgA1C) has been demonstrated with low socioeconomic status (Grey et al. 2009; Grey et al. 2013), non-Caucasian ethnicity and unmarried caregivers (Hillard et al., 2013)

Feedback. Secondary information (non-research) will be requested for participants (adolescent and caregiver) to complete voluntarily in a posttest questionnaire format, with open-ended questions 1) What was most useful in the support group or group intervention, 2) What

was least helpful, 3) Suggestion for improvement, 4) Would you recommend this support group?

This information would provide feedback and gather information for future diabetic support groups.

Data Collection Process

Approval for the study by the university's Institutional Review Board (IRB) and school district will be approved prior to commencing this study. A letter will be sent to the school board superintendent describing the study and requesting permission to utilize school facilities and contact nurses, school psychologist, students diagnosed with T1D and caregivers. Students and their caregivers will be approached for participation by a district nurse by telephone and/or by letter if not able to make contact by phone. Flyer information will be posted at school sites and on the school districts health web-site for advertisement of "Diabetic Support Group/Group Intervention" for students and caregivers. Families interested in participating in the study will complete a consent and an assent for participants under the age of 18 years old.

Metabolic controls (HbA1c laboratory values) will be provided by parent at first visit and after the interventions (within three months). The PedsQL 3.0 T1D questionnaire will be completed by student pre/post intervention. Approval for the use of the questionnaire is in progress and will be obtained prior to the start of the study. The questionnaires will be given an identification number when distributed to ensure confidentiality of participants. All contents will be kept in an envelope with an identification number and all documents will be labeled with the same identification number.

Coding and Scoring

Demographic data will be scored using ratio with means (SD) and nominal data: age: (years); gender: 1- male, 2 – female, 3 – transgender; racial ethnicity: 1 - Caucasian, 2 – Hispanic, 3 – African American, 4 – Asian, 5 - other; Family income: 1 - <\$39,000, 2 - \$40,000-79,000, 3 - >\$80,000; Marital status: 1 – married/cohabitating, 2 – single parent; Insurance type: 1 – No insurance, 2 – Private, 3 – Tricare, 4 – Medi-Cal; Diabetes duration (years),. Metabolic controls will be scored using ratio data with means (SD). PedsQL 3.0 T1D will be scored as ordinal data using a 1-5 point Likert scale.

Data Analysis

Statistical analysis of the data will be accomplished by using SPSS 21 (SPSS Inc., Chicago, IL, USA). Means, median and mode will be computed for demographics, metabolic control measurements, and PedsQL total scores. All analyses will be significant at alpha .10 unless otherwise specified.

Research Question

The research question is “Does a diabetic support group or group intervention for adolescence (eleven to fifteen years of age) with Type 1 Diabetes (T1D) statistically change (decrease) metabolic controls (HbA1c) and improve Quality of Life (QoL) for middle school adolescence?”

Bias

Sampling biases may be present in this study. The approach of convenience sampling allows individuals to select themselves as participants and they may not be a true representation of the population. Convenience sampling is the weakest form of sample population (Polit &

Beck, 2012). Secondly, self-report on questionnaire may be subjective to bias due to age (adolescence) and English Language learners. In addition, limitations to this study are metabolic controls from different laboratories have different measures, however the participants in this study will be obtaining metabolic controls results from their existing diabetic provider, limiting multiple laboratories.

Ethical Considerations

All information collected during the course of the study will be kept confidential. Internal review board approval will be obtained prior to the start of the study. Individuals considered at risk such as participants under eighteen years of age will only attend with permission from the individual (assent) and their caregivers consent to participate (Child Assent and Parental Consents may be found in Appendix B & C). Participants can only participate in the study if it is co-attended by student and caregiver. No incentives were offered to participate in the study.

Summary

The purpose of this study is to develop and implement a support group or group intervention and evaluate the effectiveness in adolescents with T1D, by comparing QOL and metabolic controls prior to and following the initiation of group interventions. Research has already shown that providing additional support to current management improves quality of life for adolescents. Diabetes is a chronic disease which requires the development of life-long skills for improve management and prevention or the delay of long-term problems associated with diabetes.

Table 1: *Complications associated with diabetes*

Hypoglycemia and hyperglycemia
High blood Pressure
High blood LDL cholesterol
Heart disease
Stroke
Blindness and eye problems
Kidney disease
Amputations
Other complications (neuropathy, hepatic disease, periodontal disease, hearing loss, erectile dysfunction, depression, and complications of pregnancy)

(CDC, National diabetes statistics report 2014)

CHAPTER FOUR: GRANT ELEMENTS

Potential grants (feasibility of each)

There were several grants to select from with a variety of funding and qualifications. Three of the potential grants assessed are described in this section to include the feasibility of each grant and grant selection.

Selected Grant

R21, Chronic Condition Self-Management. The National Institute of Health (NIH) is the largest public funder of biomedical research and is composed of 27 institutes and centers; 24 of those centers offer grant and funding. The NIH offers a wide variety of grants and grants are

categorized by activity codes. The most appropriate grant for the planned research study is a Research Project Grant and designated as an R01, Chronic Condition Self-Management in Children and Adolescents.

