

Self-Management Program on Pain and Function in Patients with Osteoarthritis of the Knee

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Abstract

Over 27 million people suffer with osteoarthritis in the United States, a chronic disabling condition. The purpose of the pilot project was to determine whether an education self-management program of physical activity in adult patients with osteoarthritis of the knee, at a large urban academic medical center whom presented to the emergency department and orthopedic clinic setting, improved pain and function. The project study design was quasi-experimental with pre and post testing at 6 weeks. The evidence-based intervention was an educational self-management program from the National Physical Activity Guidelines. The outcomes measured for a difference in pain and function by the Western Ontario and McMasters Universities scale index pre and post the intervention. After 6 weeks, the participants reported lower WOMAC scores ($p = .021$, $p = .037$), reflecting a better outcome overall and in function respectively. Pain score difference ($p = .051$) was marginally close but was not statistically significant. In an effort to address the societal cost and impact of osteoarthritis, health providers can provide early education to osteoarthritis patients to self-manage their symptoms.

Keywords: Osteoarthritis, physical activity, adults,

Self-Management Program on Pain and Function in Patients with Osteoarthritis of the Knee

The Department of Health and Human Services', *Healthy People 2020*, arthritis specific objective is to increase the number of adults who have evidence-based arthritis education as an integral part of the health management of their condition. Since emergency departments are often the *first* and sometimes the *only* point of entry into the healthcare system, they can provide chronic illness education to osteoarthritis patients.

Significance

Over 27 million people suffer with osteoarthritis in the United States (Lawrence et al., 2008). In the state of Missouri, 1.4 million patients suffer with joint pain ("MO Arthritis: Arthritis," n.d.). The emergency department at this large academic medical center sees approximately 1,000 patients a year diagnosed with osteoarthritis of the knee (personal communication March 6, 2015). Missouri spends close to 3 billion dollars in total arthritis care. ("MO Arthritis: Arthritis," n.d.). Medicare and Medicaid spends approximately \$1100 dollars per osteoarthritis patient for ambulatory, emergency department visits, and prescription drugs to cover the health care expenditures (Johnson & Stahl-Moncada, 2008). To address the cost and impact of osteoarthritis, health providers help osteoarthritis patients self-manage their symptoms with the recommended regular physical activity. The importance of osteoarthritis (OA) management should not be ignored, as impacts on disability and physical function of patients (Nelson, Allen, Golightly, Goode, & Jordan, 2014)p. 702). Osteoarthritis (OA) is a chronic disease effecting adults, and can be debilitating and costly (Nelson et al., 2014). Nelson et al., (2014) reported that 13% of adults had self-reported arthritis-attributable activity limitations.

The significance is of this pilot project was to identify osteoarthritis patients and help

them self-manage their symptoms. Osteoarthritis is pain and joint swelling, and or crepitus with eventual impairment movement of the knee (Hochberg et al., 2012). Increasing age, obesity, active sports, and previous joint trauma can lead to osteoarthritis. Since there is no cure for osteoarthritis, the progressive illness has become a major health concern (Lawrence et al., 2008).

Economic

The economic burden associated with osteoarthritis is disability, co-morbidities, and cost of medications (Bitton, 2009). Esser and Bailey (2011) reported the cost of “osteoarthritis care is estimated to be \$5700 total per person, with national cost of \$15.5–\$28.6 billion per year” (Bhatia, Bejarano, & Novo, 2013). Besides the financial cost, osteoarthritis can affect the patient’s profession, leisure activities and overall quality of life (Bennell, Dobson, & Hinman, 2014).

Policy, Health System

The Emergency department (ED) of this large medical center serves all patient populations despite an identified payer source. It provides 11 percent of all uncompensated care in the State of Missouri. The medical center provides healthcare services to 7.2 percent of the Missouri Medicaid population and 15.7 percent of the Medicaid population (Quality Measures, 2013).

Diversity

Cultural competent providers should be aware of disparities in healthcare delivery systems. This pilot study was set in a single center, large academic medical center providing culturally sensitive care to adults from a diverse population. The academic medical center Emergency department had 71,000 Emergency department patient visits in 2014, in which the patient demographics breaks down to 51% White /Caucasian, 35 % African – American, 4% Hispanic / Latino, and 1 % Asian. The insurance payer distribution is 36 % self-pay, 21 %

commercial insurance, 28% Medicaid, 13 % Medicare, and 2 % other. The literature describes an association between providing cultural competence, quality health, and eliminating racial and ethnic disparities in health care (Betancourt, Green, Carrillo, & Park, 2005). The diverse and culturally competent healthcare providers can increase positive patient outcomes.

Problem Statement

Osteoarthritis is pain and swelling of the joint, with eventual impaired movement of the knee. Increasing age, obesity, active sports and previous joint trauma can lead to osteoarthritis. As there is no cure for osteoarthritis, it becomes a major health concern for providers and patients to manage. Regular physical activity has shown substantial benefits of improved physical function and reduction of pain in adults with osteoarthritis. The National Physical Activity guidelines of 150 minutes of physical activity a week are recommended for everyone to improve health. An education self-management program can improve care of patients with Osteoarthritis of the knee as established with recommendations from evidence-based clinical practice guidelines for osteoarthritis knee pain.

Purpose

The purpose of this quasi-experimental study was to determine the effectiveness of providing an educational self-management program using the National Physical Activity Guidelines to adult patients with osteoarthritis of the knee, previously seen in the emergency department or orthopedic clinic setting, to decrease pain and increase function as measured by the Western Ontario and McMaster Universities (WOMAC) scale after 6 weeks.

Facilitators & Barriers

The facilitators of the project were the academic medical center setting, which is ideal for clinical practice as well as research. The onsite staff, Emergency physicians, and orthopedic

clinic were supportive of the study to improve osteoarthritis care. Barriers to the study were allocating money to progress with the study (see Appendix A for Cost Table). Requesting funds through a grant alleviated the funding barrier. Another barrier was the limited time to conduct this study.

Review of the Evidence

PICOT

In patients with osteoarthritis of the knee ages 21 to 80, will providing a self management educational program including the National Physical Activity Guidelines to manage symptoms of osteoarthritis help to decrease pain and increase function as measured by Western Ontario and McMaster Universities (WOMAC) scale, after 6 weeks' time, at a large urban academic Medical Center?

Search Strategies

The Literature Review was organized from a central concept “osteoarthritis “and the general term was narrowed down further to specify the joint and search “osteoarthritis of the knee “. The Literature Review searched the databases Medline, Cumulative Index to Nursing and Allied Health Literature (CINHAL), PubMed, Google intranet and Cochrane Library. The literature review’s purpose was to obtain multiple research resources and to increase the credibility of the literature search (see Appendix B for Acronyms and Definition of Terms).

The keywords and search term were “ osteoarthritis, osteoarthritis of the knee, adults with osteoarthritis, physical activity, exercise, walking”. The search subheadings utilized were “adults, evidence based practice, and evidence based guidelines and nursing”. The combination of search terms “clinical guidelines, osteoarthritis, and emergency department” did not yield results. There were 2 Systematic Reviews relevant to PICO level of evidence 1, there were 3

Clinical Practice Guidelines aligned with PICO and one critical appraisal of both clinical practice guidelines and systematic review (Grade A). It included 6 randomized control trials at Level 11 of evidence, a pilot study, a cohort study at Level 111, a case scenario Level 1V, a descriptive study Level V1 and few expert opinion articles. The literature review was limited to studies in the English language. Most articles and clinical practice guidelines older than 5 years old were avoided to stay relevant, except for the National Physical Activity guidelines, which have not been updated since 2008.

