Abstract

Type 2 diabetes mellitus (T2DM) is a serious and costly metabolic disease that is a growing concern in the United States. T2DM is associated with numerous comorbid conditions that can lead to negative patient outcomes. Comorbid chronic pain is very common in T2DM due to the presence of diabetic neuropathy and musculoskeletal conditions that are associated with prolonged hyperglycemia. Neuropathic pain is the most common type of comorbid pain studied in T2DM, while musculoskeletal pain has received less attention in the literature. However, recent studies have highlighted types of musculoskeletal pain that appear to be highly prevalent in T2DM such as arthritis and low back pain. These studies have suggested that comorbid musculoskeletal pain may limit important self-care activities, particularly physical activity, in individuals with diabetes. Based on the existing research, further exploration of the impact of pain in T2DM is warranted. The current study will examine the prevalence, characteristics, and severity of comorbid pain conditions using interviews and self-report questionnaires in a sample of adults with T2DM attending two diabetes clinics in Southeast Ohio. The study will also assess psychosocial variables related to pain to examine 1) the impact of neuropathic and musculoskeletal pain in patients with T2DM in terms of quality of life, disability, physical activity, and other self-care activities, 2) the relationships among symptoms of depression, anxiety, and pain in T2DM, and 3) how pain coping strategies may be related to self-care in T2DM. Further research in this area will help to expand existing knowledge of different types of comorbid pain conditions in T2DM and can also help to inform clinical interventions to address pain and improve self-care in this population. Results of the current study will be presented at the Society of Behavioral Medicine Annual Meeting in April 2011.
Narrative

**Type 2 diabetes mellitus** (T2DM) is a serious and costly metabolic disease that is a growing concern in the United States (CDC, 2007; Leahy, 2008). Chronic pain is one type of **comorbid condition** that is very common in T2DM due to the presence of **diabetic neuropathy** and **musculoskeletal conditions** that are associated with prolonged **hyperglycemia** (Burner & Rosenthal, 2007; Krein et al., 2005; Wolak et al., 2001). Although neuropathic pain is most commonly studied in T2DM research, recent studies have highlighted several types of musculoskeletal pain that appear to be highly prevalent in T2DM such as arthritis and low back pain (CDC, 2008; Gore et al., 2006; Hoff, Midthjell, Zwart, & Hagen, 2008; Mantyselka, Miettola, Niskanen, & Kumpusalo, 2008; Tishler et al., 2003). These studies have also suggested that chronic musculoskeletal pain may limit **self-care activities**, particularly physical activity, in individuals with diabetes (Burner & Rosenthal, 2009; Butchart et al., 2009; Krein et al., 2005). This is concerning in T2DM due to the importance of adherence to **self-care activities** to maintain control of blood sugar levels (American Diabetes Association [ADA], 2007; Kerr et al., 2007). However, since most studies have only considered the role of neuropathic pain in T2DM, more research is needed to determine how musculoskeletal types of pain may be related to self-care adherence. Research on pain conditions in other medical illnesses has also found a relationship between pain and **psychiatric comorbidity** (Bair, Robinson, Katon, & Kroenke, 2003). For example, individuals with comorbid pain and depression may have worse health outcomes than those without depression (Kerr et al., 2007). Although few studies have examined this relationship in T2DM, this is an important area to consider due to the high rates of depression in T2DM (Anderson, Freedland, Clouse, & Lustman, 2001).
In light of existing research, further exploration of the impact of different types of pain in T2DM is warranted (Kim et al., 2001; Krein et al., 2005). Research in this area will help to expand existing knowledge of comorbid pain in T2DM and can help to inform clinical interventions to address pain in diabetes treatment settings. The current study will involve a comprehensive assessment of the types of pain present in adults with T2DM in a clinical setting. The study will also examine 1) the impact of comorbid pain in patients with T2DM in terms of quality of life and self-care activities, 2) the relationships among symptoms of depression, anxiety, and pain in T2DM, and 3) pain coping strategies in adults with T2DM that may influence self-care activities and other patient outcomes. Although previous studies have examined some of these variables in terms of neuropathic pain in T2DM, this will be the first study to include both neuropathic and musculoskeletal pain conditions while assessing for psychiatric comorbidity and other psychosocial variables that may be related to pain. Based on prior research it is hypothesized that the presence of comorbid chronic pain will be associated with higher levels of psychiatric comorbidity, lower levels of quality of life, and lower levels of self-care adherence. Since pain coping strategies have not been examined previously in T2DM, analyses related to coping will be exploratory in nature.

