META-ANALYSIS OF QUALITY OF LIFE OUTCOMES

FOLLOWING DIABETES SELF-MANAGEMENT TRAINING

A dissertation presented to
the Faculty of the Graduate School at
The University of Missouri-Columbia

In Partial Fulfillment of the Requirements for the Degree

Doctor of Philosophy

By

JANE COCHRAN

Dr. Vicki S. Conn, Dissertation Supervisor

December 2007

The undersigned, appointed by the dean of the Graduate School, have examined the dissertation entitled:

META-ANALYSIS OF QUALITY OF LIFE OUTCOMES FOLLOWING DIABETES SELF-MANAGEMENT TRAINING

presented by Jane Cochran,

a candidate for the degree of doctor of philosophy,

and hereby certify that, in their opinion, it is worthy of acceptance.

Professor Vicki Conn

Professor Cindy Russell

Professor Jane Armer

Professor Kay Libbus

Professor David Gardner

DEDICATION

I would like to dedicate this to all of my family and friends who have made this work possible. I would especially like to thank my husband, Steve, my sons, Matthew and David, my parents, Cecil and Jean Hulsey, and my sister, Sarah Smith, for all of their support.

ACKNOWLEDGEMENTS

I would like to thank all of my dissertation committee members, Dr. Vicki Conn, Dr. Cindy Russell, Dr. Jane Armer, Dr. Kay Libbus, and Dr. David Gardner. I sincerely appreciate all of their support, assistance and guidance during this process.

I would like to give special acknowledgement to Dr. Vicki Conn, dissertation supervisor and mentor, for all of her patience and encouragement and truly without whom this project would not have been able to be completed.

I would also like to acknowledge University of Missouri Health Care and especially the Division of Endocrinology, Diabetes, and Metabolism for their support in my studies.

I would also like to thank the Sinclair School of Nursing faculty and staff, as well as the other doctoral students for making my doctoral study experience so rich and rewarding.

TABLE OF CONTENTS

LIST OF TABLES

ABSTRACT

Diabetes is a common chronic illness that requires daily diet, exercise, and medication management. Both disease management and diabetes complications may affect quality of life. Despite the importance of quality of life outcomes, no previous meta-analyses have synthesized findings from diabetes self-management intervention studies.

Extensive literature searching located published and unpublished diabetes self-management intervention studies that measured quality of life outcomes among at least 5 subjects with type 1 or 2 diabetes. Data were extracted from primary study reports which included interventions designed to improve self-management and adequate data to calculate effect sizes. Random-effects meta-analytic procedures were used to estimate overall effects between treatment and control groups at outcome assessment and between baseline and outcome data for both treatment subjects and control subjects.

Exhaustive searching yielded 20 comparisons across 1,892 subjects. The comparisons between treatment and control group outcomes following interventions yielded an effect size of 0.281. The comparisons between treatment group at baseline and outcome measurement yielded an effect size of 0.312 to 0.313. Each of these effect sizes were statistically significant, meaning that the hypothesis that interventions to improve diabetes self-management results in

increased quality of life outcomes was supported. Control subjects did not experience improved quality of life while participating in studies.

These findings document that people with diabetes experience improved quality of life from participation in interventions designed to increase self-management. Future diabetes self-management intervention studies should include quality of life outcomes so that this important outcome can be further studied. After more primary studies are available future meta-analyses can explore important moderator analyses.

CHAPTER 1

INTRODUCTION

Diabetes affects millions of people and its incidence is predicted to continue to dramatically increase in the near future. Persons living with this chronic illness are expected to perform numerous daily self-management behaviors to care for their diabetes in order to achieve glycemic control and thus to reduce the risks of both acute and chronic diabetes complications. These recommended self-management activities include diet changes, regular exercise, taking medication as prescribed, and self blood glucose monitoring. In addition, people must deal with medication side effects, acute metabolic complications, chronic complications and co-morbidities.

An aspect of diabetes care that has been gaining increasing attention is the effect that diabetes, the care burden required of people with diabetes, and diabetes complications and co-morbidities have on the quality of life of persons living with diabetes. The importance of quality of life has been recognized as an important outcome of diabetes care as well as a factor in sustaining the ongoing performance of diabetes self-care activities. “The ultimate goal of diabetes care is to preserve and if possible to enhance patients’ perceived quality of life. Indeed, the true challenge in diabetes care is to help patients balance short and long-term quality of life against the burden of daily intensive self-management” (Snoek, 2003 p 1).

Quality of life for diabetes patients has been studied in clinical trials in relation to a number of different aspects of diabetes and its care. These include glycemic control (Aalto, Uutela, & Aro, 1997; Cerrelli et al., 2005; & Brancati, 2003) and various self-management behaviors and interventions (Ahlgren, Shultz, Massey, Hicks, & Wysham, 2004; Aikens, Aikens, Wallander, & Hunt, 1997;Chantelau, Schiffers, Schutze, & Hansen, 1997; Chumbler et al., 2005; Franciosi et al., 2001; Holton, Colberg, Nunnold, Parson, & Vinik, 2003; Menard et al., 2005) as well as other physical and psychosocial factors (Aalto et al., 1997; Basa & McLeod, 1995; Boye, 2006; Brod, Skovlund, & Wittrup-Jensen, 2006; Chang, 2004; Eiser, Riazi, Eiser, Hammersley, & Tooke, 2001; Evans & Pinzur, 2005; Hill-Briggs, Gary, Baptiste-Roberts, & Brancati, 2005; Kaholokula, Haynes, Grandinetti, & Chang, 2003; Lloyd et al., 1999; Pibernik-Okanovic, Prasek, Poljicanin-Filipovic, Pavlic-Renar, & Metelko, 2004; Rose, Fliege, Hildebrandt, Schirop, & Klapp, 2002; Shah, 2006; Trief, Wade, Britton, & Weinstock, 2002). While the importance and study of quality of life are increasing, in general these clinical trials have had not had conclusive results regarding the effects of these various factors on quality of life.