Research Project Grant are the most commonly used grant programs and are used to support a specified defined research program. There is no specific funding amount and is usually awarded for a three to five-year period. The funding opportunity announcement number is PA-17-115 with a companion funding opportunity PA-17-116, R21 Exploratory/Developmental Research Grant, which encourages new developmental and exploratory research projects, such as pilot studies and feasibility studies. However, the R21 grant funding may not exceed \$270,000 and is limited of up to two years of funding (NIH, 2017).

The Chronic Condition Self-Management in Children and Adolescents, funding promotes self-efficacy in children and adolescence with chronic disease and recognize the challenges within this population. Chronic disease affects QOL and improving QOL can improve chronic disease management and prevent or mitigate long-term complications. Additionally, this funding acknowledges the importance of family or caretaker involvement and the psychosocial and environmental factors which influence adolescence during this vulnerable time. The research objectives for this research grant require multiple test or tools to be tested or developed to meet the research objectives. The proposed research pilot study will utilize the PedsQL tool and metabolic controls (HbA1C) before and after the group intervention to assess interventions for improvements, and will use demographic data to identify any associative factors, such as youths living in single parent household, custodial grandparent, low income etc., which may correlate to

decrease QOL or increase HbA1C levels. The NIH grant was selected as a feasible grant for the proposed pilot study.

Lions Club International Foundation. The second potential grant reviewed was the Lions Clubs International Foundation, Core 4 Diabetes grant. The Lions Club International is the world's largest service organization, and its mission is to serve communities, meet humanitarian needs and encourage peace. They provide services for communities, children and youths, disaster relief, assistance request and health programs. Their health-related programs are sight, hearing and diabetic awareness programs. The Core 4 diabetes grant program recognizes both type 1 and type 2 diabetics are at risk for losing sight due to diabetes eye disease and is the leading cause of new onset blindness, as well as other complications due to insufficient management. This program advocates for the support of public health efforts that focus on expansion and sustainability, in diabetic prevention, education and support and access to treatment. The researched proposed focus is to provide interventions which provides support and education to adolescence with T1D in a community setting. The intent is for the group intervention to focus on diabetes management, self-management, psychosocial issues and barriers to improve metabolic controls and QOL; Hopefully preventing short and long-term complications. To utilize this grant, some minor adjustments would have to be made such as hands-on activities provided by the Lion's Club and to identify the project closely with the Lions Club, to be completely be eligible for this grant; therefore, a future grant would be possible implementing these minor revisions of the above eligibility requirements prior to submission (Lions Club International, 2017).

Kaiser Permanente. The last grant reviewed for the research study was the Community Benefit Grant Kaiser Permanente Riverside and Moreno Valley Medical Center. Kaiser Permanente Riverside County, is dedicated to improving health within the local community by offering grants to non-profit organizations, to assist with building programs and program support that address the needs within Riverside County. Kaiser Permanente Riverside grants are intended to provide support to the underserved and culturally diverse communities, by improving access to health care, mental and behavior health, obesity, diabetes and healthy eating active living. The grant award is \$50,000 and submission are accepted January through March annually. A significant requirement for this funding is to work collaboratively with other organizations for the common good of the community. The desired benefit for organizations to work together towards improving care within a community is an important aspect of the Riverside and Moreno Valley Kaiser Permanente's Community Benefit grant (Kaiser Permanente, 2017). Currently, the local school district, for whom the research grant is proposed, collaborates with many community agencies and organizations within the Riverside County lines and is in an underserved area. The community agencies that have built a partnership within the local school district and who provide assistance to our underserved families are the Lions Club for vision exams and glasses; Vista Community Clinics for Chiropractic, Women's Health, Pediatrics, Immunizations, Family Planning, Dental, Behavioral Health, Adults and Family services; Dr. Vu Lakeside Family Optometry, Family Care Center Riverside County Public Health, and Walmart Pharmacy (Immunizations). These agencies work together with the local school district to provide access to care for families within the community. Currently there are no preventative programs for T1D within this community, therefore access to preventative

interventions are not available to youths or their families within their immediate community. The group intervention or support group will provide the needed education resources for students with type 1 diabetes, as clinics or hospitals providing the clinical support for the youths are not within the local community; many are an hour away (Rady's Children San Diego, Children's Hospital Orange County or Los Angeles, and Loma Linda University). The objective of this research proposal is to provide support group or group interventions within the local community, while utilizing real estate of the Vista Community Clinics or school district site as a venue for conducting the meetings. The intent is to start with providing group interventions for T1D and add other group interventions in the future for type 2 diabetes, nutrition and other preventative services that are identified as needed recourses. While this grant would be ideal for the research proposal the funding in not adequate to support the pilot study, therefore this grant was not selected.

Budget Justification

Personnel. Personnel needed for the proposed pilot study will include a principle investigator (PI) and a research assistant (RA), and mentor. The PI will be responsible for the entire study and completion of the project. This includes Institutional Review Board (IRB) applications, data collection, budget oversight, compiling and summarizing results, and distribution of results. The estimated time that is needed will be two days per week, eight hours per day, for a four-month period. Days outside of the 10-week support group or group intervention can be flexible for data analysis and compiling results. It is essentially a 0.5 position with an annual salary of \$81,658 for per year, according to the local school districts certificated salary schedule. The PI's salary would be \$41,000, not including fringe benefits.

According to California State University San Marcos, the standard fringe benefits are calculated at 0.26 percent, adding an additional \$11,000 to the PI salary; therefore, the total salary requested for entire two-year study is \$104,000.