Participants will be recruited from the University Medical Associates Endocrinology and Diabetes Centers in Athens, Ohio and Belpre, Ohio (see Appendix for letter of support). A priori power analyses indicated that approximately 100 participants will be needed to complete proposed study analyses with a power of .80. In order to complete recruitment and data collection, the principal investigator (PI) will be present in the diabetes clinics on days when patients with T2DM are seen by their physicians. Data collection will take place between May 2010 and August 2010. Eligible participants (individuals over age 18 with T2DM) will receive a
study flyer when they arrive for their physician’s appointment. If a patient expresses interest, the PI will complete the informed consent process with the participant, which will include a HIPAA Authorization Release Form to review their medical records. The participant will complete a brief interview (15-20 minutes) with the PI to assess types of pain experienced, frequency of pain, severity of pain, and how pain interferes with daily activities. The interview will include items from the Brief Pain Inventory (BPI) and the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS), two well-validated measures of pain assessment (see Appendix for sample items; Bennett, 2001; Cleeland & Ryan, 1994; Tan, Jensen, Thornby, & Anderson, 2004). By using both of these measures, the PI will be able to determine if the participant is experiencing chronic pain and whether the pain is neuropathic or musculoskeletal. The participant will complete 6 additional study questionnaires on a touch-screen laptop computer with audio computer-assisted self-interview software. The software will allow participants to listen to the questions while wearing headphones instead of reading them if they prefer. The questionnaires will include a demographics form, the Coping Strategies Questionnaire – Revised (CSQ-R) to assess types of pain coping, the Self-Care Inventory – Revised (SCI-R) to assess self-reported adherence to diabetes self-care activities, the Patient Health Questionnaire (PHQ) to assess the presence of symptoms of psychiatric disorders such as depression and anxiety, the Hospital Anxiety and Depression Scale to assess the severity of symptoms of depression and anxiety (HADS), and the Short Form 12 Health Survey (SF-12) to assess quality of life (Spitzer, Kroenke, & Williams, 1999; Rosentiel & Keefe, 1983; Ware & Sherbourne, 1992; Weinger, Butler, Welch, & La Greca, 2005; Zigmond & Snaith, 1983). The total time to complete the questionnaires will be approximately 30-45 minutes. If the participant is not able to complete the questionnaires prior to the start of their doctor’s appointment, they will have the opportunity to
finish them after meeting with their doctor. Participants will also be given the option of completing paper and pencil versions of questionnaires and returning them by mail. The interview and questionnaires will be given in a separate education room in the clinics to ensure participant privacy. After completing the interview and questionnaires, the participant will be paid $20 for their time. The participant will then receive a pedometer and 2-week activity log on which to record their daily steps and activity. The log will take approximately 1-2 minutes per day to complete. After returning the completed activity log (in the stamped envelope provided), the participant will be paid an additional $20 for their time. Participants will be able to keep the pedometer for personal use. The PI will collect data related to diabetes severity, medications, and comorbid conditions from the participant’s medical record (with their permission) for use in study analyses.

The primary aim of the current study is to explore the prevalence, frequency, and severity of various types of pain in patients with T2DM which will be determined by descriptive analyses. Correlations will be conducted in order to determine whether there are significant associations between the main study variables of pain severity, pain interference, pain coping strategies, diabetes self-care adherence, and physical activity. Finally hierarchical regression analyses will be conducted to determine if pain severity, interference, and coping strategies are able to predict two dependent variables, 1) quality of life and 2) self-care adherence in the presence of variables related to diabetes severity.