Purpose

This project examined the impact of diabetes self-management training on the quality of life in adults with diabetes. A meta-analysis of the literature of studies of diabetes self-management training with a reported quality of life outcome was performed as part of a larger meta-analysis project. The parent

project examined the effects of interventions to increase physical activity in adults with chronic illness and interventions to improve self-management among adults with type 1 and type 2 diabetes. This meta-analysis was warranted since it is recognized that quality of life is an important outcome of diabetes self-management training but no previous meta-analysis was found that addressed this particular question. The research question for this meta-analysis was:

Does diabetes self-management training affect the reported quality of life of adult diabetes patients?

CHAPTER 2

BACKGROUND

Diabetes

There are two main types of diabetes mellitus. Type 1 diabetes is often diagnosed at a younger age and always requires exogenous insulin as part of its treatment. Type 2 diabetes may be treated with diet and exercise only or with the addition of diabetes oral medication, injectable medication and/or exogenous insulin. With both types of diabetes diet, exercise, side-effect and complication management are part of their self-management requirements.

During the last decade not only has the prevalence of diabetes greatly increased but there have also been dramatic increases in treatment options. Some of the newer treatments have made caring for diabetes easier (e.g. improvements in blood glucose monitoring technology). Others, that while improving glycemic control require additional care burden (e.g. more frequent insulin injections and newer injectable diabetes medications). It has been found that treatment satisfaction is most associated with how well the treatment works, decreased treatment burden and decreased side-effects (Brod, Cobden, Lammert, Bushnell, & Raskin, 2007). Interventions that increase glycemic control but decrease quality of life are not likely to be sustained (Snoek, 2003). “The

goals in treating patients with diabetes are, most importantly, a sufficient blood glucose regulation and a quality of life with as few restrictions as possible" (Rose et al., 2002, p 40).

Quality of Life and Self-Management among Adults with Diabetes

Quality of life has been found to be lower in persons with diabetes compared to individuals that do not have diabetes (Maddigan, Feeny, & Johnson, 2005; Saito et al., 2006). The multi-national Diabetes Attitudes Wishes and Needs (DAWN) Study was designed to increase understanding of psychosocial factors affecting and affected by diabetes care. Structured interviews, in person or over the phone, were performed with over 5100 diabetes patients. It found that 41% of the participants reported poor psychological well-being (Peyrot et al., 2005; Rubin, Peyrot, & Siminerio, 2006). It has also been found that quality of life in adults with diabetes decreases over time despite improvements in clinical outcomes. This decrease in quality of life is possibly due to diabetes care burden, symptoms and side effects (Hill-Briggs et al., 2005).

An accepted part of the standard of care for persons with either type of diabetes is diabetes self-management training. Diabetes self-management training is designed to increase the person's ability and skill to perform the self-management activities required to effectively care for one's diabetes (Mensing et al., 2007). Recently there has been a movement away from didactic teaching

alone to a focus on attitudes, coping and self-efficacy (Snoek, 2003). Increased diabetes care self-efficacy has consistently been linked to increased quality of life in patients with type 1 and type 2 diabetes (Kuijer & de Ridder, 2003; Pibernik-Okanovic et al., 2004; Rose et al., 2002).

While the impact of diabetes on quality of life has garnered increasing attention, it is important to note that quality of life is an ill-defined, imprecise concept with no universally agreed upon definition. Often the terms of well-being, happiness, doing well, life satisfaction, coping, self-actualization and fulfillment are used synonymously with the term quality of life. Although the concept was mentioned as far back as Aristotle the term quality of life was not routinely mentioned in the literature until the 1900's (Fayers & Machin, 2007). Definitions generally "specify that quality of life is an *individual psychological* perception of the *material reality* of aspects of the world" (Rapley, 2003 p 50). Health-related quality of life is also a loose term with no agreed upon definition. Despite these conceptual ambiguities, there is widespread agreement that both health care and health research should assess quality of life outcomes.

Assessing patients' quality of life has numerous benefits. It allows health care providers and researchers to better understand what aspects of the illness and treatment the patient views as having the greatest impact on their quality of life. It may also be found that the quality of life outcomes of a particular therapy outweighs its potential benefits. Quality of life effects of various diabetes treatments may impact patients sustaining health care activities and health care providers decision-making. Understanding quality of life may also be useful in

communicating to future patients about expectations of the impact treatment has on quality of life (Fayers & Machin, 2007).

As with the definition of quality of life, there is no one accepted measurement instrument for quality of life. There are general quality of life measures as well as disease-specific and complication-specific instruments (Fayers & Machin, 2007). The Patient-Reported Outcomes and Quality of Life Instrument Database is an international comprehensive data base for quality of life measures that currently includes 470 measurement instruments (Emery, Perrier, & Acquadro, 2005). Quality of life measurement is subjective because of individuals' differing values and ideas regarding quality of life. It has also been found that family, friends and health care providers are often poor judges of a patient's self-reported quality of life (Fayers & Machin, 2007).

Quality of life in diabetes patients has been studied in relation to patient demographics, type of diabetes, diabetes treatment and diabetes self-management training intervention. However quality of life is often not measured as part of diabetes clinical trials. Glasgow (1999) found that only 17% of diabetes self-management training clinical trials reported in the late 1990's included a quality of life outcome. Much of the quality of life research is methodologically flawed and the use of different quality of life measures affects the ability to generalize and compare results (Rapley, 2003).

No previous meta-analyses have addressed quality of life outcomes after diabetes self-management interventions. As part of their meta-analysis of the effects of diabetes education, Norris, Engelgau and Narayan (2001) found only

three studies that had quality of life as an as outcome. Two of these found no change in quality of life with the third showing an improvement in quality of life. Norris et al. did not synthesize across this small number of studies. A meta-analysis of psychological outcomes and symptoms (Ismail, Winkley, & Rabe-Hesketh, 2004) found a slight decrease in psychological distress in the five studies included in their meta-analysis of psychologically-focused interventions in diabetes patients. In a review of randomized controlled trials of diabetes educational interventions between 2001 and 2005, eight studies found improvements in well-being, anxiety and attitude towards diabetes after the intervention (Sigurdadottir, Jonsditter, & Benediktsson, 2007). This study fills the need to synthesize the effects of self-management education on quality of life outcomes.