The research assistant (RA) will assist the PI in the research study, additional responsibilities will include: compile data, process data, data input, maintain records, attend and participate in meetings and training groups, various clerical duties, typing, answering phones, preparing correspondence and coordinate planned meals, set-up and clean-up. The RA will be supervised and trained by the PI. The RA is not directly responsible for the outcome of the research study. The RA would be offered a temporary 0.5 part-time position, consisting of eight hour days. The average salary range for a RA is \$17 per hour according to Indeed.com, which is approximately \$36,000 annually. A part-time position will include a salary of \$18,000 and fringe benefits of \$4,700, for a total of \$22,700. The total salary requested for the entire two-year study is \$45,400.

A mentor will be an experienced and trusted advisor to the PI. The committee chair will be the mentor and facilitate the process of the proposed research study. Dr. Deborah Bennett, PhD, MS, BSN, is the committee chair and is a full-time faculty member at California State University San Marcos (CSUSM), currently acting as Pediatric Course Coordinator and Nursing Simulation Director. She has participated in several research projects and has extensive knowledge with the pediatric population. Additionally, she has over 35 years of nursing experience. The mentor will be available approximately 0.2 or two months each year. The average base professor salary at CSUSM is approximately \$100,000. This position will include a salary of \$17,000 with standard fringe benefit of \$4,420, for a total cost of \$21,420.

Additional personnel needed for this study will be a school nurse and school psychologist. They will help with the support group or group intervention and will be needed for 12 days, 2.5 hours each week. The hourly rate will commensurate with their current salary as listed in the local school district salary certificated salary wage. The estimated salary for certificated salary hourly pay (additional hours) is \$45 per hour. Therefore, each nurse and psychologist will be paid \$1,350, per year for their time facilitating group interventions.

Consultation Cost. Consultation for a statistician is required once data is collected. The statistician will assist with data analysis and statistics using Statistical Product and Service Solution (SPSS) current edition. The estimated time required is 20 hours of statistician consultation at \$200 per hour for a total of \$4,000 requested for this project.

Supplies. A laptop computer and dedicated printer are required for reports, correspondence, advertisement (flyers), and to analysis statistical data by the PI using SPSS. The laptop will include windows 7, Intel processor 1GHZ or higher, 1 GB RAM, and 1 GB hard drive space, which is the minimum requirement needed to run SPSS. The average cost for a laptop computer and printer that meet the requirements is approximately \$660. Statistical software for analysis and data management required is IBM SPSS statistical standard basic package for single user, with one-year technical support and software subscription (\$1210). Additionally, an external hard drive up to 1TB (average price \$75) and encrypted software using Symantec (\$189 for one-year subscription) will be required for additional security measures as data is collected and stored. Finally, general office supplies which includes printer paper, envelops, labels, pens, etc. (\$100). Total equipment and supplies is estimated at \$3,800 for the two-year timeframe.

Travel Cost. The cost of travel for the PI would entail traveling to Lake Elsinore from Temecula, California. This is approximately 20 miles one-way, and round trip is 40 miles. According to the Internal Revenue Service (IRS), the rate for standard reimbursement is 53.5 per miles as of January 2017. Requested travel cost for the PI would be \$5,140, for the two-year research period. There are no parking fees associated with the local school district.

Timeline

The expected timeline will be a two-year timeline. Upon approval of funding, the pilot research study will begin starting with preparation, data collection over different periods (to obtain a sufficient number of participants), data entry and review of data, data analysis, documentation and dissemination of the pilot research study. Table 2 provides the dates and description of what is to be accomplished.

Table 2: *Two-year timeline*

Pending School District's legal department form and IRB for reviewing the proposed project.	Estimated approval date: January 2018
Research study preparation	July 2018 – Secure statistician/consultant, training, coordinate site location and schedule, purchase equipment and supplies.
Data Collection, Data Review/Entry	August 2018 – December 2018 & August 2019 – December 2019
Data Analysis	December 2018 – February 2019 December 2019 – February 2020
Data Documentation	February – March 2019 February - March 2020
Dissemination of Finding	March 2020

Note: Project timeline for the pilot research study of T1D group support or group interventions.

Plan for dissemination of findings

Dissemination Cost. The plan to disseminate findings will be conducted at the California Association of Nurse Practitioners (CANP) 43st Annual Educational Conference, held in March 2020, location not known at this time. Registration for conference is approximately \$600 for non-members and poster presentation. At this time, there is no information for registration fees for members, therefore the registration cost is calculated for non-membership. The cost associated for poster construction is \$0.67 per linear inch, therefore, cost is approximately \$35 for a 48x36 poster, and will be used to present research study findings.

Additional cost would be for lodging and mileage. At this time, there is no information on location or lodging facilities for conference attendees, therefore cost estimates will be based on conference cost for March 2018. A three-night stay at the Sheraton San Diego Hotel would be approximately \$427 per night. This does not include a discount block room rate provided by the hotel. For purposes of planning the room rate mentioned above will be used for a total stay \$1,281, plus 12 percent California tax charge of \$154, resort charge \$22 per day and self-parking fee of \$32 per day. Lastly, roundtrip travel to the conference by the PI would be approximately \$58. Total fees for dissemination cost would be approximately \$2,322. However, since the PI lives within close proximity and commuting distance (54 miles one-way), it would be more cost effective for the PI to commute to and from the conference daily. Therefore, the total dissemination cost would be \$995, (travel \$232, parking \$128, registration \$600 and poster \$35). This would provide a cost saving of \$1,327. Note the above estimate is for a Southern California conference location. California Association of Nurse Practitioners alternate between Southern

and Northern, California locations, 2020 would be a Southern, California location.