Osteoarthritis

In the review of literature osteoarthritis was defined by clinical presentation, patient symptoms clinically or by radiograph or both. Osteoarthritis is the knee pain, stiffness < 30 minutes a day and or crepitus. Osteoarthritis initial treatment as stated in the clinical practice guideline are: self-management, patient education, exercise and weight loss as a multi-component strategy to treat patients with symptomatic osteoarthritis (Robbins & Kulesa, 2012).

American Academy of Orthopedic Surgeons (AAOS) published evidence-based practice guidelines with recommendations to treat osteoarthritis (Jevsevar et al., 2013). AAOS first recommendation includes self-management and physical activity consistent with national physical activity guidelines (Jevsevar et al., 2013). The Department of Health and Human Services Physical Activity guidelines for adults recommend 150 minutes of physical activity (exercise) each week, as well as muscle strengthening at least 2 days a week (“Physical Activity for Everyone,” n.d.) as reported by the Center for Disease Control and Prevention (CDC). Despite these national recommendations of physical activity, 33% of Americans do not participant in physical leisure time activity (Tucker, Welk, & Beyler, 2011).

The Ottawa panel evidence-based clinical practice guidelines recommend first line conservative treatment such as aerobic walking program for osteoarthritis management (Loew et al., 2012). The panel further states a walking program helps relieve pain and increase function without increasing stress in the affected joint (Loew et al., 2012). Osteoarthritis patients should maintain their physical activity intensity at a safe level (Loew et al., 2012). Walking programs are effective interventions to improve stiffness, mobility, strength and endurance in management of osteoarthritis patients. The greatest improvement or outcomes were seen in patient's reported quality of life, pain and function (Loew et al., 2012).

Pedometers

In a home based walking study, older adults increased their step count by 23 % and overall improved function performance of walk (Talbot, Gaines, Huynh, & Metter, 2003). The participants were age 60 or older, walked with a pedometer, over 6 months period in addition to 12 hours of instructional education as the intervention (Talbot et al., 2003). Another study, *Impact of the Arthritis Foundation's Walk With Ease Program on Arthritis Symptoms in African Americans* found positive results with walking (Wyatt et al., 2014). Participants were given education, brochures, and pedometer for 6 weeks tracked the efficacy of the program for 117 patients (Wyatt et al., 2014). There was convincing evidence of decrease in pain and stiffness yet not patient fatigue (Wyatt et al., 2014). The study also added a satisfaction scale with the 6 week program that showed 92% patient participants satisfied with intervention of physical activity program (Wyatt et al., 2014).

Pedometers can provide a reliable and valid measure of physical activity (Tudor-Locke, Hart, & Washington, 2009). A pedometer is a tool to measure distance traveled by foot usually, in calibrating a person's step count. Pedometers are easy to use, efficient, and affordable

recording devices (Tudor-Locke et al., 2009). Using a pedometer may actually increase motivation to engage in physical activity and, therefore help maintain the health of individuals with osteoarthritis (White et al., 2014) (see Appendix C for Synthesis of Evidence Table).

Physical Activity

The large prospective cohort study *Daily Walking and the Risk of Incident Functional Limitation in Knee Osteoarthritis* (White et al, 2014) looked at physical activity over 2 years of walking steps per day among patients with osteoarthritis to measure their functional status. (White et al., 2014). Another community-walking program, the Walking for Well being in the West study, increased walking performance with the use of pedometers (Baker et al., 2008). The purpose of this research was the use of a pedometer-based intervention, physical activity consultation, and walking steps on health related outcomes over a period of 12 weeks (Baker et al., 2008). Sixty four percent of the participants increase daily walking by 3,000 steps, walking up to 5 times a week. Physical activity steps was measured by pedometer, while the health outcome was measured by the Positive and Negative Affect Scale (Baker et al., 2008).

Adherence to physical activity guidelines, self-management, and exercise, education and weight loss are key management strategies to treating osteoarthritis symptoms (Robbins & Kulesa, 2012; White et al., 2014). A review of literature by Bennell and Hinman (2011) concluded osteoarthritis patient's adherence to regular exercise improves patient outcomes. A multi-center longitudinal cohort study by White et al. (2014) strongly suggest simple exercise of walking prevents problems with physical functioning in patients with osteoarthritis. The study noted walking is inexpensive and achievable for patients with osteoarthritis (White et al., 2014). It is recommended that, instead of using a universal goal of 10,000 steps that is widely accepted

but lacks scientific evidence, patients can have a physical activity goal for approximately 3,000 per step count (White et al., 2013).

Walking 10,000 steps a day may be unrealistic for many people with knee OA. Rather than promoting potentially difficult-to-achieve walking activity goals that could further discourage people with knee OA, White et al (2014) study suggest that a lower goal of steps per day may still provide therapeutic benefits. The latest research study by White et al (2014) found walking 6,000 steps a day is beneficial in overall function of the knee joint. The study was even more lenient, to make at least 3,000 to 6,000 steps a day a goal for patients with osteoarthritis. An additional 1000 steps a day was determined that it can decrease functional limitation (White et al., 2014b) in patients with osteoarthritis of the knee.

Theory

The Integrated Theory of Health Behavior Change (ITHBC) guided the evidence-based project. The health theory suggests that patient's behavior change can be enhanced by providing knowledge and beliefs, increasing self-regulation skills and abilities, and enhancing social facilitation (Ryan, 2009). Social facilitation means that people do better when in the presence of other people. Humans are social beings and human relationships can improve life. A successful outcome and long term success has to be specifically stated and well planned to be obtained. The integrated theory can be generalized to the chronic illness osteoarthritis (Ryan, 2009). The health theory encouraged patients to identify a support person, because studies have shown that people are more likely to sustain their physical activity with support from others (Adams-Fryatt, 2010; Ryan & Sawin, 2009). The theory distal outcome is dependent of the success of the proximal outcome to maintain behavior changes (see Appendix D). As explained, when the proximal behavior or physical activity is achieved, as the distal outcome is their well-being or

overall health improves. Healthcare professional had assumed that educating patients about the health benefits would provide sufficient motivation to change behavior, but it is now believed behavioral as well as cognitive therapy is needed to actually change patient behaviors (Woodard & Berry, 2001).

Method

IRB Approval, Site, Ethical issues

The primary Institutional Review Board (IRB) was from the University of Missouri - Kansas City as an expedited review on November 30, 2015. The Emergency Department Research Coordinator helped guide student investigator through research conducted in the Emergency Department. The Privacy Board and The Emergency Department Research Board approved the Doctorate student's research project. The student investigator completed both the Group 1 Biomedical and Group 2 Social / Behavioral Citi Training for the research study.

The research ethics involved in the research project were patient privacy protection, no coercion and no risk to patients who enter the study. The ethical principles from the Belmonte Report of research conduct were patient respect, beneficence (do no harm), and justice for patients was followed. Subject participants choosing to participate, could withdraw from the study without penalty or affecting their care. There was no foreseen risk to the patient with the education intervention.

Funding

Funding for the project was obtained from a grant from the University of Missouri Kansas City's Women Council Graduate Assistance fund for travel to disseminate study results. The Emergency Department Internal Research grant was received for supplies and postage. Some educational material by the Arthritis Foundation was donated to save cost.

Setting & Participants

The setting was a large Level I trauma, academic medical center serving a geographic area of 700,000 citizens (Quality measures, 2013) in Kansas City, Missouri. A convenience sample of adults with osteoarthritis of the knee was recruited from an electronic medical record (EMR) inquiry for prescreening that presented to the Emergency Department or Orthopedic clinic.