CHAPTER 3

METHODS

This project was performed using meta-analysis methods. Meta-analysis is the systematic integration of primary studies with statistical analysis of their results in order to calculate a pooled effect size for the dependent variables under study (Conn, 2004). Meta-analysis is most useful with topics that primary studies have provided conflicting or inconsistent results (Sauerbrei & Blettner, 2003). It also allows for further examination of the effect of moderators on the dependent variable across studies (Conn, 2004). For example, potential moderators might include intervention characteristics or various study sample attributes. Meta-analysis can also be helpful in integrating the results from primary studies that may have had inadequate sample sizes in order to have sufficient power to establish significance (Conn, Valentine, Cooper, & Rantz, 2003). Further details of the meta-analysis methods used in the parent study are available elsewhere (Conn, Hafdahl, LeMaster, et al., 2007; Conn Hafdahl, Mehr, et al., 2007; Nielsen, Hafdahl, Conn, LeMaster, & Brown, 2006).

Inclusion Criteria and Search Strategies

This project utilized data from a large meta-analysis that examined the effects of interventions designed to increase physical activity in adults with chronic illnesses. The parent study retrieved any intervention study that included a recommendation to increase physical activity, including diabetes self-

management interventions that usually suggest subjects increase their physical activity (Conn, Hafdahl, Mehr, et al., 2007). A subset of these studies examining diabetes self-management training in adults with diabetes with reported quality of life outcomes was analyzed for this project. An extensive literature search was performed identifying primary studies from 1970 to April 2005 that identified quality of life outcomes following a diabetes self-management training intervention with an identified exercise component.

The literature search included published and unpublished studies to avoid publication bias. Examples of unpublished studies include dissertations, conference abstracts and unpublished manuscripts. Publication bias may over estimate the total effect size because negative results or results that failed to reach statistical significance are often not published (Conn et al., 2003; Czienskowski, 2003).

To be comprehensive it is important to search multiple electronic databases when doing meta-analyses of diabetes interventions (Royle, Bain, & Waugh, 2005). A reference librarian was utilized to perform an electronic search of 11 databases including CINAHL, Clinical Evidence, Cochrane Central Register of Controlled Trials, Dissertation Abstracts, EMBASE, ERIC, HealthStar, MEDLINE, PsychInfo, and SportDiscus. The following terms were used when searching the databases for papers on diabetes self-management interventions with a physical activity component: adherence behavior therapy, clinical trial, compliance, counseling, evaluation, evaluation study, evidenced-based medicine, health care evaluation, health behavior, health education, health

promotion, intervention, outcome and process assessment, patient education, program, program development, program evaluation, self-care, treatment outcome, validation study, exercise, physical activity, physical fitness, exertion, exercise therapy, physical education and training and walking. Hand searches were performed by the research team in the journals *Diabetes, Diabetes Care, The Diabetes Educator, Diabetes Medicine, Diabetes Research and Clinical Practice, Diabetes Spectrum* and *Diabetologia.* Conference abstracts from the American Diabetes Association and the American College of Sports Medicine were explored.

In an effort to be comprehensive, ancestry searches of the identified primary studies, narrative reviews and syntheses of the topic were done. Searches of National Institutes of Health funded study register were also performed. Additionally senior authors of primary studies were contacted and computerized searches of senior authors were conducted (Dickersin, 2005; Hopewell, Clarke, & Mallet, 2005).

The following inclusion criteria were used for the primary studies included in this project:

- participants 21 years of age or older,
- participants with diagnosed diabetes (either type 1 or type 2),
- a diabetes self-management intervention designed to increase physical exercise either as the primary outcome or as part of multiple diabetes self-management behavior outcomes,

- a quality of life measurement post-intervention with sufficient data to calculate an effect size.

Both two-group and single-group comparisons were included. Two group studies compare treatment and control subjects following the intervention. Single group studies only compare pre- and post-intervention data from the same group of subjects. We also coded baseline and outcome data for both treatment and control subjects, and analyzed these as single-group data even among studies with both treatment and control groups. The two-group and single-group primary studies were analyzed separately. We did not limit our inclusion to studies with a particular research design, to capture the broad spectrum of completed primary studies (Conn, Valentine & Rantz, 2003).

Data Extraction

The primary reports were coded using a coding frame that had been developed for the project, then piloted with ten primary studies and revised accordingly. It was based on the coding frame from the parent meta-analysis so all of the items except the diabetes-specific items were extensively tested. To enhance coding reliability, each primary study was independently coded by two coders with the principal investigator of the larger meta-analysis resolving any discrepancies between coders. Primary studies were coded as having a quality of life outcome if the following terms were used: quality of life, health-related quality of life, life satisfaction, well-being, or psychosocial adaptation to illness. These terms were chosen because of their frequency of use as synonyms of

quality of life within the literature. The identification and measurement of mood, anxiety and depression were not coded as quality of life outcomes.

Primary studies were coded for year of publication, study type, participant age, type of diabetes, gender, body mass index (BMI), ethnicity, glycemic control pre- and/or post-intervention, length of time between the intervention and the most distal quality of life outcome measurement, intervention duration, group versus individual intervention, characteristics of exercise prescription, exercise as only behavioral target or multiple self-management behavior targets, intervention components, fitness level, quality of life pre- and/or post-intervention, time between intervention and outcome measures, and type of quality of life measurement tool.

Analysis

The effect size was determined by calculating the standardized mean difference (*d*) for each comparison between treatment and control groups or pre- and post-intervention results for studies with a single group design. This calculation of effect size reflects comparable mean results regardless of the quality of life outcome measure used. Pooling different quality of life measures for determining effect size in meta-analyses has been supported in the literature although caution should be used depending on the constructs being tested and responsiveness of instruments and lead to altered effect sizes (Puhan, Soesilo, Guyatt, & Schunemann, 2006).