Dissemination cost would be for the second year of the research study only.

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Appendix A: Example Curriculum

Proposed curriculum: Group Interventions by weeks

Weeks	Intervention(s)
1	Introductions and Development of Rapport – decrease anxiety and development of group cohesion
2	Goals - development of short and long-term goals to improve diabetes management
3	Goals part 2 – finalize goals and promote goal achievement
4	Self-Esteem – to build self-esteem and self-expression
5	Transition to Self-management & School Issues – promote medical adherence and develop problem-solving skills
6	Stress Management – improve coping skills
7	Communication – increase communication skills with caregivers
8	Physical Exercise – promote healthy lifestyle and appropriate diabetes management
9	Diabetes Knowledge and High-Risk Behaviors – to increase diabetes knowledge, promote problem-solving skills, and reduce high-risk behaviors
10	Nutrition – to promote healthy diet, increase knowledge and skills in healthy meal preparation

(Based from the curriculum from Cespedes-Knadle et al., 2011.)

Appendix B: Informed Assent



California State University
SAN MARCOS

Study # _____

Diabetic Education for Students

Lorraine Assumma is leading a study on diabetic education for students who have type 1 diabetes and their parents, as partial completion of course requirements for the Family Nurse Practitioner program at California State University San Marcos (CSUSM). You are invited to take part in this study because you have Type 1 diabetes.

This study has three goals:

1. To better understand how diabetic education can help you.
2. To see if diabetic education can improve hemoglobin A1C and how you feel.
3. To determine if the diabetic education was helpful.

If you agree to be in this study, you will be asked to do the following:

1. Provide recent (within 3 months) hemoglobin A1C results before/after diabetic education
3. Participate in diabetic education
4. Complete a survey

There are no risks involved to participate in this study. Your interview and survey response will be kept in secret and are available only to the research team for study purposes, and will be destroyed at the end of the research. You should know that CSUSM Institutional Review Board (IRB) may inspect study records to make sure they are safe for you.

You will be provided information for your participation in diabetic education. Participation in this study is voluntary, and you may withdraw from the study at any time without penalty. If you do not participate in this study, you will still have the ability to attend diabetic education.

The experimenter will answer any questions that you have. If you have further questions, please contact Lorraine Assumma, RN. Questions about your rights as a research participant should be directed to our Institutional Review Board at CSUSM. You will be given a copy of this form to keep for your records.

I agree to take part in this research study. The experimenter has answered all or any questions I had.

Participants Signature (Minor)

Date

Appendix C: Informed Consent



California State University
SAN MARCOS

Study # _____

Diabetic Education for Care Givers

Lorraine Assumma is conducting a study on diabetic education and group support for students who have type 1 diabetes and their parents, as partial completion of course requirements for the Family Nurse Practitioner program at California State University San Marcos (CSUSM). You are invited to take part in this study because you have a child with Type 1 diabetes.

This study has three objectives:

1. To better understand the influence of diabetic education
2. To demonstrate if diabetic education has an effect on hemoglobin A1C and quality of life.
3. To determine if the diabetic education was helpful.

If you agree to participate in this study, you will be asked to do the following:

1. Provide recent (within 3 months) hemoglobin A1C results before/after diabetic education
3. Participate in diabetic education
4. Complete questionnaire

There are no risks involved participating in this study. Your interview and survey responses will be kept confidential, are available only to the research team for study purposes, and will be destroyed at the end of the research. You should know that CSUSM Institutional Review Board (IRB) may inspect study records as part of its auditing program to make sure they are safe for participants.

Participating in this study, should provide you additional information and offer support while you assist in the management of diabetes. You will be provided information for your participation in diabetic education.

Participation in this study is voluntary, and you may withdraw from the study at any time without penalty. If you do not participate in this study, you will still be able to attend diabetic education.

The experimenter will answer any questions that you have. If you have further questions, please contact Lorraine Assumma, RN. Questions about your rights as a research participant should be directed to our Institutional Review Board at CSUSM. You will be given a copy of this form to keep for your records.

I agree to participate in this research study and I give permission as the care giver for my son/daughter to participate. The experimenter has answered all or any questions I had.

Participants Signature

Date

Appendix D: PedsQL questionnaire (Sample)

ID#

Date: _____

PedsQL™
Pediatric Quality of Life
Inventory

CHILD REPORT (ages 8-12)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There are no right or wrong answers.

If you do not understand a question, please ask for help.

In the past ONE month, how much of a problem has this been for you ...