The sample population was patients who had presented to the emergency department or orthopedic clinic with symptomatic osteoarthritis of the knee. Inclusion criteria were patients willing to participate, who can read and speak the English language. Adults age 21 to 80 years old with symptomatic pain, knee joint stiffness < than 30 minutes a morning, confirmed radiographic diagnosis of osteoarthritis of the knee, willingness to participate and had given informed consent. The exclusion criteria was unwillingness to participate, non-English speaking and severe co-morbidities inhibiting participation or vulnerable populations.

EBP Intervention

The evidence-based intervention was education of self-management as recommended by AAOS clinical practice guidelines for management of osteoarthritis of the knee. It is recommended that patients with symptomatic osteoarthritis of the knee participate in self-management programs, strengthening, low-impact aerobic exercises, and neuromuscular education; and engage in physical activity consistent with national guidelines with a Strength of Recommendation as strong (Jevsevar et al., 2013). American College of Rheumatology (ACR) first recommendation is also self-management programs to learn more about arthritis and how to manage the disease (Hochberg et al., 2012; "National Guideline Clearinghouse | American College of Rheumatology 2012 recommendations for the use of non-pharmacologic and

pharmacologic therapies in osteoarthritis of the hand, hip, and knee.” n.d.)

Implementation Plan

Recruitment of patient participants was through peer physician awareness, and inclusion and exclusion criteria. To reduce cost, a potential pool of convenience sample was identified by electric medical record inquiry for prescreening. A Partial Waiver for Authorization request to access Protected Health Information in preparation for research or for study recruitment was warranted to establish a prescreening list for primary recruitment. The second method of recruitment was approaching potential patients at discharge for voluntary project enrollment. A written informed consent and authorization was obtained prior to participation in the study. A Release for Participation form and Participants Information Survey was filled out by participants. Pre- test administration of the WOMAC index was completed in the initial face-to-face contact or telephone contact with participants. The intervention was educational self-management and the Walk With Ease booklet provided by student investigator. The educational information was written at a 5th grade level, in the English language for ease of retention and reading. Walk with Ease booklet was a community-based walking program developed by the Arthritis Foundation. The evidence-based program is self-guided workbook to complete in 6 weeks. There is a mix of physical activity and managing arthritis educational topics in the workbook.

Post-test administration of the WOMAC index was completed in follow up telephone contact with patients after 6 weeks. The Western Ontario and McMaster Universities (WOMAC) index was the measurement tool as patient’s self-report of reduction of pain, stiffness and function (Woolacott, Corbet, & Rice, 2012). The WOMAC index and completion questionnaire took 10-15 minutes to complete. It is on a Likert scale with a range of 0 (none) to 4 (extreme)

pain. Data collection occurred over a 4-month period of time. The measurement tool WOMAC index, used throughout the study was reliable and valid. All data was secured in a source storage file. The research study results were disseminated April 14, 2016 by a poster presentation at the 9th annual Evidence Based Practice conference at the University of Missouri. A manuscript is to be completed by June 2016, ideally for submission into the Advanced Nursing Emergency Journal (see Appendix F for Timeline).

Change Process

The Logic Model provided the framework for this study (see Appendix G). The inputs and outputs led to successful osteoarthritis project outcomes. The issue identified as osteoarthritis as a problem for the healthcare organization. The key to the IOWA model is the pilot project prior to implementation (“Evidence- Based Practice: Understanding the Process: Implementing Evidence-Based Practice: The Iowa Model,” n.d.). The EBP project was adopted because of the beneficial outcomes approved by the interdisciplinary stakeholders (M G Titler, 2002). The student investigator’s Osteoarthritis project had preliminary buy-in for osteoarthritis care from the Emergency department.

The selected change theory for this project was the pioneer Kurt Lewin, Change theory. It states change is a process through stages. The Unfreezing is a need for change. The Moving and Refreezing phases of change is the implementation process. Lewin’s change theory worked well for the project as it a problem solving –approach to providing early education to osteoarthritis patients on self-management of symptoms. The Lewin’s change theory can be small-scale projects, and worked well for student investigator’s osteoarthritis education of physical activity study change (Mitchell, 2013).

Study design

The study design was quasi- experimental, of patients with osteoarthritis of the knee were studied without a comparison group. A pre-test and post-test design with an educational intervention was conducted at the beginning of study and again at 6 weeks from baseline. The differences in patient outcomes of pain and function were analyzed with nonparametric Wilcoxon test. Demographic information was by descriptive analysis (see Appendix J). Demographic information, such as age, gender, and race was helpful to describe the population, find similarity and generalize the results.

Validity

The internal validity was bias with selection as there was no control group with this quasi-experiment study. The integrity of the data was maintained by student investigator collecting and securing data. There are other confounding variable to attribute to the effects of education on study patients. There was no testing bias with a pre-test affecting or influencing the scores of the post-test. The measurement tool (WOMAC) remained the same consistently throughout the study.

The unique program features jeopardized the external validity, by the perception of personal attention or extra time spent with patients could affect data results. There is optimism that study results could be replicated in other emergency department or ambulatory care setting with osteoarthritis patients. The study results can be generalized to other osteoarthritis patient population such as hip pain.

Outcomes

The outcomes pain and function were measured by difference on the WOMAC scale between pre and posttest. The evidence-based practice project outcomes are patient will have decreased knee pain and increase function with education self-management program. The

primary outcome of the study was improved score on the WOMAC index and increase function, after the educational self-management program. The improved overall WOMAC score indicated decreased pain stiffness, and increase function for participants.

Measurement Instruments

The Western Ontario McMaster Universities Osteoarthritis (WOMAC) index was developed to assess and quantify pain, joint stiffness and function related to osteoarthritis of the knee and hip (Appendix H). The WOMAC scale has been found to be valid and reliable in osteoarthritis research. The WOMAC includes a pain subscale. In 1994 a consensus meeting recommended the use of WOMAC as a primary measure of efficacy in Osteoarthritis (Woolacott, Corbett, & Rice, 2012). The WOMAC index is self-reports patient questionnaire, which takes 10-15 minutes to complete. The WOMAC Index contains 24 questions, 5 related to pain, 2 to stiffness and 17 to physical function. It has test-retest reliability. It has known content validity by expert judgment. It can be used to monitor the course of the disease or to determine the effectiveness of a variety of interventions (Woolacott, Corbett, & Rice, 2012).

The student investigator was given permission to use the measurement tool WOMAC by Dr. Bellamy (see Appendix I). The cost of the WOMAC was on a cost recovery basis as long as utilized for academic, clinical or educational purposes. Student investigator obtained release from the copyright for permission.

The studies utilized WOMAC index to measure patient pain, stiffness and function. Pain is generally a subjective term so the WOMAC measurement scale is valuable. The WOMAC used in this study was the Likert version 3.1 standardized with English, consisting of 24 self-administered questions that were answered for each item on a 5-point Likert scale (none, mild, moderate, severe, and extreme). It was reported as three separate subscales: pain, physical

function, and stiffness (Woolacott et al., 2012). Woolacott (2012) systematic review encouraged consistent use of the WOMAC index as primary measure of disability and pain in osteoarthritis patients.

Quality of Data

Data analysis was completed on the study outcomes. There was careful detail to correct and complete records to provide for the accuracy of results and the quality of data (Hogan & Wagner, 1997). Determining the optimal sample size for a study assures an adequate power to detect statistical significance but was waived, as it was a pilot study. The privacy and confidentiality of the data was maintained throughout the study. The student investigator abided by strict confidentiality precautions, utilizing a locked storage box for data.

Analysis Plan

The differences between patient outcomes of pain, stiffness, and function was analyzed by the Wilcoxon signed ranked test. Demographic information was analyzed by descriptive analysis. The student investigator requested assistance from a statistician for the evidence based project study statistical analysis (see Appendix L). The study's statistical analysis was to determine the effect of educational self-management intervention on pain and function in participants with osteoarthritis of the knee.