The calculation of effect size necessitates either a control group or pre- and post-test for comparison. A positive treatment effect on quality of life is

reflected by a positive *d* score. A conventional heterogeneity statistic (*Q)* was performed to determine effect size homogeneity between primary studies. To account for differing sample sizes in the primary studies, the effect size's of the individual studies were weighted by the inverse of their variance thus giving larger sample primary studies more influence on overall quality of life effect size values.

Studies using two-group comparisons were analyzed separately from studies with a single-group design. Studies with multiple treatment groups but no control group were included with the single-group studies. Analysis of single-group studies can be problematic since the pre- and post-test results are most likely correlated. Unfortunately none of the primary studies reported this information, therefore the analyses were conducted using the assumption of no correlation as well as the assumption of a strong positive correlation between pre- and post-test scores. Both data are presented.

A random effects model was used in the analysis. The random-effects model assumes that there are sampling errors as well as study implementation variances that may affect the effect sizes of the primary studies. Use of a random-effects model is appropriate for this meta-analysis because the implementation of self-management training is heterogeneous. The random effects model allows for increased generalization of the findings to other studies with differing characteristics (Hartung & Knapp, 2003; Sauerbrei & Blettner, 2003). The between study variance was computed by the weighted method of moments.

Due to there being insufficient information about potential moderating factors reported in the primary studies, a formal analysis of potential moderator variables' effects on quality of life was not done. Various participant, intervention and source descriptive data that have previously been found to impact quality of life were tabulated from the primary studies. Participant variables included age, gender, type of diabetes, body mass index, ethnicity, fitness level and glycemic control. Intervention variables included group vs. individual exercise, duration of intervention, presence and type of exercise prescription, exercise specific or general diabetes self-management training, intervention use of self-monitoring and social modeling, length of time between intervention and outcome measure. Source variable was year of publication.

CHAPTER 4

RESULTS

Extensive searching yielded 2,807 citations for possible inclusion. Abstracts and full papers were evaluated for each of the inclusion criteria listed above, which dramatically narrowed the potential studies. Papers were commonly excluded because the study lacked either an intervention or a quality of life measure. The final yield was 20 comparisons across 1,892 subjects that were eligible for inclusion. (Primary study reports included in the meta-analysis are indicated in the reference list.) The earliest study was published in 1991, most of the studies (k = 13) were published in 2000 or later (k denotes the number of comparisons). Nineteen studies were published; one was a dissertation. Two studies were not funded; the remainder received some source of funding to conduct the study.

Samples included in Primary Studies

Descriptive information about the studies is provided in Table 1. Most samples were middle-aged and older. Only 4 studies reported a mean age under 57 years. Women were well represented in these samples. Only 2 studies excluded women. Only 6 studies reported including African-Americans. Among these 6 studies, 3 studies focused exclusively on African Americans. None of the studies that included African Americans and other subjects reported data separately for African Americans. No studies reported including Hispanic or

Native American subjects.

Few studies reported education or socioeconomic level of subjects. Most studies contained many overweight subjects (mean BMI = 33.34). Only 2 of the 7 studies that reported BMI reported means less than 30. Metabolic control on entry into studies was poor (mean HbA1c = 8.74), with 4 studies reported entry HbA1c over 10. Too few studies reported HbA1c levels after the interventions to analyze outcomes. Sixteen studies focused on adults with type 2 diabetes, 3 included only type 1 diabetic subjects, and 1 study included both types of diabetes. Inclusion of subjects with co-morbidities was too inconsistently reported for analysis.

Table 1

Characteristics of Primary Studies Included in Meta-Analyses

Characteristic	*k*	Minimum	Mean (SD)	Maximum
Mean age (years)	18	44.50	59.08 (8.00)	79.00
Sample size per study	20	8.00	104.75(120.16)	386.00
Number subjects- treatment group	20	8.00	65.45 (60.48)	240.00
Number of control group subjects	8	23	98.25 (69.53)	203
Proportion attrition-treatment group	18	0	.16 (.13)	.50
Proportion attrition-control group	7	0	.12 (.12)	.35
Baseline HbA1c	14	7.05	8.38 (1.59)	11.30
Baseline body mass index	7	28.67	33.34(3.29)	36.50
Percent women	17	0	55 (37)	100
Number education/motivation sessions	18	2	7.67 (5.46)	24
Minutes/session education/motivation	13	15	117.69 (79.57)	300
Weeks over intervention delivered	18	1	27.56 (46.71)	208

Interventions

Interventions varied greatly (Table 1). Two studies delivered interventions in 15 minute sessions and 4 studies used sessions of at least 3 hours. Four studies used more than 10 intervention sessions. Over half of the interventions were delivered in 4 months or fewer. One study delivered the intervention over 1 year and 1 study spread the intervention over 4 years. Only 3 studies reported theoretical frameworks for interventions (transtheoretical model: 1; cognitive behavioral theory: 1; behavior modification theory: 1). In addition to diabetes self-management education, the most frequent intervention components included barriers management (7), problem solving (7), goal setting (5), social support (5), social modeling (4), relapse prevention education (2), and supervised exercise (2). Intervention strategies reported by only 1 study included competition, rewards, decision making, exercise prescription, fitness testing, and self-reevaluation. Two interventions were individually tailored for subjects. Over half of the intervention sessions used discussion format as well as didactic lecture. Six studies delivered at least part of the intervention via telephone and 1 study used mail delivery. Only 2 studies did not include any face-to-face delivery of interventions. Among the studies that reported the physical setting where interventions were delivered, 9 were in ambulatory care settings, 4 were in community centers, and 1 was delivered to in-patients. Seven studies presented interventions to individual subjects while 13 used groups. Most of the 17 studies that described interventionist professional characteristics reported combinations of health professionals as interventionists (k=10).

Methodological Characteristics

Small samples were common (Table 1). Six studies included less than 30 subjects. Six of the two-group comparisons used random assignment of subjects to treatment and control groups. Two of the two-group comparisons did not use random assignment. Quality of life was most often measured by the Medical Outcomes Study Short Form 36 (*k* = 6). Only 1 study used an investigator developed instrument and while the remainder used previously developed measures of quality of life. Eight comparisons could be made between treatment groups and control groups following interventions. Twenty studies provided baseline and outcome data for treatment subjects for making single group pre- versus post-group comparisons.