Results from the current study will help to guide further research on pain in T2DM and can also inform the development of clinical interventions for pain management that can be used within diabetes treatment settings. Study findings will be presented at the Society of Behavioral Medicine Annual Meeting in 2011.
Literature Cited


## Budget

### Budget Items to be Partially Covered by GSS Original Works Grant

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<thead>
<tr>
<th>Item</th>
<th>Source</th>
<th>Cost per item</th>
<th>Total</th>
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<tbody>
<tr>
<td>100 Yamax Digiwalker CW 701 Pedometers</td>
<td>Step Into Health</td>
<td>$28.00</td>
<td>$2,800.00</td>
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<tr>
<td>HADS(^{a}) Manual &amp; 100 questionnaires</td>
<td>GL Assessment</td>
<td>$188.00</td>
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<td>SF-12(^{b}) Manual &amp; 100 questionnaires</td>
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<td>Postage for return of 2-week activity logs (2 stamps each)</td>
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<td>1 box of 100 9”x12” manila envelopes</td>
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<td>Photocopying costs (consent forms, questionnaires)</td>
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### Budget Items not Covered by GSS Original Works Grant

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<td>Participant Compensation (100 participants)</td>
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<td>QDS Audio Computer Assisted Self-Interview (ACASI) software</td>
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<td>4 Dell Latitude Netbooks (with touch-screen option)</td>
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### Budget Summary

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<td>Total Amount Requested from GSS Original Work Grant</td>
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<td>Remaining Costs (covered by personal funds)</td>
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</table>

\(^{a}\)Hospital Anxiety and Depression Scale (HADS)

\(^{b}\)Short-Form 12 Health Survey (SF-12)
Budget Justification

*Yamax Digiwalker CW-701 Pedometers:* Pedometers will provide a more objective measure of participant physical activity by allowing participants to record their steps walked per day. Pedometers are also less expensive option than accelerometers, and studies have demonstrated that this model is among the most accurate available for research purposes (Crouter et al., 2003; Schneider, Crouter, & Bassett, 2004). The CW-701 model includes 7-day memory which reduces inaccurate reporting that can occur when participants forget to reset their pedometers daily. Participants will be allowed to keep pedometers for their personal use in order to increase interest in the study.

*HADS and SF-12 Manuals and Questionnaires:* Although many of the study questionnaires are available at no charge for student use, these two questionnaires require copyright fees for each copy of the measure in addition to mandatory purchase of the survey manual. However, due to their strong psychometric properties for use in medical settings, these measures are still the best choice for the current study.

*Postage and envelopes:* These supplies will be used to allow participants to return their completed activity logs and any remaining questionnaires.

*Photocopying and printing costs:* Although computer-assisted questionnaires will reduce photocopying costs, copies of consent forms will be needed along with color copies of the study flyers. Additionally, paper copies of the questionnaires may be needed for participants who prefer to complete the study at home.
Participant Compensation: Due to the total time requirement (1.5-2 hours) and length of study participation with regards to the 2-week activity log, compensation will be provided for both parts of the study. Participants in previous studies at the UMA diabetes clinics have received $20 for a one-time only questionnaire completion. In order to ensure adequate recruitment, participants will receive $20 after completing their interview and questionnaires. After completing and returning the 2-week activity log, they will be mailed an additional $20 for their time.

QDS - ACASI Software: Computer-assisted software allows participants to complete questionnaires with potentially sensitive topic matters (e.g., psychiatric symptoms) in privacy while reducing the number of skipped or inaccurate items. Audio-assisted software can also guide individuals in answering questions which can be helpful in samples with variable reading levels.

Dell Latitude Netbooks: These laptops will allow multiple participants to complete the self-report questionnaires at once in the clinics. The touch-screen feature will make it easier for participants to choose answers to the self-report questions.
Jennifer Merrill
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Phone: (740) 597-2564
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Education:
Ph.D. Candidate, Clinical Psychology
Ohio University, Athens, OH
Specialty Track: Health
Current GPA: 3.88
Anticipated June 2012

Master of Science, Clinical Psychology
Ohio University, Athens, OH
Master’s Thesis Title: Perceived Spousal Criticism, Self-Efficacy, and Adherence to Diet and Exercise Self-Care Behaviors in Adults with Type 2 Diabetes
August 2008

Bachelor of Arts, Psychology, with Honors
Washington University, St. Louis, MO
May 2003

Pre-Doctoral Positions:
Diabetes and Depression Laboratory
Department of Psychology
Ohio University, Athens, OH
Position: Graduate Research Assistant
Supervisor: Mary de Groot, Ph.D.
September 2005-June 2009