Results

Setting & Participants

The setting was single large urban academic medical center. The participants were English-speaking adults ages 30-65 years old with symptomatic pain, knee joint stiffness < than 30 minutes a morning, confirmed radiographic diagnosis of osteoarthritis of the knee, were willing to participate and had given informed consent. The subject number from the initial

patient population EMR inquiry was over 900 patients. By sampling randomization 38 were contacted, of which 12 were willing participants. Of the original 12 participants, ten completed both the pre and posttest. Therefore the sample size was 10 participants.

Participants were recruited from a list generated by the Informational Technology department from the Electronic Medical Records as arm 1 of recruitment. The patients that had presented to the Emergency department or orthopedic clinic with osteoarthritis knee pain. Participants were also recruited as arm 2 of recruitment from peer colleagues in the Emergency Department at time of discharge.

Intervention Course

The participants consented to the study before participating. Participant's demographic information of gender, age, race and health status was collected. Nine participants were from the Emergency department and one participant from the Orthopedic clinic. All participants completed the WOMAC index. The osteoarthritis education was given to participants along with Walk With Ease booklet. Participants were contacted 6 week later by telephone for follow up posttest of WOMAC index and a questionnaire.

Outcome Data

Descriptive Analysis:

The participant's demographics of age, gender, ethnicity, and health status were analyzed by descriptive analysis (see Appendix M). The sample size was 10 participants. The participants in the study self-reported they were in fair to good health. Of the 10 participants, 7 were female and 3 were male. Six participants were recruited for the EMR inquiry phone contact, of which 1 had presented to the orthopedic office; the other 4 were recruited in person from the Emergency Department. In total, 9 were from the Emergency department. Of the participants, 50% were

African American; 40% were Caucasian, and 10 % self -reported as other. The mean age was 47.9 years old, ranging from 30 to 65 years old.

Statistical Analysis:

WOMAC Scores

The difference in outcomes after the administration of the osteoarthritis self-management educational program intervention was calculated with a Wilcoxon signed-rank test. The Wilcoxon signed-rank test showed that an Osteoarthritis self-management educational program did elicit a statistically significant change in WOMAC index score in osteoarthritis patients ($Z = -2.310$, $p = .021$). The median WOMAC score was 61.9 at baseline pre test and 40.2 posttest to reveal a difference. Only the 10 participants with both pre and post test scores as data were analyzed.

The measure of Physical Activity was by the amount of time participants self reported their physical activity of walking. The range was from 0 to 1200 minutes a week of physical activity among the 10 participants. The reported mean Physical Activity was 258 minutes a week, after 6 weeks time reported 203 minutes of walking. The educational program did not elicit a significant difference in physical activity score ($Z = -.700$, $p = .484$) in osteoarthritis patients.

Pain Stiffness and Function Scores

The Osteoarthritis self-management educational program did not elicit a statistically significant change in the WOMAC subscale pain scores in osteoarthritis patients ($Z = -1.947$, $p = .051$). The median pain score was 13.1 at baseline pretest and 9.0 after 6 weeks at post testing.

The Osteoarthritis self-management educational program did not elicit a statistically significant change in the WOMAC subscale stiffness scores in osteoarthritis patients ($Z = -1.065$, $p = .287$).

The median stiffness score was 5.4 at baseline pretest and was 4.3 after 6 weeks post test.

The Osteoarthritis self-management educational program did elicit a statistically significant change in WOMAC function subscale score in osteoarthritis patients ($Z = -2.090$, $p = .037$). The median function score was 43.8 at baseline pretest and was 31.9 after 6 weeks post test.

The findings reveal the difference of WOMAC index, pain, stiffness, and function in osteoarthritis 6 weeks from baseline. The lower reported score indicates improvement in pain, stiffness, and function (see Appendix M for Outcome Results). Study results indicate that the overall WOMAC index and function scores were statistically improved at 6 weeks.

Efficacy and Satisfaction Scores

All of the participants that completed the satisfaction survey stated they were satisfied or very well satisfied with the osteoarthritis education program provided by the Advanced Practice Nurse. Specifically, at follow up, the question was “to what extent were you satisfied with the educational program? (1= very well satisfied, 2= satisfied, 3= fairly satisfied, 4= not at all satisfied). The efficacy of the program was measured by asking “ How confident are you that you will continue walking or being physically active after this education and Walk with Ease program?” (1= extremely confident, 2= fairly confident, 3= slightly confident, 4= not at all confident). The measurement is the lower the score indicates higher ratings or satisfaction. Satisfaction and efficacy was analyzed by frequency, revealing 60 % were extremely confident in continuing or sustaining their physical activity. Of the participants completing the 6 weeks, 100 % were satisfied or very well satisfied with the osteoarthritis educational program.

Discussion

Successes

The most important success was the participant's improved scores of the WOMAC index and function score. The second success was an 83 % response rate after 6 weeks follow up. A general or global success was the study brought awareness of the painful chronic disease of osteoarthritis.

Study Strengths

The strength of the study was that it was conducted in an academic arena with support for research. The department chairpersons and nursing director were willing to accept the research proposal. There was buy –in and support from upper management. Strength is the measurement tool WOMAC index utilized in this study as well as multiple previous osteoarthritis research studies is a valid and reliable tool.

Results compared to Literature Evidence

Previous literature, noted both education and physical activity were recommended by all clinical practice guidelines for the management of osteoarthritis, aligning with this pilot study's intervention (Jevsevar et al, 2013, & Loew et al, 2012). This self-management program study findings correlate with an osteoarthritis study by Talbot, 2003, found WOMAC index score significance ($p = .001$). These study findings also correlate on self reported physical activity improves function. White et al, 2014 study found walking even 3,00 steps a day to be beneficial for overall function in patients with osteoarthritis, similar to this study. Also similar were satisfaction scores, in a prior research study of Walk with Ease program in African American population by Wyatt et al, 2014, the study added a satisfaction scale after the educational that showed 92% of participants were satisfied with the osteoarthritis educational program (Wyatt et al., 2014).

Limitations

Internal Validity effects

The internal validity could have been bias with selection as there is no control group with this quasi-experiment study. There was no testing bias noted with a pre-test affecting or influencing the scores of the post-test as a length of 6 weeks time had passed. There was limited sample size. There could be other confounding variable to attribute to the effects of education on study patients. However, the measurement tool (WOMAC) stayed the same consistently throughout the study.

External Validity effects

The unique program features may have jeopardized the external validity. A perception of personal attention and extra time spent with patients at discharge should not have effect on data results. There is optimism that results of project could be replicated in other emergency department or ambulatory care setting with osteoarthritis patients. The study results could maybe be generalized to other osteoarthritis patient population such as hip pain.

Sustainability and Plan to Maintain Effects

Participant's sustainability was given information to maintain their health behavior change. Participants were encouraged to adhere to health changes by social facilitation. Organizational sustainability is plans to maintain early osteoarthritis education from the Emergency Department will be addressed at an Emergency Department throughput meeting in the future.

Efforts to Minimize the Study Limitations

The results are limited by the small sample size. The time limit for the research project was short, 4 months. Therefore sample size was less than ideal and made this pilot study. It

would be logical to increase the sample size, replicate it in a larger study to validate these pilot study findings.

Interpretation

Expected and Actual Outcomes

Expected results are a decrease in participant's WOMAC index scale. It was expected to decrease pain level yet study results did not show a reportable difference although pain ($p = .051$) was marginally close yet not statistically significant. The WOMAC and Function score was to be improved and it was statistically reportable as significant. The lower scores indicate a better outcome. The observed outcomes were promising. The study gives strength to the body of knowledge for Osteoarthritis care. The difference between outcomes could be contributed to the participants' active engagement in the self-management educational process.