Quality of Life Outcomes

The comparison between treatment group and control group outcomes following interventions yielded an effect size of 0.281 ($\hat{\mu}_\delta = 0.281$) (Table 2). The comparison between treatment group at baseline and outcome measurement yielded an effect size of 0.312 ($\hat{\mu}_\delta = 0.098$) (Table 2) under the assumption of high correlation between pre- and post-test scores. Results of the analysis with the assumption of no correlation for single-group pre- versus post intervention comparison was similar with an effect size of 0.313 ($\hat{\mu}_\delta = 0.110$). Each of these effect sizes were statistically significant, meaning that the hypothesis that interventions to improve self-management results in increased quality of life outcomes was supported.

In contrast, neither of the effect sizes for control group pre- versus post-

intervention quality of life scores were significantly different from 0 (Table 2). Control subjects did not experience improvements in quality of life by participating in these studies.

The *Q* values reported in Table 2 document that the studies were significantly heterogeneous across two-group (72.934) and single-group comparisons (490.271 and 109.546). This was expected because diverse interventions were tested in varied samples using a wide range of methods in these primary studies.

Table 2

Random Effects Analysis of Quality of Life Effect Sizes

Comparison	k	$\hat{\mu}_\delta$	$SE(\hat{\mu}_\delta)$	95% CI for μ_δ	$\hat{\sigma}_\delta$	*Q*
Treatment vs. control at outcome	8	0.281*	0.171	-0.053, 0.616	0.029	72.934***
Treatment outcome vs. treatment baseline (0.80 association) [a]	20	0.312***	0.098	0.120, 0.505	0.010	490.271***
Treatment outcome vs. treatment baseline (0.00 association) [a]	20	0.313**	0.110	0.098, 0.529	0.012	109.546***
Control group outcome vs. treatment baseline (0.80 association) [a]	7	-0.227	0.139	-0.499, 0.045	0.019	414.504***
Control group outcome vs. treatment baseline (0.00 association) [a]	7	-0.165	0.146	-0.451, 0.122	0.021	29.612***

[a]Treatment outcome vs. treatment baseline comparisons conducted under two distinct assumptions regarding correlation between pre- and post-test scores: .80 association and .00 association

* <.10

** p < .01

*** p <.001

CHAPTER 5

DISCUSSION

The meta-analysis findings document that people with diabetes experience improved quality of life after receiving interventions designed to improve their diabetes self-management behaviors. Previous reviews retrieved too few studies to conduct a meta-analysis (Norris et al., 2001). Two previous syntheses of small numbers of primary studies found decreases in psychological distress and symptoms, but did not directly address quality of life (Ismail et al., 2004; Sigurdadottir et al., 2007). This is the first meta-analysis to synthesize quality of life outcomes in adult diabetes patients following diabetes self-management training. These findings are important because health care is increasingly focused not only on decreasing morbidity, mortality, and costs but also on increasing quality of life especially among those with major chronic illnesses such as diabetes.

The magnitude of the effect size is difficult to assess because too few studies used any single measure in exactly the same way to allow us to convert the effect size to an original metric. Although .28 effect size may appear small, a recent meta-analysis of HbA1c outcomes reported an effect size of .29 which equated to post-intervention HbA1c of 7.38 for treatment subjects as compared to 7.83 for control subjects (Conn, Hafdahl, LeMaster, et al 2007). Thus what appears to be a small effect size may be clinically meaningful. As more studies use identical measures of quality of life, the amount of change required to be clinically meaningful may become clearer. Since quality of life is a complex phenomena likely affected by diverse

factors, any statistically significant improvement is probably clinically important.

Diabetes is a demanding chronic illness that requires continued and daily activities to maintain control. People with diabetes may avoid changing diet and exercise behavior because they fear their quality of life will be adversely affected by these changes. This study's findings suggest the opposite is true. Diabetes health professionals can tell patients that others generally experience improvements in quality of life by participating in classes designed to increase metabolic control. The reasons for this quality of life improvement are not known since the interventions were not designed to affect quality of life. It is possible that people may feel better with improved metabolic control following interventions. We were unable to assess this link through moderator analyses because too few studies reported both quality of life and HbA1c outcomes.

One possible explanation for the improvement in quality of life involves self-efficacy. Extant research reported that self-management education increases self-efficacy (Pibernik-Okanovic et al., 2004). Previous research has documented that self-efficacy predicts quality of life (Kuijer & de Ridder, 2003; Rose et al., 2002). Thus the influence of self-management interventions on quality of life may be mediated by self-efficacy. Another possible explanation is that people may experience improved quality of life when they have an enhanced sense of mastery over the potential consequences of diabetes that may come from better education. An alternative explanation is that people may experience improved quality of life as a result of changing their diet and exercise behavior. Some previous research has documented improved quality of life following positive health behavior change

among adults with diabetes (Li, Ford, Mokdad, Jiles, & Giles, 2007). It is also plausible that subjects experience group camaraderie or social support during the group diabetes classes that results in better quality of life outcomes. Future research needs to address these issues.

Very few of the primary studies in this meta-analysis included African Americans and no studies noted inclusion of Hispanic or Native Americans. This relative lack of ethnic inclusion was surprising because of the disproportionate burden diabetes has in these populations.

The parent project for this study included studies with either exercise or HbA1c outcomes. Far too few of the studies with other diabetes outcomes measured quality of life. Future research should include measures of quality of life since widely available measures have documented validity and add little respondent burden.