<i>About My Health and Activities (PROBLEMS WITH...)</i>	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

<i>About My Feelings (PROBLEMS WITH...)</i>	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

<i>How I Get Along with Others (PROBLEMS WITH...)</i>	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

<i>About School (PROBLEMS WITH...)</i>	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

Appendix E: Detailed Budget (PHS 398)

Program Director/Principal Investigator (Last, First, Middle): Lorraine Assumma

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 07/01/2017	THROUGH 07/01/2018
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List PERSONNEL (Applicant organization only)
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Lorraine Assumma	PD/PI	6	0	0	81,658	41,000	11,000	52,000
TBD	RA	12	0	0	30,000	18,000	4,700	22,700
Dr. Bennett	Mentor	2	0	0	100,000	17,000	4,420	21,420
SUBTOTALS →						76,000	20,120	96,120

CONSULTANT COSTS
Methodologists/Statistician \$200/hr for 20 hours 4,000

EQUIPMENT (Itemize)

SUPPLIES (Itemize by category)
External hard drive 1TB (\$75)
 Symantec encryption software 1 yr subscription (\$180)
 IBM SPSS Statistics Standard Base package (\$1210)
 Laptop (\$600)
 Printer (\$60)
 4500 poster (\$35.00)
 Office Supplies (\$100) 2,269

TRAVEL
Conference/dissemination cost (\$960) & Travel expense (\$2,570) 3,530

INPATIENT CARE COSTS 0

OUTPATIENT CARE COSTS 0

ALTERATIONS AND RENOVATIONS (Itemize by category)

OTHER EXPENSES (Itemize by category)
 School Psychologist Facilitator/group intervention (\$45/hr x 2.5 hrs \$112 x 12 days = \$1,350)
 School Nurse provide group intervention (\$45/hr x 2.5 hrs \$112 x 12 days = \$1,350) 2,700

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (Item 7a, Face Page)		\$ 108,619

CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$ 108,619

Program Director/Principal Investigator (Last, First, Middle): Lorraine Assumma

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>	96,120	96,120			
CONSULTANT COSTS	4,000	4,000			
EQUIPMENT	0	0			
SUPPLIES	2,269	1,499			
TRAVEL	2,570	3,530			
INPATIENT CARE COSTS	0	0			
OUTPATIENT CARE COSTS	0	0			
ALTERATIONS AND RENOVATIONS	0	0			
OTHER EXPENSES	2,700	2,700			
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i>	107,659	107,849			
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS	107,659	107,849			
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD					\$ 215,508

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

See attachment

Appendix F: IRB Application



California State University
SAN MARCOS

Application for Approval for Research Involving Human Subjects:
Full or Expedited Review

Submission Procedures:

1. The researcher completes application
2. If the researcher is a student, their faculty advisor must review the application and **sign the application in IRBNet**. Additional instructions can be found on the last page of this application. **
3. The researcher submits the application and accompanying documents to IRBNet. <http://www.csusm.edu/gsr/irb/forms.html>
For assistance completing this form, please review the resources located at www.csusm.edu/irb.
If you have any questions, please refer to the [IRB website](#) or contact the IRB staff at (760) 750-4029 or irb@csusm.edu.
Please answer each section completely and as concisely as possible. Use lay terms as IRB members have diverse backgrounds.

 Full Review Expedited ReviewProposed Start Date Project
Title**Faculty/Staff Investigator:**

Name Department/College
 Phone Number E-mail
 Date CITI Completed

Student Investigator: (if the student is the primary investigator) **

Name Department/College
 Phone Number E-mail
 Date Training Completed CITI IRB Workshop

Faculty Advisor Name: Department/College
 Phone Number E-mail Date CITI Completed

Checklist: Check which of the following items are included, as applicable:

- Certification of Human Subjects Protection training **for each researcher and the faculty advisor**.
- Letter/email of organizational support (Required if recruiting or interacting with participants at a specific site or through a specific organization outside of CSUSM.) If sent in an email, must include organization and position of the person who approved.
- Recruitment flier(s) or advertisements, scripts for radio or TV.
- Survey(s), questionnaires, or interview questions. If this is an online survey, please provide a pdf copy of the survey.
- Consent and/or child assent form(s) or information sheet(s).
For online surveys, provide a pdf copy of the introduction/information screens.
 1. Provide unique forms for each population in your research.
 2. Use official letterhead or the masthead found in the samples on the IRB website
 3. Include contact information for the Researcher, faculty mentor, and IRB office.
 4. Be sure the information in your consent/information sheet **MATCH your application** information!
- Students Researchers ONLY:** Faculty advisor has approved the project and has signed the application in IRB Net.
- Ed.D Students ONLY:** Attach the required **UCSD-CSUSM-JDP IRB Cover Sheet**. Please be sure to **sign** the form, scan it, and submit it with your application as a separate document.

1. Purpose of Project and Project Background

Describe your research question, including **why** the question is important, and **how** your study will attempt to answer it. Include how your literature review supports this with at least three citations. (Do not exceed one page--Use lay language.)

The purpose of this research is to identify if there is a difference in metabolic controls (blood sugar) and quality of life perception for middle school adolescence (ages eleven to fifteen) who have Type 1 diabetes (T1D) after the exposure to a diabetic support group or group intervention in a community setting.

Type 1 diabetes is a chronic condition that is on the rise. It is estimated in the United States there are up to three million individuals diagnosed with T1D (Chiang, J., Kirkman, M., Laffel, L., & Peters, A., 2014; Juvenile Diabetes Research Foundation, 2014). The prevalence of T1D has been increasing by two to five percent worldwide, and accounts for five to ten percent of total cases (National Center for Biotechnology Information, 2016). The incidence of T1D, in those newly diagnosed and under the age of 20 was estimated to be 18,436 in 2009, in the United States (CDC, National Diabetes Statistical Report 2014). Type 1 diabetes is more common in non-Hispanic whites 1.5-2 times compared with other groups, and sixty percent are under the age of eighteen when diagnosed (CDC, 2014; Golden, A., Thomas, D., and Porter, B., 2015, p. 876).