Interventions' effectiveness

The effectiveness of the educational intervention is associated with better outcomes. The educational self-management OA program is associated with improved WOMAC, function and patient satisfaction scores. The research process incorporated multiple disciplines to accomplish the best outcomes. The study had support of EBP guidelines and The Arthritis Foundation to educate patients. The study intervention is most likely to be successful in a setting with both education and community resources for long-term impact on osteoarthritis patients.

Intervention revision

A revision of the intervention education would be a short video to inform participants of the osteoarthritis self-management program. The study investigator could develop a "chronic care pathway for osteoarthritis" to help the Medical Center bundle their care by saving resources. Healthcare providers in the Emergency Department only need to minimally modify the discharge

education techniques to incorporate the community resources of this study intervention.

Expected and Actual Impact

Expected and actual impact on the health care system, cost, and policy will vary on the setting where osteoarthritis patients are educated. The actual impact of the EBP study was a greater awareness of chronic illness osteoarthritis in the Emergency Department. Also an underlying empathy for patients with osteoarthritis was apparent.

Conclusion

There is a need for improvement in the care of chronic illnesses osteoarthritis. The evidence is favorable for physical activity in osteoarthritis patients. It is feasible to integrate the early education of the Osteoarthritis self-management program in the Emergency Department. Physical activity can improve one's health, joint function, and decrease pain. The project successfully provided educational self-management program to patients with osteoarthritis of the knee in anticipation of a difference in pain and function as measured by the WOMAC index after 6 weeks.

Clinical Relevance and Practical Implications

Clinical implications of the study are that health care providers can provide early counsel to osteoarthritis patients on physical activity goals. The implication that walking as physical activity is practical and feasible because walking is free. It is feasible to integrate Osteoarthritis education self-management program to patients in the high risk, often-underserved population of the Emergency Department. In an effort to address the enormous cost and impact of osteoarthritis pain, healthcare providers can be proactive by offering early education to osteoarthritis patient in self-management of their condition.

Further Study of Intervention

This physical activity evidence based practice project could be the basis of further studies in other chronic illnesses or other subpopulations, such as hip osteoarthritis. Further studies to include the National Physical Activity standards, combination of behavioral skills and education to produce a health change are still essential. Tailored long-term studies, such as 16 weeks and a 1-year interval, can help osteoarthritis patients sustain self-management goals.

Dissemination

Many studies and Clinical Practice Guidelines agree there may be a problem with dissemination and implementation of osteoarthritis recommendations but **not a lack** of quality clinical guidelines (Jevsevar et al., 2013; Li, n.d.). Education and physical activity can be an effective strategy for improving osteoarthritis outcomes. Dissemination of the student investigator's evidence-based project results was April 14, 2016 at Evidenced Based Practice Conference at the University of Missouri.

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Appendix A

Cost Table for Project

Funding for the project was secured by the Emergency Research grant. A grant application for the osteoarthritis physical activity study was submitted to graduate assistance fund and approval for travel to disseminate research. The booklets were provided in the Walk with Ease arthritis foundation kits.

Type of Expense	Dollar Amount
Equipment: Tablet	300.00
Supplies ; WOMAC	312.00
Printing & Copying	40.00
Postage & Delivery, Stamps	139.00
Other: Locked Storage	260.00
Booklets, Education, space Statistical analysis (In kind donations)	
Total Expenses	\$ 1051.00

Postage & delivery (3 x 30) = 90.00

Stamps: .49 cents x 100 = 49.00

Printing: .08 cents x 500 = 40.00

Mini tablet (survey) = 300.00

Locked storage = 260.00

Womac permission = 312.00

Appendix B

Definition of Terms

Osteoarthritis - Chronic progressive disease of joints from loss of cartilage leads to pain, swelling and inflammation

Osteoarthritis of the knee – Pain or inflammation of the hinged joint of the lower extremity

Adults with osteoarthritis - Human adults age 21- 80 years old

Physical activity – Expenditure of energy, such as walking, biking, gardening, swimming, yoga

Exercise - Expenditure of energy

Acronyms

ARHQ Agency for Healthcare Research and Quality

CDC Center for Disease Control and Prevention

ED Emergency Department

OA Osteoarthritis

PA Physical Activity

WWE Walk with Ease

Appendix C

Evidence Table

Synthesis of Evidence Table

Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness
Nelson , 2014, A systematic review of recommendations and guidelines for the management of osteoarthritis <i>Seminars in Arthritis and Rheumatology</i>	Improve OA management Identify barriers or issues	PRISMA , SR Level I	16 Articles Work group of Bone& Joint	Pain and Function by AGREE 11 Recommend Inconclusive, Not recommend	Strong recommend for self management No agreement on acupuncture, intra-articular, and glucosamine	Limited by only 1 database Medline Strength in quality yet Weakness in dissemination of info to PCP
White, 2014, Daily walking and the risk of incident functional limitation in knee osteoarthritis	Examine association btw physical activity walking and function in OA patients	Multi-center longitudinal cohort study Level III	1895 patient Ages 50 -79 Community dwelling with OA pain	WOMAC measure function and pain with highest reliability Gait and Speed	Daily walking decreased functional limitations at 2 years in people with and at risk for OA Compliance 82%	Limitations non PA not accounted for Prior to study was a Gap in precise amount and frequency of PA study suggest 3,000

<i>Arthritis Care and Research</i>				Adjusted for confounding variables		start and 6,000 goal need more research Strength – inexpensive
Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness

<p>Jevsevar , 2013</p> <p>Osteoarthritis of the knee clinical practice guidelines</p> <p><i>The Journal of Bone and Joint Surgery</i></p>	<p>Clinical Practice Guidelines to help clinical decision making in treatment of osteoarthritis of the knee</p>	<p>Evidence rating</p> <p>Strong</p>	<p>OA</p> <p>Adults = 19 year old or older</p>	<p>Pain = measured WOMAC and VAS</p> <p>Function = measured by WOMAC</p> <p>ROM / Stiffness = measured by WOMAC</p>	<p>String recommendation for PA as self management of symptoms of OA along with low impact aerobics, strengthening,</p> <p>Rec by expert consensus</p> <p>Determined benefits exceed the potential harm and /or quality of support for evidence is high</p>	<p>Practitioners should follow these clinical guidelines</p> <p>Self management of symptoms</p> <p>Usefulness potential limit as no cost analysis performed</p>
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<p>Author Year Title Journal</p>	<p>Purpose</p>	<p>Research Design Evidence Level</p>	<p>Sample & Sampling Setting</p>	<p>Measure & Reliability</p>	<p>Results & Analysis Used</p>	<p>Implications & Usefulness</p>
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<p>Loew, 2011 Ottawa Panel <i>Archives of Physical Medicine and Rehabilitation</i></p>	<p>Clinical Practice Guidelines management, of osteoarthritis patients and obesity</p>	<p>Level of Evidence I – RCT II – Nonrandomized studies Strength by 2,2,1</p>	<p>OA adults = 40 years old or greater with OA of knee 7 studies Obese = BMI > 25</p>	<p>Pain = measured by WOMAC and VAS Function = Measured by SF 36 Stiffness = measured by WOMAC Mobility = measured by walking speed BMI = measured by Height and weight, and circumference</p>	<p>Walking improved pain stiffness, mobility, and endurance</p>	<p>Offered management treatment and counseling for adults with obesity and OA Expert consensus used to formulate the recommendations</p>
<p>Author Year Title Journal</p>	<p>Purpose</p>	<p>Research Design Evidence Level</p>	<p>Sample & Sampling Setting</p>	<p>Measure & Reliability</p>	<p>Results & Analysis Used</p>	<p>Implications & Usefulness</p>