This study shares the limitations of all meta-analyses. The finding are not causal because all meta-analysis findings are observational. As expected, we retrieved a heterogeneous set of studies. This was expected because the interventions used in practice and research vary widely, as do subjects included in samples. After more primary studies become available, heterogeneity may be explored through moderator analyses. This meta-analysis was limited by the number of studies that provided quality of life outcome data despite extensive comprehensive searching. We retrieved too few studies to conduct moderator analyses. After more primary studies with quality of life outcomes accrue, moderator analyses can determine the impact other variables on quality of life, such as sample characteristics like age, ethnicity, gender, type of diabetes, and type of diabetes

treatment; intervention attributes such as content and dose; and other outcomes such as the extent to which subjects actually changed their behavior and HbA1c changes.

These findings may be useful in practice settings. Providers might tell patients that evidence suggests people who attend self-management programs experience improved quality of life. Dramatic changes in diet and exercise may feel overwhelming to patients confronted with the need for life long behavior change. Patients may fear a decline in their quality of life if they make these changes. Reassurance that they are likely to experience improvements could be helpful.

In conclusion, this meta-analysis documented improvements in quality of life outcomes among adults with diabetes following interventions designed to enhance their diabetes self-management. Clinicians may use these finding to encourage patients to participate in diabetes education programs. We encourage researchers and providers evaluating diabetes self-management programs to include quality of life outcome measures in their project so future meta-analyses can examine important potential moderators.

REFERENCES

*Denotes studies included in meta-analysis

Aalto, A. M., Uutela, A., & Aro, A. R. (1997). Health related quality of life among insulin-dependent diabetics: disease-related and psychosocial correlates. *Patient Education and Counseling, 30*(3), 215-225.

Ahlgren, S., Shultz, J., Massey, L., Hicks, B., & Wysham, C. (2004). Development of a preliminary diabetes dietary satisfaction and outcomes measure for patients with type 2 diabetes. *Quality of Life Research: An International Journal of Quality of Life Aspects of Treatment, Care & Rehabilitation, 13*(4), 819-832.

Aikens, K. S., Aikens, J. E., Wallander, J. L., & Hunt, S. (1997). Daily activity level buffers stress-glycemia associations in older sedentary NIDDM patients. *Journal of Behavioral Medicine, 20*(4), 379-390.

*Baran, R. W., Crumlish, K., Patterson, H., Shaw, J., Erwin, W. G., Wylie, J. D., et al. (1999). Improving outcomes of community-dwelling older patients with diabetes through pharmacist counseling. *American Journal of Health System Pharmacy, 56*(15), 1535-1539.

*Basa, R. P., & McLeod, B. (1995). Evaluation of a diabetes specialty centre: structure, process and outcome. *Patient Education and Counseling, 25*(1), 23-29.

Boye, K., Matza, L., Ogelsby, A. Malley, K. Kim, S., Hayes, R. & Brodows, R. (2006). Patient reported outcomes in a trial of exenatide and insulin glargine for the treatment of type 2 diabetes. *Health & Quality of Life Outcomes, 4*(80). doi:10.1186/1477-7525-4-80.

Brod, M., Cobden, D., Lammert, M., Bushnell, D., & Raskin, P. (2007). Examining correlates of treatment satisfaction for injectable insulin in type 2 diabetes: lessons learned from a clinical trial comparing biphasic and basal analogues. *Health & Quality of Life Outcomes, 5*(8). doi:10.1186/1477-7525-5-8.

Brod, M., Skovlund, S. E., & Wittrup-Jensen, K. U. (2006). Measuring the impact of diabetes through patient report of treatment satisfaction, productivity and symptom experience. *Quality of Life Research, 15*(3), 481-491. doi: 10.1007/s11136-005-1624-6.

Cerrelli, F., Manini, R., Forlani, G., Baraldi, L., Melchionda, N., & Marchesini, G. (2005). Eating behavior affects quality of life in type 2 diabetes mellitus. *Eating and Weight Disorders, 10*(4), 251-257.

Chang, T. (2004). *Testing a conceptual model of factors affecting glycemic control and quality of life in Taiwanese older adults with type 2 diabetes mellitus.* (The University of North Carolina at Chapel Hill) Ph.D. 229 p.

Chantelau, E., Schiffers, T., Schutze, J., & Hansen, B. (1997). Effect of patient-selected intensive insulin therapy on quality of life. *Patient Education and Counseling, 30*(2), 167-173.

Chumbler, N. R., Neugaard, B., Kobb, R., Ryan, P., Qin, H., & Joo, Y. (2005). Evaluation of a care coordination/home-telehealth program for veterans with diabetes: health services utilization and health-related quality of life. *Evaluation and the Health Professions, 28*(4), 464-478.

Conn, V., Hafdahl, A. R., Lemaster, J. W., Ruppar, T., Cochran, J., & Nielsen, P. J. (2007). Meta-analysis of health behavior change interventions in type 1 diabetes. *Amerian Journal of Health Behavior, In Press*.

Conn, V., Valentine, J. C., Cooper, H. M., & Rantz, M. (2003). Grey literature in meta-analyses. *Nursing Research, 52*, 256-261.

Conn, V. S. (2004). Meta-analysis research. *Journal of Vascular Nursing. 22(2), 51-2.*

Conn, V. S., Hafdahl, A. R., Mehr, D. R., Lemaster, J. W., Brown, S. A., & Nielsen, P. J. (2007). Metabolic effects of interventions to increase exercise in adults with type 2 diabetes. *Diabetologia.* 50(5), 913-921.

Czienskowski, U. (2003). Meta-analysis - not just research synthesis. In R. Schulze, H. Holling & D. Bohning (Eds.), *Meta-Analysis New Developments and Applications in Medical and Social Sciences* (pp. 141-152). Canbridge, MA: Hogrefe and Huber.

*de Weerdt I, Visser AP, Kok GJ, et al. (1991). Randomized controlled multicentre evaluation of an education programme for insulin-treated diabetic patients: effects on metabolic control, quality of life, and costs of therapy. *Diabetic Medicine, 8*, 338-345.

Dickersin, K. (2005). Publication bias: recognizing the problem, understanding its origins and scope, and preventing harm. In H. Rothstein, A. Sutton & M. Borenstein (Eds.), *Publication Bias in Meta-Analysis Prevention, Assessment and Adjustments* (pp. 11-34). West Sussex, England: Wiley and Sons Inc.