Living with a severe chronic disease such as diabetes requires continuous maintenance of the disease to prevent associated complications. Everyday management is intensive and demanding, requiring frequent monitoring of blood glucose level, diet control of carbohydrate counting, and daily insulin administration by injection or infusion pump multiple times per day. The fine balance needed to manage diabetes and maintain near normal blood glucose can be challenging, which can impact quality of life (QOL) especially for adolescents and their caregivers. Adolescence is a difficult time and self-management of diabetes decline significantly during this vulnerable time. Self-management can be a very complex and challenging undertaking for most adolescence, as they often are not ready or mature to handle the full responsibilities to self-manage their diabetes (Céspedes-Knadle, & Muñoz, 2011; Grey et al., 2009). Additionally, hormonal changes during puberty influence metabolic demands and insulin sensitivity (Céspedes-Knadle et al., 2011). Adolescents desire for increase autonomy and peer pressure influence their decision making and affect metabolic controls and overall poor medical adherence (Grey et al, 2009; Céspedes-Knadle et al., 2011).

To improve blood sugar controls, diabetic management interventions are available to youths and their families during their routine quarterly visits with their provider. During the visit medical adherence is the primary focus reviewing and evaluating HgbA1C levels, diabetic management, diet, and insulin is adjusted (if needed). However, there is little focus on psychosocial issues. Additionally, the diabetic support team is usually located within the hospital or clinical facility where the individuals obtain quarterly visits, and for many individuals this involves a lengthy commute up to an hour or greater. Therefore, support between quarterly visits entails phone calls to their providers or additional visits with a diabetic nurse if warranted. Support groups or diabetic classes are not available at all provider locations, so depending on the location of the provider, support resources differ. Lastly, support groups or group interventions are lacking within local communities for adolescence with T1D and their caregivers; to assist them in functioning with everyday management and psychosocial issues. Providing support groups or group interventions for T1D within the community, is an attempt towards proving interventions locally, to improve QOL and possibly decrease metabolic controls (blood sugar levels).

--

2. Recruitment Procedures & Participant Population

A) List the expected number of participants for each population group included in this study.

The expected number of participants would be n=62 middle school (age 11-15) adolescents and their caregiver

B) Describe all characteristics relevant to being selection of participants. (e.g., demographics, ethnicity, vulnerabilities, etc.) Explain why you are targeting this specific population.

The participants for this pilot research study will be adolescent students (ages eleven to fifteen years of age) with type 1 diabetes for more than one year and their caregivers. They must attend the group interventions with their caregiver, speak English and have no additional major health problems (exception those with asthma or hypothyroid). They will be from a public school district located in Riverside County, California. All type 1 diabetics within the school district will be invited to attend, however only adolescence attending middle school (ages eleven to fifteen years of age) will participate in the pilot research study.

The target population is early to mid adolescence (eleven to fifteen year of age) as this age group has been identified in research to be a difficult time for individuals to self-manage diabetes. Additionally, this public institution has an increase population (62%) enrolled in the federal reduce and free lunch program for the school year 2015-1016, this is 13,762 student of the total 22, 346 students enrolled, indicating a high amount of low income. Lastly, this community is located at least an hour from many of the well known established children's medical centers in San Diego and Orange County, limiting diabetic resources and there are no T1D education services available within the community.

C) Indicate whether anyone might be *excluded* from participating and explain why.

--

To participate in this study inclusion/exclusion criteria includes: participants must be middle school adolescents (ages eleven to fifteen) diagnosed with T1D for more than one year, attend the diabetic support group or group intervention with caregiver, speak and read English, and no additional major health problems (including those with asthma or hypothyroidism). Type 1 diabetics will be invited to attend, however only adolescence attending middle school (ages eleven to fifteen years of age) will participate in the study.

D) How will you find, recruit, or identify potential subjects? How will you select, from the volunteers, the final group of participants? Submit flyers, posters, or other oral or written invitations used to recruit potential participants.

The sampling method will be a snowball and convenience sample, as participants will be adolescent students (ages eleven to fifteen years of age) with type 1 diabetes and their caregivers from different schools throughout the school district located in Riverside County. District nurses will provide information to all students who have been diagnosed with T1D and their caregivers, regarding a diabetic support group or group interventions.

Students and their caregivers will be approached for participation by a district nurse by telephone and/or by letter if not able to make contact by phone. Flyer information will be posted at school sites and on the school districts health web-site for advertisement of "Diabetic Support Group/Group Intervention" for students and caregivers.

Selection process will be accomplished by the researcher as all middle school students w/ T1D will be selected per selection criteria as mentioned above.

E) Will you be offering an incentive?

Yes No

If yes, please explain procedure for any incentives that will be offered. Include how much participants must do to be eligible to receive credit.

No incentive will be offered.

3. Informed Consent Process.

Explain for each population participating in your research.

See the IRB web page on [Informed Consent](#). See also [Language Requirements](#).

A) How and when will you explain the study and the required elements of Informed Consent? Will you be doing this or will it be handled by a research assistant?