<p>White, 2012</p> <p>When it hurts, a positive attitude may help: The association of positive affect with daily walking in knee OA: The MOST study</p> <p><i>Arthritis Care and Research</i></p>	<p>To explore the positive effects of walking with pedometer and association between walking the knee</p>	<p>MOST study</p> <p>Cross-sectional analysis</p>	<p>2330- down to 1018 participants</p> <p>50 – 79 years of age with OA</p>	<p>OA = measured by radiograph</p> <p>Depression = measured by OESD</p> <p>Waking = measured by step-count per pedometer</p> <p>Knee pain – w/in the past 30 days</p> <p>Corrected for confounding variables</p>	<p>+ Substantial significance with effect and knee pain</p> <p>Increase walking correlated with + effect</p> <p>Decrease steps with depression symptoms</p>	<p>Positive effect of steps of walking</p>
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Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness
Patrella , 2008 Is exercise effective treatment of Osteoarthritis of the knee British Journal of Sports Medicine	To review and determine the effectiveness of exercise treatment in OA of the knee	SR MesH	18 studies OA inclusion by radiograph or clinical OA Treat with 8 weeks of aerobics PA Walk 3x / week	Lack of standard measure of pain	Too small to measure effect of Physical Activity	Small result of walking improvement Need to help long-term goal be lifetime goals

Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness
Talbot, 2003, A home-based pedometer- driven walking program to increase physical activity in older adults with osteoarthritis of the knee <i>Journal of the American Geriatric Society</i>	Would walking with pedometer > PA ,> strength and function in older adults OA knee	RCT John Hopkins RN trained for rater reliability Level Ib	64 patients Community dwelling Older Adult , Age = 60 or older 12 hours of Education over 24 weeks	WOMAC p=.001 PA per steps ANCOVA alpha 0.05 Adjusted for age variable	Found 23 % increase in steps > walking and quad strength small sample size unable to see large effect Compliance 76%	Suggest f/u phone calls for adherence and motivation Pedometer + education increased PA walking Strength – inexpensive Suggests further research

Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness
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<p>Tudor- Locke, Expected values for pedometer-determined physical activity in the older adult <i>International Journal of Behavioral Nutrition and Physical Activity</i></p>	<p>To update expected values for pedometer-determined physical activity in free-living healthy older populations.</p>	<p>Review Graded as High Moderate Low Very Low</p>	<p>28 studies, over 3,000 adults Age 50 – 94</p>	<p>PA = measured by steps measured by pedometer</p>	<p>Mean pedometer-determined physical activity ranged from 2,015 steps/day to 8,938 steps/day.</p>	<p>Usefulness for optimal steps for PA in adult Limits not necessary OA adults</p>
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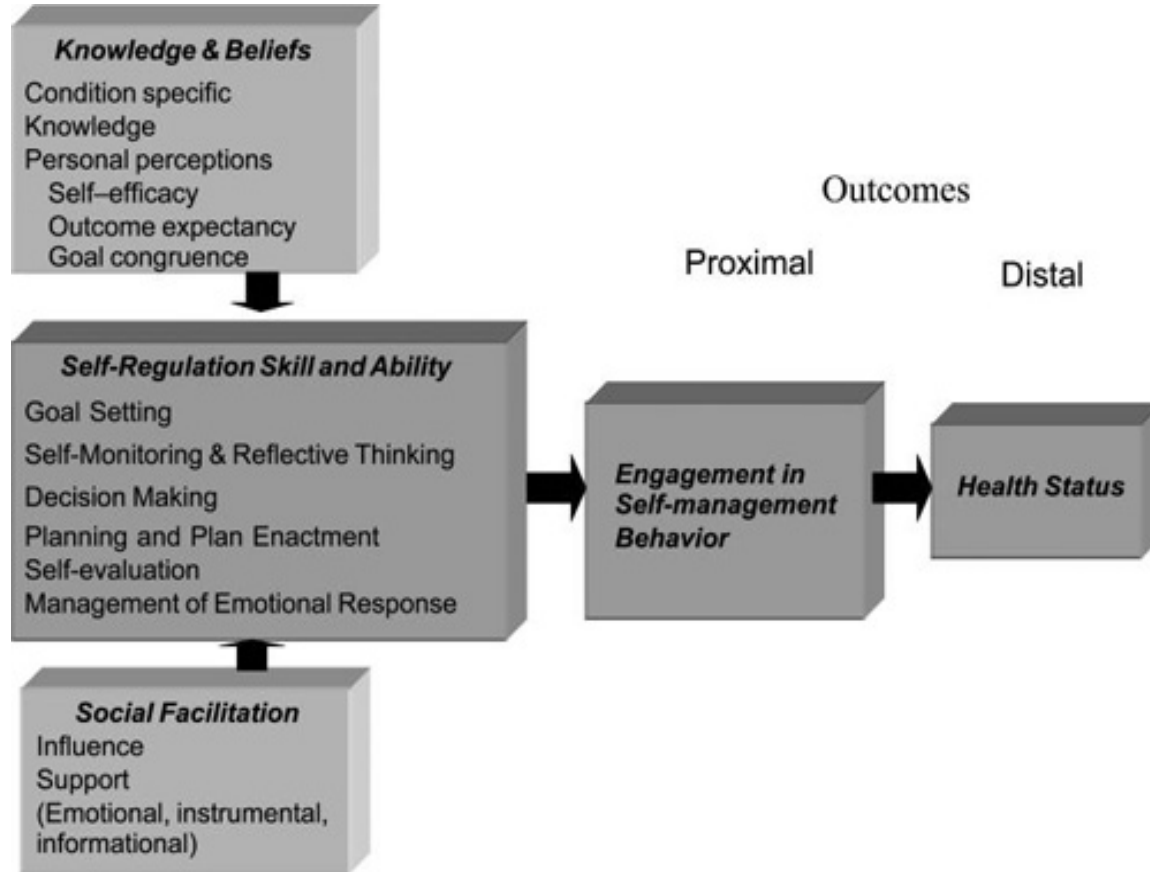
SELF-MANAGEMENT PROGRAM ON PAIN AND FUNCTION

Author Year Title Journal	Purpose	Research Design Evidence Level	Sample & Sampling Setting	Measure & Reliability	Results & Analysis Used	Implications & Usefulness
Baker, et al, 2001 The efficacy of the home-based progressive strength training in older adults with OA: a randomized control trial <i>Journal of Rheumatology</i>	To test high intensity strength training in home based on symptoms of OA of the knee	RCT	46 community dwellers age >55 = older adult	Pain = measured by WOMAC Function = measured by WOMAC	71 % showed improvement in strength, and knee extension,	Improvement in strength, pain, function and quality of life
Wyatt et al, 2014 Impact of the Arthritis Foundation's Walk with Ease program on arthritis symptoms in African Americans <i>Prevention of ChronicDisease</i>	To evaluate the effectiveness of the program in a subsamples of American Americans who were part of larger study that established evidence in program's efficacy	RCT	117 African American	Pain Stiffness Fatigue Satisfaction with program descriptive statistics	Decrease in pain and stiffness scores No change in fatigue 92 % satisfaction with program	Culturally appealing interventions may increase use of existing arthritis programs

Appendix D

Theory to Application Diagram

Integrative Theory for Health Behavior Change



Ryan, P. (2009). Integrated Theory of Health Behavior Change. *Clinical Nurse Specialist CNS*, 23(3), 161–172.

doi:10.1097/NUR.0b013e3181a42373

Appendix E
Orthopedic Communication

From: Bogener, James W

Sent: Friday, April 24, 2015 1:45 PM

I was contacted by Amy Siebes, NP in the ED about a quality improvement project for our patients with osteoarthritis.