Childhood Bereavement Program
Department of Psychiatry
Weill Cornell Medical College, New York, NY
Position: Research Coordinator
Supervisor: Cynthia Pfeffer, M.D.
August 2003-July 2005

Cognitive Control and Psychopathology Lab
Department of Psychology
Washington University, St. Louis, MO
Position: Undergraduate Research Assistant
Supervisor: Deanna Barch, Ph.D.
January 2003-May 2003

Membership in Professional Societies:
2006-Present Society of Behavioral Medicine
2005-Present American Diabetes Association
2005-Present American Psychological Association
Publications:


Manuscripts Under Review:


Manuscripts in Preparation:


Poster Presentations and Abstracts:


Research Experience:

**Research Assistant and Study Therapist**  
2006-2009

**Depression Treatment for Type 2 Diabetes Appalachians: Program ACTIVE**

Principal Investigator: Mary de Groot, Ph.D.

This project was funded by the National Institute for Diabetes, Digestive Disease & Kidneys (#R34DK071545).

- Assisted in recruitment and coordination of study activities.
- Provided 10-week CBT intervention for study participants.
• Completed SCID interviews for study participants at baseline, post-intervention, and follow-up visits.
• Met with study participants for weekly contacts to monitor adherence and safety in exercise intervention.

Project Coordinator 2007-2009
Psychosocial Aspects of Diabetes Among Medical Patients in Athens County: 4 Year Follow-Up
Principal Investigators: Mary de Groot, Ph.D.
This project was funded by the Ohio University Diabetes Research Initiative
• Coordinate preparation of study materials, recruitment, data collection, and data entry and analysis.

Project Coordinator 2005-2006
Caring for Diabetes: A Family-Based Educational Intervention for Patients with T2DM.
Principal Investigators: Mary de Groot, Ph.D.
This project is funded by the Ohio University Diabetes Research Initiative
• Coordinated preparation of study materials, recruitment, data collection, entry, and analysis.
• Assisted with planning and implementation of two one-day educational interventions.

Clinical Experience:

Supervision Trainee March 2009 – June 2009
Ohio University Psychology and Social Work Clinic, Athens, OH
Supervisor: Kevin Byrd, Ph.D.
• Provided clinical supervision to a second-year graduate student using a competency-based approach that incorporated setting goals with the supervisee, providing feedback on videotaped sessions, and incorporating outside materials and reading related to supervisee goals for the quarter.
• Received weekly umbrella supervision from licensed clinical supervisor that included review of supervision tapes, feedback on supervision strategies, and role-playing of supervisory techniques.

Health Psychology Trainee September 2008 - June 2009
O’Bleness Family Practice Clinic, Athens, OH
Health First Care Center, Athens, OH
Supervisors: Bernadette Heckman, Ph.D., Joseph Bianco, Ph.D., & Mary de Groot, Ph.D.
• Completed patient consultations as requested by physicians and provided feedback regarding their referral questions.
• Educated patients about the Health Psychology Service and provided appropriate referrals to outside providers when necessary.
• Conducted intake assessments with new patients to determine their presenting concerns, psychosocial and medical history, health behaviors, treatment needs, and recommendations for physicians.
• Tailored brief individual psychological interventions for patients as needed for health psychology concerns including: smoking cessation, medication adherence, physician-patient
communication, coping with stressful events, building social support, assertive communication, weight management, and pain management.

**Psychology Trainee**  
**New Horizons Youth and Family Center, Lancaster, OH**  
**Supervisor:** John McNamara, Ph.D.

- Conducted intake assessments with child, adolescent, and adult clients to evaluate presenting concerns and psychosocial history, determine preliminary diagnoses, and refer to appropriate treatment options within the agency.
- Provided individual therapy to approximately 7 adult clients and couples therapy for 2 adults and their spouses using a combination of cognitive behavioral therapy techniques and interpersonal therapy.

**Graduate Student Clinician**  
**Ohio University Psychology and Social Work Clinic, Athens, OH**  
**Supervisors:** Heather Alvarez, Ph.D., Christine Gidycz, Ph.D., Melissa Buelow, M.S., Paul Castelino, Ph.D., John Garske, Ph.D., and Timothy Anderson, Ph.D.