The research assistant will provide consent forms for all participants and have them complete and sign forms at the first meeting of the support group or group intervention. Caregivers participating in the study will complete a consent and adolescents participating will complete an assent (those under the age of 18 years old). Caregivers will be informed of consent forms when contacted initially by district nurses.

B) How much time will participants have to consider participating between the explanation described above, the receipt of the consent document, and the beginning of study?

The participants will have approximately two to three week time-frame to consider if they would like to participate in the study. Initial contact will be prior to the starting of school year (August 2017). All district nurses will contact all caregivers who have a student with type 1 diabetes and meet with the diabetic caregiver and students to collect and gather documentation for the school year (this is standard care for all diabetic receiving insulin at school).

C) If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

When the district nurse meets with the caregiver and student, the student will be informed and asked if he or she would like to participate in the research study. They will be provided with the information regarding support group, topics to be discussed and asked if they would like to be mentors to other student.

D) If you are requesting a Waiver of Consent or a Waiver of Documentation of Consent, explain why this waiver is needed. Outline alternative procedures for obtaining consent or providing study information (e.g., information sheet, introduction screen for web survey, etc.).

no

E) Indicate the primary language(s) of your participants. If any participants' is not fluent and comfortable with English, explain how you will ensure that participants' understanding of the activity for which they are giving consent.

Participants participating in this pilot research study will be English speaking or comfortable with English as the primary language. Further studies will incorporate Spanish speaking translators and materials if identified as necessary.

4. Procedures and Methodology

Provide descriptions of each distinct procedure and each population group.

A) Provide a step-by-step explanation of your research activities and methodologies that involve human subjects. Be thorough.

1) The research design will be a single group pre-test/post-test descriptive design to compare metabolic controls (HbA1c) and PedsQL Diabetes Module 3.0 version for adolescence with T1D pre and post support group or group intervention. The rationale for the pre-test/post-test descriptive design is to observe if there is a change in QOL after an intervention. Additionally, we would compare HbA1c values to identify if the values maintained (did not get worse) or if they actually decreased.

2) Pre/post levels of metabolic controls (HbA1c levels) and PedsQL will be collected from student participants. The data

analysis will begin with a careful examination of the effects of the intervention by using a single sample paired t-test for each variable. Pre and post-test diabetic support group intervention will be analyzed for comparison of hemoglobin A1C and PedsQL to determine if there is a difference pre and post-test.

3) Metabolic controls (Hemoglobin A1C) will be obtained from caregiver prior to the start of the intervention (a copy of the lab results within three months), from their provider. This will be a pretest measurement.

4) Metabolic controls (Hemoglobin A1C) will be obtained from caregiver after the intervention (a copy of the lab results within three months), from their provider. This will be a posttest measurements. Hemoglobin A1C is a measurement of glycosylation of the hemoglobin molecule and it reflects the individual's average blood glucose over the past three months (Grey et al. 2009). Standard practice for routine HbA1c is collected every three months. An optimal HbA1c for diabetics is below 7.5% (ADA, 2014).

5) PedsQL Diabetes Module 3.0 version for adolescence (thirteen to eighteen) and child (eight to twelve) instrument will be completed pretest measurement.

6) PedsQL Diabetes Module 3.0 version for adolescence (thirteen to eighteen) and child (eight to twelve) instrument will be completed posttest measurement. PedsQL is used to explore the difference in quality of life for middle school adolescents (ages eleven to fifteen) with T1D after attending a diabetic support group or group intervention (see attachment).

7) Demographic data and diabetes information will be obtained from caregivers (see attachment) prior to the start of the interventions. Demographic data is important as previous research has indicated that a decrease metabolic controls (increased HgA1C) has been demonstrated with low socioeconomic status (Grey et al. 2009, Grey et al. 2013), non-Caucasian ethnicity and unmarried caregivers (Hillard et al).

8) Non-research information will be requested for participants (adolescent and caregiver) to complete voluntarily in a posttest questionnaire format, with open-ended questions (see attached).

9) Statistical analysis of the data will be accomplished by using SPSS 21 (SPSS Inc., Chicago, IL, USA). Means, median and mode will be computed for demographics, metabolic control measurements, and PedsQL total scores.

The effects of the intervention will be tested by using a single sample paired t-test to analyze pre and post support group intervention, for data comparison of metabolic controls (HbA1c) and PedsQL 3.0 scale to determine if there is a difference.

B) Where will the research will be conducted? Describe any risks or confidentiality issues related to using this location.

The research study will be conducted within the community at the school district site (conference room TDB). There are no risk or confidentiality issues.

C) State the specific dates/timeframe in which you plan to conduct your research.

The research study will start on Wednesday, August 23, 2017, from 5:00-6:30 p.m.

5. Participant Debriefing or Feedback.

If deception is involved in your research, participants should be debriefed about the nature of the study as soon as possible.

Participants should be given the opportunity to request a copy of the results of the study/your final report.

A) Describe any feedback or information you will offer participants.

n/a

6. Risks

List risks for each population participating in the research and for each methodology.
Please be sure the risks listed here match the risks mentioned in your consent letter or information sheets.
Consider all risks very carefully. For more information on risks, see Examples of Risk.

A) Explain potential risks to your participants. Risks may be physical, psychological (e.g., strong emotional reactions to research questions), or inconveniences (e.g., time required).