This sounds like a great idea, especially if we can initiate treatment when they are seen in the ED (things like rest, activity modification, NSAIDS, home exercise program, etc).

Any ideas would be appreciated, and Amy feel free to reply all and fill in the details for us. Haley, it would dovetail nicely into some of the pain management work you are doing (as many of our patients can't do NSAIDS if we could develop a multimodal approach to pain control and do some teaching it might be a good QI project).

We could score patients before and after and measure results...and the work could be presented at the ACGME conference (for resident involvement in QI), AAOS, or the Hip and Knee society.

I've copied the PGY-1's on this e-mail as it may be a good project for them to work on.

James W. Bogener, M.D.

Assistant Professor

Associate Program Director

Director, Orthopaedic Surgical Skills Laboratory

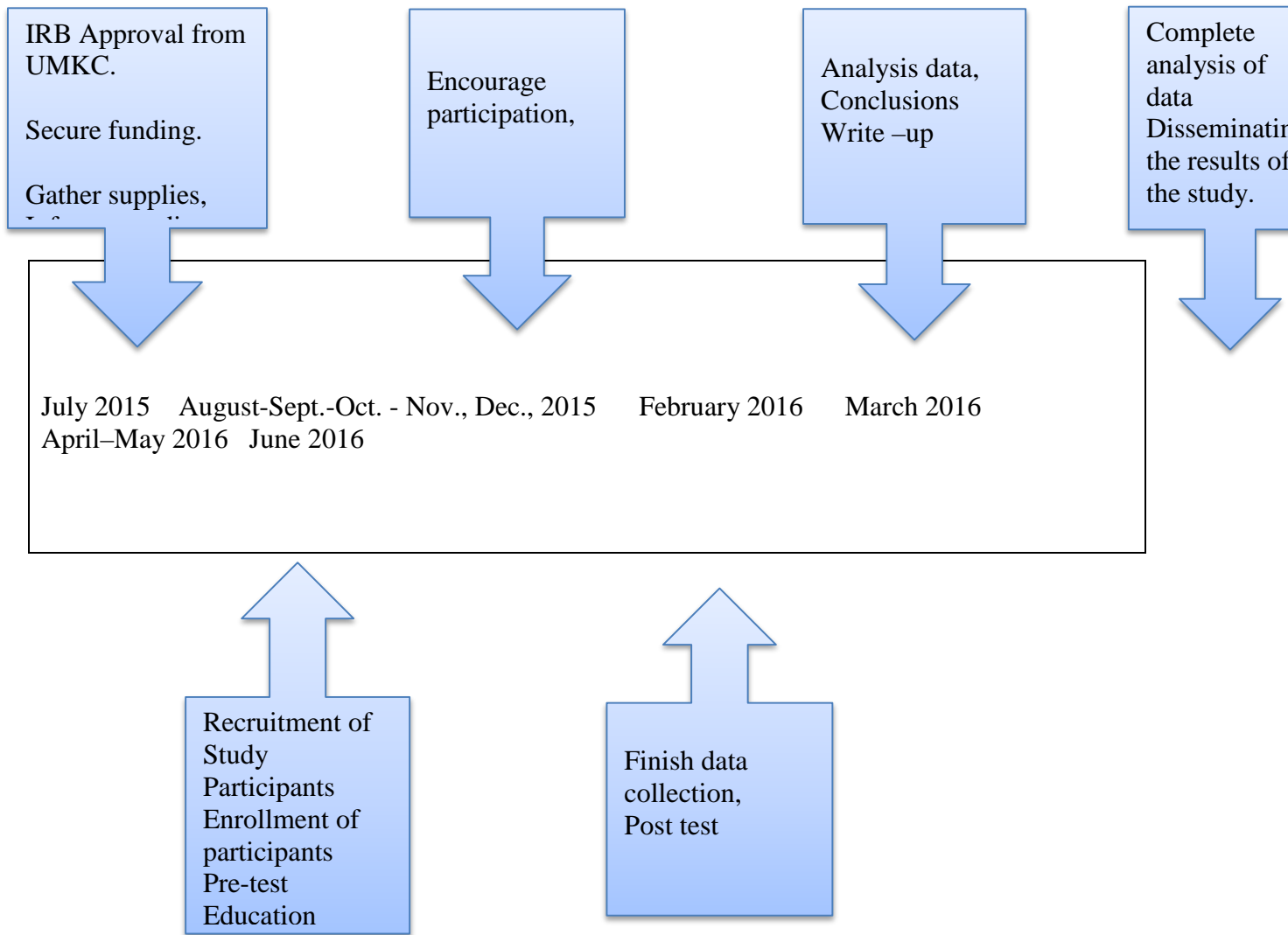
Fellowship Trained in Foot and Ankle Surgery

Board Certified in Orthopaedic Surgery

University of Missouri-Kansas City School of Medicine

Appendix F

**Intervention Implementation / Project Timeline
Plan Flow Diagram**



Appendix G

Logic Model for DNP Diagram

Student: Amy Siebes

PICOT Question: In adults with osteoarthritis of the knee, age 21 – 80 years old, to provide education of the national physical activity guidelines and walk with ease to improve symptoms of osteoarthritis to decrease pain and maintain function after 6weeks.

Inputs	Intervention(s) Activities		Outputs Participation		Short	Outcom Me
<p>Evidence, sub-topics</p> <p>Evidence-based clinical practice guidelines for osteoarthritis</p> <p>Major Facilitators or Contributors</p> <p>DNP Student – NP Research Coordinator Academic Center support Orthopedic clinic ED Chairperson</p> <p>Major Barriers or Challenges</p> <p>Sample-size dependent on return rate, patient compliance.</p> <p>Funding</p> <p>Time to conduct project</p>	<p>The EBP intervention which is supported by the evidence in the Input column</p> <p>Knowledge of Physical activity as self management of osteoarthritis symptoms of pain and knee function</p> <p>Major steps of the intervention</p> <p>Exact inclusion and exclusion criteria</p> <p>Exact information to given to patients, written or audio / video</p> <p>IRB approval</p> <p>Privacy Board</p> <p>ED Research approval</p> <p>Recruit OA patients</p>	<p>The participants (subjects)</p> <p>Adult patients with osteoarthritis of the knee, age 21 – 80</p> <p>Site TMC Kansa City, Missouri</p> <p>Time Frame Summer 2015 IRB-approval</p> <p>Summer /Fall 2015 Data collection - 8 weeks</p> <p>Spring 2016 Data analysis</p> <p>Consent Needed or other Consent IT – data collection TMC Policy ED TMC Research</p> <p>Person(s) collecting data DNP student – NP</p> <p>Others directly involved. Physician, Nurses Research coordinator</p>	<p>(Completed as a student).</p> <p>Education self management program can improve OA pain and function</p> <p>Outcome(s) to be measured with reliable measurement tool(s)</p> <p>WOMAC – scale for pain and function</p> <p>Pedometer – step count</p> <p>Statistical analysis to be used.</p> <p>Data Analysis - Wilcoxon sample ranked test</p> <p>Descriptive analysis – for demographics</p>	<p>Outcome measure student t</p> <p>Patients s and Func</p>		

Adapted from Logic-Model Worksheet content revisions by Dr. Lyla Lindholm (Rev. 7/09, 1/2015, http://www.uwex.edu/ces/lmcourse/interface/coop_M1_Overview.htm)

Appendix
Osteoarthritis Physical Activity Program
Intervention Materials

Osteoarthritis Education

Osteoarthritis of the Knee is a chronic disease.

Osteoarthritis usually causes pain and stiffness.

National Guidelines recommend **150 minutes of physical activity a week** for everyone, even if you have arthritis, do what you can, with 2 days of strength training.