Dzewaltowski, D. A., Estabrooks, P. A., & Glasgow, R. E. (2004). The future of physical activity behavior change research: what is needed to improve translation of research into health promotion practice?. *Exercise & Sport Sciences Reviews. 32(2):*57-63.

Eiser, J. R., Riazi, A., Eiser, C., Hammersley, S., & Tooke, J. (2001). Predictors of psycological well-being in types 1 and 2 diabetes. *Psychology & Health, 16*, 99-110.

Emery, M., Perrier, L., & Acquadro, C. (2005). Patient-reported outcome and Quality of Life Instruments Database (PROQOLID): frequently asked questions. *Health & Quality of Life Outcomes, 3*(12). doi:10.1186/1477-7525-3-12.

Evans, A. R., & Pinzur, M. S. (2005). Health-related quality of life of patients with diabetes and foot ulcers. *Foot & Ankle International, 26*(1), 32-37.

Fayers, P., & Machin, D. (2007). *Quality of Life* (2nd ed.). West Sussex, England: Wiley and Sons Inc.

Franciosi, M., Pellegrini, F., De Berardis, G., Belfiglio, M., Cavaliere, D., Di Nardo, B., et al. (2001). The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients: an urgent need for better educational strategies. *Diabetes Care, 24*(11), 1870-1877.

Gary, T. L., Genkinger, J. M., Guallar, E., Peyrot, M., & Brancati, F. L. (2003). Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *The Diabetes Educator, 29*(3), 488-501.

*Glasgow, R. E., Toobert, D. J., Hampson, S. E., Brown, J. E., Lewinsohn, P. M., & Donnelly, J. (1992). Improving self-care among older patients with type II diabetes: the "Sixty Something" study. *Patient Education & Counseling, 19(1)*, 61-74.

Glasgow, R. E. (1999). Outcomes for and of diabetes research. *The Diabetes Educator, 25,* 74.

Hartung, J., & Knapp, G. (2003). An alternative test procedure for meta-analysis. In R. Schulze, H. Holling & D. Bohning (Eds.), *Meta-Analysis New Developments and Applications in Medical and Social Sciences* (pp. 53-70). Cambridge, MA: Hogrefe & Huber.

*Hendricks, L. E., & Hendricks, R., T. (2000). The effect of diabetes self-management education with frequent follow-up on the health outcomes of African American men. *Diabetes Educator, 26(6),* 995-1002.

*Hernandez, C., Hume, R., Rodger, N. (2003). Six-month evaluation of a diabetes self-awareness intervention. *Outcomes Management, 7,* 148-158.

Hill-Briggs, F., Gary, T. L., Baptiste-Roberts, K., & Brancati, F. L. (2005). Thirty-six-item short-form outcomes following a randomized controlled trial in type 2 diabetes. *Diabetes Care, 28*(2), 443-444.

Holton, D. R., Colberg, S. R., Nunnold, T., Parson, H. K., & Vinik, A. I. (2003). The effect of an aerobic exercise training program on quality of life in type 2 diabetes. *The Diabetes Educator, 29*(5), 837-846.

Hopewell, S., Clarke, M., & Mallet, S. (2005). Grey literature and systematic reviews. In H. Rothstein, A. Sutton & M. Borenstein (Eds.), *Publication Bias in Meta-Analysis Prevention, Assessment and Adjustments* (pp. 49-72). West Sussex, England: Wiley and Sons Inc.

Ismail, K., Winkley, K., & Rabe-Hesketh, S. (2004). Systematic review and meta-analysis of randomised controlled trials of psychological interventions to improve glycaemic control in patients with type 2 diabetes. *Lancet, 363*(9421), 1589-1597.

Kaholokula, J. K., Haynes, S. N., Grandinetti, A., & Chang, H. K. (2003). Biological, psychosocial, and sociodemographic variables associated with depressive symptoms in persons with type 2 diabetes. *Journal of Behavioral Medicine, 26*(5), 435-458.

*Keyserling, T. C., Samuel-Hodge, C. D., Ammerman, A. S., et al. (2002). A randomized trial of an intervention to improve self-care behaviors of African-American women with type 2 diabetes: impact on physical activity. *Diabetes Care, 25(9)*, 1576-1583.

*Klepac, M. P. (2000) *Integrative diabetes education: expansion and evaluation of a holistic program using quantitative and qualitative methodology*. Dissertation, Pennsylvania State University.

Kuijer, R. G., & de Ridder, D. T. (2003). Discrepancy in illness-related goals and quality of life in chronically ill patients: the role of self-efficacy. *Psychology & Health, 18*(3), 313-330.

Li, C., Ford, E., Mokdad, A., Jiles, R., & Giles, W. (2007). Clustering of multiple healthy lifestyle habits and health-related quality of life among adults with diabetes. *Diabetes Care, 30*, 1770-1776.

Liu, H., Hays, R. D., Adams, J. L., Chen, W., Tisnado, D., Mangione, C. M., et al. (2005). Imputation of SF-12 health scores for respondents with partially missing data. *Health Services Research*. 40(3), 905-21.

Lloyd, C. E., Dyer, P. H., Lancashire, R. J., Harris, T., Daniels, J. E., & Barnett, A. H. (1999). Association between stress and glycemic control in adults with type 1 (insulin-dependent) diabetes. *Diabetes Care, 22*(8), 1278-1283.

Maddigan, S. L., Feeny, D. H., & Johnson, J. A. (2005). Health-related quality of life deficits associated with diabetes and comorbidities in a Canadian National Population Health Survey. *Quality of Life Research, 14*(5), 1311-1320.

Menard, J., Payette, H., Baillargeon, J., Maheux, P., Lepage, S., Tessier, D., et al. (2005). Efficacy of intensive multitherapy for patients with type 2 diabetes mellitus: a randomized controlled trial. *CMAJ: Canadian Medical Association Journal, 173*(12), 1457-1463.