The risk is no more than attending group counseling sessions outside the community. None of the group interventions are expected to cause any emotional reaction. If there were to be any strong emotional response, a licensed school psychologist will be available to help with the response on-site during the event. In addition, parents will be co-located with students.

B) Vulnerable Subjects: Select which, if any, of the following vulnerable subjects will be involved in your research.

- Pregnant women, human fetuses, neonates (see Federal Guidelines, 45CFR26, subpart B)
- Prisoners (see Federal Guidelines, 45CFR26, subpart C)
- Children (see Federal Guidelines, 45CFR26, subpart D)
- Other Vulnerable Populations such as persons with cognitive disabilities, economically or educationally disadvantaged persons, etc.

C) Describe and special risks to vulnerable populations or your population profile

There are no special risk involve to participate in this study. Students will attend only with their caregiver (parent or guardian).

D) List risks related to confidentiality of data. What could happen if an unauthorized person accessed the data? For instance, participant's identify or personal information could be known by others

Confidentiality will be maintained by numerically assigning students a number. No identification data will be on collected paperwork except for demographics completed by parents and an assigned a number. Participants will be identified by an assigned number. Therefore, the risk related to confidentiality of data is minimal. Staff may know the parents and or student, however this study is on a volunteer basis, so confidentiality will be limited to student responses with an assigned number. Demographic data will be stored in a locked file cabinet. Computer stored information will be saved on to an external drive with security settings and stored in a lock file cabinet. The file cabinet is located in an office with a lock door.

E) Will any **personal identifying data** be recorded? If so, what information will be recorded?
(e.g., Social security number, drivers license number, student id, address, phone number, birth date, personal email address)

Only demographic data will be recorded. These responses are completed by parents prior to the

interventions and will be assigned a study number.

7. Safeguard Procedures to Minimize Risks.

A) Please respond to each risk that you listed in #6 above. State how you will minimize each risk and protect confidentiality.

If there were to be any strong emotional response, a licensed school psychologist will be available to help with the response on-site during the event. In addition, parents are required to attend with student and will be co-located with students.

B) How you will safeguard data? Where/how will data be stored? Who will have access to the data? How will access be limited?

The questionnaires will be given an identification number when distributed to ensure confidentiality of participants. All contents will be kept in an envelope with an identification number and all documents will be labeled with the same identification number. All data will be stored in a locked file cabinet and locked room. Access to the data will only be by the researcher and research assistant.

C) List referrals and/or resources that may be offered if a participant has a strong emotional response or a physical injury (e.g., clinics or shelters, medical or psychological referrals).

A school psychologist and registered nurses will be at the location of the intervention. Follow-up can be made by the school site psychologist and registered nurse.

8. Study Benefits

A) Discuss any potential individual and/or societal benefits. Note, often there is no direct benefit for the participants. However, the study may contribute to the literature and/or future research.

- 1) Potential benefits of this study include improve quality of life for caregivers and adolescents.
- 2) Participants questions and concerns will be answered.
- 3) This study can potentially contribution to future research.

B) Do the benefits from this study exceed the risks to participants? Please explain.

Yes, the benefits from this study exceed the risk to the participants, as the participants will be exposed to diabetic education and interventions which can help them manage diabetes, learn coping techniques and self-monitoring skills to improve quality of life.

9. Researcher(s) qualifications and experience.

A) Briefly outline the primary researcher(s)'s qualifications and experiences relative to the subject of this research.

The primary researcher has been a registered nurse for twenty years and a school nurse for four years. Additionally, she works with adolescent population, caregivers and type 1 diabetics.

B) If this is a student project, include faculty sponsor's qualifications.

A mentor will be an experienced and trusted advisor to the PI. The committee chair will be the mentor and facilitate the process of the proposed research study. Dr. Deborah Bennett, PhD, MS, BSN, is the committee chair and is a full-time faculty member at California State University San Marcos, currently acting as Pediatric Course Coordinator and Nursing Simulation Director. She has participated in several research projects and has extensive knowledge with the pediatric population. Additionally, she has over 35 years of nursing experience.

C) If using student or research assistants, please state how you will ensure that these assistants are trained and qualified to assist. All assistants should complete the CITI training on the protection of human participants in research.

The research assistant will be trained and supervised by the researcher throughout the entire study.

Time to Review:

Expedited reviews are reviewed by one committee member with an average approval time of approximately three weeks. Questions from reviewers and approval paperwork will be sent to the email address provided on the application at the time of submission.

Full reviews are reviewed by the full committee at an IRB meeting. Approvals on full reviews may take 4-6 weeks. Questions from the committee and approval paperwork will be sent to the email address provided on the application at the time of submission. All "full review" applications are copied to Risk Management.

Faculty Advisor Approval: **

Once the student researcher has completed the application, they must e-mail their application to their faculty advisor for review. When the faculty advisor pre-approves the application, the student will upload their application and documents to IRBNet and share the package with the faculty advisor for official approval. The faculty advisor must have an account in IRBNet to approve the application. The faculty advisor will receive a notification via e-mail that the application package has been shared with them and that they need to sign off on the application package in IRBNet.

Instructions on sharing the project can be found on the IRBNet video training site. There is a section in the video called **Sharing This Project**. The link and the login for the training is on the CSUSM IRB website under **How to Submit to IRBNet**
<http://www.csusm.edu/gsr/irb/forms.html>