- Provided brief and long-term individual psychotherapy to university students.
- Applied interventions from multiple theoretical orientations including: cognitive-behavioral, psychodynamic, and interpersonal therapies.
- Received 1-2 hours of individual supervision and 2 hours of group supervision per week. Supervision included case presentations, review of videotaped sessions, and feedback on case conceptualizations, intervention techniques, and ethical issues.

**Psychology Trainee**  
**HeartWorks Cardiopulmonary Rehabilitation Program**  
**Cornwell Center, O’Bleness Memorial Hospital, Athens, OH**  
**Supervisors:** Joe Bianco, Ph.D. and Mary de Groot, Ph.D.

- Conducted individual psychosocial assessments with patients at intake and discharge.
- Provided psychoeducational lectures about cognitive behavioral interventions for stress management.
- Led 15-minute in-vivo relaxation groups for patients using visualization and progressive muscle relaxation techniques.
- Tailored brief individual psychological interventions for participants as needed for psychosocial issues relevant to cardiopulmonary health including: smoking cessation, medication adherence, physician-patient communication, coping with stressful events, building social support, assertive communication, couples issues, and coping with emotional trauma following medical procedures.
- Received 1.5 hours of individual supervision per week and attended monthly team meetings to present and discuss case material.
Glossary

**a priori power analyses**: analyses conducted prior to a study to estimate sample size needed.

**comorbid conditions**: medical conditions that exist in addition to the primary illness.

**correlation**: a measure of the relationship between two variables.

**descriptive analyses**: statistics to describe the main features of data such as means, standard deviations, range, and distribution.

**diabetic neuropathy**: damage to the nerves or nerve cells that can occur in diabetes and may cause symptoms of numbness, tingling, or pain.

**musculoskeletal conditions**: these conditions involve the muscles or components of skeletal system such as tendons or joints (e.g., arthritis, gout, foot problems).

**hierarchical regression**: a form of regression that examines in which order the independent variables (predictors) influence the dependent variable (outcome).

**HIPAA**: Health Insurance Portability and Accountability Act forms protect participant information and explain how their health information will be used in the study.

**hyperglycemia**: high blood glucose (sugar) levels that can occur in diabetes.

**psychosocial**: related to psychological aspects (e.g., depression, anxiety) and social aspects (e.g., quality of life, interference with social activities).

**psychiatric comorbidity**: psychological disorders (e.g., depression, anxiety) that exist in addition to the primary illness.

**self-care activities**: aspects of treatment for individuals with diabetes that include diet, exercise, taking medications, and monitoring blood glucose levels.

**type 2 diabetes mellitus**: the most common form of diabetes in which the body does not produce enough insulin or cells cannot use the insulin properly, leading to an excess of glucose (or sugars) in the bloodstream.
Appendix

**Anticipated Project Timeline**

<table>
<thead>
<tr>
<th>May 2010</th>
<th>June 2010</th>
<th>July 2010</th>
<th>August 2010</th>
<th>September 2010</th>
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</thead>
<tbody>
<tr>
<td>Begin recruitment and data collection</td>
<td>Data collection</td>
<td>Data collection</td>
<td>Data analysis</td>
<td>Data analysis and SBM(^1) abstract preparation</td>
</tr>
</tbody>
</table>

\(^1\)Society of Behavioral Medicine (SBM)

**Sample Questions from Pain Interview**

*Brief Pain Inventory*

1. Please rate your pain by circling one number that best describes your pain at its worst in the last week.

   0  1  2  3  4  5  6  7  8  9  10

   No pain                             Pain as bad as you can imagine

2. What treatments or medications are you receiving for your pain?

4. In the last week, how much relief have pain treatments or medications provided?

   0%  10%  20%  30%  40%  50%  60%  70%  80%  90%  100%

   No relief                              Complete relief

*Leeds Assessment of Neuropathic Symptoms and Signs*

1. In the area where you have pain, do you also have “pins and needs”, tingling, or prickling sensations?

2. Does your pain make the affected skin abnormally sensitive to touch? Getting unpleasant sensations or pain when lightly stroking the skin might describe this.