Mensing, C., Boucher, J., Cypress, M., Weinger, K., Mulcahy, K., Barta, P., et al. (2007). National standards for diabetes self-management education. *Diabetes Care, 30*(suppl 1), S96-103.

Nielsen, P. J., Hafdahl, A. R., Conn, V. S., LeMaster, J. W., & Brown, S. A. (2006). Meta-analysis of the effect of exercise interventions on fitness outcomes among adults with type 1 and type 2 diabetes. *Diabetes Research and Clinical Practice, 74*(2), 111-120.

Norris, S. L., Engelgau, M. M., & Narayan, K. M. V. (2001). Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care, 24*(3), 561-587.

Peyrot, M., Rubin, R. R., Lauritzen, T., Snoek, F. J., Matthews, D. R., & Skovlund, S. E. (2005). Psychosocial problems and barriers to improved diabetes management: results of the Cross-National Diabetes Attitudes, Wishes and Needs (DAWN) Study. *Diabetic Medicine, 22*(10), 1379-1385.

Pibernik-Okanovic, M., Prasek, M., Poljicanin-Filipovic, T., Pavlic-Renar, I., & Metelko, Z. (2004). Effects of an empowerment-based psychosocial intervention on quality of life and metabolic control in type 2 diabetic patients. *Patient Education and Counseling, 52*(2), 193-199.

Puhan, M., Soesilo, I., Guyatt, G., & Schunemann, H. (2006). Combining scores from different patient reported outcome measures in meta-analyses: when is it justified? *Health & Quality of Life Outcomes, 4*(94). doi:10.1186/1477-7525-4-94.

Rapley, M. (2003). *Quality of Life Research*. London: SAGE Publications.

Rose, M., Fliege, H., Hildebrandt, M., Schirop, T., & Klapp, B. F. (2002). The network of psychological variables in patients with diabetes and their

importance for quality of life and metabolic control. *Diabetes Care, 25*(1), 35-42.

Royle, P. L., Bain, L., & Waugh, N. R. (2005). Sources of evidence for systematic reviews of interventions in diabetes. *Diabetic Medicine, 22*(10), 1386-1393.

Rubin, R. R., Peyrot, M., & Siminerio, L. M. (2006). Health care and patient-reported outcomes: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Care. 29(6):*1249-55.

Saito, I., Inami, F., Ikebe, T., Moriwaki, C., Tsubakimoto, A., Yonemasu, K., et al. (2006). Impact of diabetes on health-related quality of life in a population study in Japan. *Diabetes Research and Clinical Practice, 73*(1), 51-57.

Sauerbrei, W., & Blettner, M. (2003). Issues of traditional reviews and meta-analyses of observational studies in medical research. In R. Schulze, H. Holling & D. Bohning (Eds.), *Meta-Analysis New Developments and Applications in Medical and Social Sciences* (pp. 78-98). Cambridge, MA: Hogrefe and Huber.

Shah, B. M. (2006). *A psychosocial investigation of depression and health-related quality of life in patients with type 2 diabetes mellitus.* Dissertation.

Sigurdadottir, A., Jonsditter, H., & Benediktsson, R. (2007). Outcomes of educational intervevtions in type 2 diabetes: WEKA data-mining analysis. *Patient Education & Counseling, 67*, 21-31.

*Smith, S., Bury, G., O'Leary, M., et al. (2004). The North Dublin randomized controlled trial of structured diabetes shared care. *Family Practice. 21(1),* 39-45.

Snoek, F. J. (2003). Improving quality of life in diabetes: how effective is education. *Patient Education & Counseling, 51*, 1-3.

*Toobert, D. J., Glasgow, R. E., Strycker, L. A., et al. (2003) Biologic and quality-of-life outcomes from the Mediterranean Lifestyle Program: a randomized clinical trial. *Diabetes Care, 26(8)*, 2288-2293.

*Trento, M., Passera, P., Bajardi, M., et al. (2002). Lifestyle intervention by group care prevents deterioration of type II diabetes: a 4-year randomized controlled clinical trial. *Diabetologia 45(9),* 1231-1239.

Trief, P. M., Wade, M. J., Britton, K. D., & Weinstock, R. S. (2002). A prospective analysis of marital relationship factors and quality of life in diabetes. *Diabetes Care, 25*(7), 1154-1158.

*Tucker, R. M., May, C., Bennett, R., Hymer, J., & McHaney B. (2004). A gym-based wellness challenge for people with type 2 diabetes: effect on weight loss, body composition, and glycemic control. *Diabetes Spectrum, 17(3)*, 176-180.

*Weinberger, M., Kirkman, S., Samsa, G. P., et al. (1995). A nurse-coordinated intervention for primary-care patients with non-insulin-dependent diabetes-mellitus - impact on glycemic control and health-related qualify of life. *Journal of General Internal Medicine, 10(2),* 59-66.

*Wendel, I., Durso, S. C., Zeble, B., Loman, K., & Remsburg, R. E. (2003). Group diabetes patient education: A model for use in a continuing care retirement community. *Journal of Gerontological Nursing, 29(2),* 37-44.

*Whittemore, R., Chase, S., Mandle, C. L., & Roy, S. C. (2001). The content, integrity, and efficacy of a nurse coaching intervention in type 2 diabetes. *Diabetes Educator, 27*(6), 887-898.

*Wierenga, M. E. (1994). Life-style modification for weight control to improve diabetes health status. *Patient Education & Counseling, 23*(1), 33-40.

VITA

Jane Cochran was born May 18, 1959 in Bonne Terre, Missouri to Cecil and Jean Hulsey and raised in Farmington, Missouri. After graduating from Farmington Senior High School, she received a Bachelor's of Science in Nursing from Avila College in Kansas City, Missouri in 1981. She received a Master's of Science in Nursing from University of Missouri-Columbia in 1987 and a Ph.D. in Nursing from University of Missouri-Columbia in 2007.

Jane is married to Steve Cochran and they have two sons, Matthew and David. She currently resides in Columbia, Missouri and is employed by the Division of Endocrinology, Diabetes and Metabolism at the University of Missouri-Columbia School of Medicine.