Physical activity can be any walking, gardening, swimming, yoga, chair exercises,

Physical Activity is 30 minutes 5 days a week

Social Support (such as a friend, sister, sibling, church group, and/or an online group) has shown to increase adherence to the your health behavior change. Stay active with someone as support.

The education pieces is a self-paced program by The Arthritis Foundation Walk with Ease guidebook

<http://www.arthritistoday.org/tool-and-resources/walk-with-ease-program/>

Appendix H
Data Collection Questionnaire

1. Gender

1. Male
2. Female

2. Age

1. 21 – 39
2. 40 -59
3. 60- 69
4. 70 – 80

3. How would you rate your health status?

1. Good
2. Fair
3. Poor

4. On average, how many days per week do you walk or do physical activity? For each day of physical activity, how much time did you spend walking? (Baseline)

1. None
2. _____ Days per week
3. _____ Minutes a day

4a. After education and the 6 weeks time, on average how many days a week did you walk or do physical activity, how much time did you spend walking? (Post 6 week)

1. None
2. _____ Days per week
3. _____ Minutes a day

5. How confident are you that you will continue walking or being physical active after this education and Walk With Ease program?

1. Extremely confident
2. Fairly confident
3. Slightly confident
4. Not at all confident

6 Overall, to what extent were you satisfied with the educational program?

1. Very well satisfied
2. Satisfied
3. Fairly satisfied
4. Not at all satisfied

7. If participants did not complete the program, what were the reasons / barriers?

Open ended – response _____

8. WOMAC index Pre-score _____ (Baseline) Post-score _____ (Post 6 week)



Principal Investigator: Renee Endicott

Protocol Number: 15-320 Protocol Title: Effect of self-management program on pain and function in patients with Osteoarthritis Type of Review: Designated Review

Date of Approval: 11/30/2015 Date of Expiration: 10/12/2016

Dear Ms. Endicott,

NOTICE OF NEW APPROVAL

The above referenced study, and your participation as a principal investigator, was reviewed and approved, under the applicable IRB regulations at 21 CFR 50 and 56 (FDA) or 45 CFR 46 (OHRP), by the UMKC IRB. You are granted permission to conduct your study as described in your application.

This study was approved with a waiver of documentation of consent pursuant to 45 CFR 16.117.

This approval includes the following documents:

Attachments

- TMC administration approval of researchMemo-2-2
- Privacy Board Authorization - PW_Siebes_16-018-2
- TMC - complete Partial_Waiver_of_Authorization Version 2 July 11 Educational Piece Version 1 August 20
- RAC Participant Information Survey - version 1 August 25
- Form- Version 1 August 25
- 320_IRBApproved.Version 5 Sept 22, 2015_Stamped
- AF participant_release Version 1 August 25
- AF RAC Actual WVE Evaluation
- AF RAC
- HIPAA Authorization-2
- MAA Sign Sheet
- Data Collection Sheet
- TMC Siebes, SoNHS proj
- AF KC
- Protocol ED TMC OA

If a consent is being used in this research study you may find the stamped version in section 16 of your application.

The ability to conduct this study will expire on or before 10/12/2016 unless a request for continuing review is received and approved. If you intend to continue conduct of this study, it is your responsibility to provide a Continuing Review form prior to the expiration of approval.

This approval is issued under the University of Missouri - Kansas City's Federal Wide Assurance FWA00005427 with the Office for Human Research Protections (OHRP). If you have any questions regarding your obligations under the Board's Assurance, please do not hesitate to contact us.

There are 5 stipulations of approval:

UMKC 5319 Rockhill Road Kansas City Missouri TEL: 816 235-5927 FAX: 816 235-5602

Page: 1



UMKC 5319 Rockhill Road Kansas City Missouri TEL: 816 235-5927 FAX: 816 235-5602

1) No subjects may be involved in any study procedure prior to the IRB approval date or after the expiration date. (PIs and sponsors are responsible for initiating Continuing Review proceedings). unanticipated or serious adverse events must be reported to the IRB. be IRB approved prior to implementation unless they are intended to reduce risk. This includes any change of investigator. 4) All protocol deviations must be reported to the IRB.

2) All
3) All protocol m

5) All recruitment materials and methods must be approved by the IRB prior to being used. **File** contact the Research Compliance Office (email: umkcirb@umkc.edu; phone: (816)235-5927) if you have questions or require further information. Thank you,

Simon MacNeill UMKC IRB

Page: 2

Measurement Tool
WOMAC Index
CONFIDENTIAL

Appendix I

Permission for WOMAC Measurement Tool

Submitted permission request April 30, 2015 at www.womac.org

Dear Amy,

Thank you for your email of 1st May 2015, and for providing further information regarding your intended use of the WOMAC® Index.

In order to provide you a cost quotation, I would be grateful if you could please identify the maximum number of patients that you intend to enrol in your study.

\May thanks for your interest in the WOMAC® Index.

Kind regards,

Jennifer Kennedy per prof Bellamy.

Nicholas Bellamy | Professor
MD MSc MBA DSc FRCP(C) FRCP (Glas,Edin) FACP FRACP
The University of Queensland | School of Medicine | RBWH
Level 8, Health Sciences Building | Building 16/901 | Herston|QLD 4029
AUSTRALIA

®WOMAC is a registered trade-mark of Nicholas Bellamy
(CDN No. TMA 545,986) (EU No. 004885235)(USA No. 3520667)

™AUSCAN is a trade-mark of Nicholas Bellamy

Dear Jennifer Kennedy,

Thank you for your quick response. I am a Nurse Practitioner in the Doctorate of Nursing graduate school at the University of Missouri - Kansas City, School of Nursing and Health Studies. I am enrolled full time class N5613 Evidence-based Practice.

Below are the answers to questions with my brief study research preview following.

1. Osteoarthritis Physical Activity program
2. WOMAC index as a measurement tool
3. Unknown patient participants
4. Points of data collection at baseline and 8 weeks
5. 8 week observation / follow up period
6. Single center study, the patient provider hospital
7. Single investigator is myself, (my advisor and faculty for IRB board is Dr Endicott)
8. No funding has been secured
9. The application is non-commercial
10. WOMAC 3.1 Likert scale format
11. In the English language
12. Paper data collection - (Do you have WOMAC on REDcap capability ?)
13. WOMAC would be response by self administered
14. Osteoarthritis of the Knee

Thank you,

Amy Siebes

School - Doctorate Nursing student at UMKC

Kansas City, Missouri 64108

Appendix J

Data Collection Template – Excel Spreadsheet

Subject ID	Name	Gender	Age	Phone	Health	Consent	WOMAC B	W 6
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Statistical Analysis Software SPSS

The difference between the patient outcomes WOMAC index, pain, stiffness and function, and physical activity will be by statistical analysis Wilcoxon signed ranked test.

The demographics age, gender, ethnicity, and health status will be descriptive analysis.

Appendix K
CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY
Effects of self-management on pain and function in Osteoarthritis

Introduction

You are being asked to volunteer for a research study. This study is being conducted at Truman Medical Center.

The researcher in charge of this study is Dr. Renee Endicott. The student investigator is Amy Siebes, MSN APRN. While she will run the study, other qualified persons who work with her may act for her.

The study team is asking you to take part in this research study because you have been seen in the Emergency department or orthopedic clinic and have osteoarthritis of the knee. Research studies only include people who choose to take part. Please read this consent form carefully. The student investigator will go over this consent form with you. Ask her to explain anything that you do not understand. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Purpose

The purpose of this research study is to determine whether an educational self-management program of physical activity on adult patients with osteoarthritis of the knee, volunteers seen in the emergency department and orthopedic clinic setting, can decrease pain, stiffness and improve function. You will be one of about 30 subjects in the study at Truman Medical Center.

Study Procedures and Treatments

If you agree to take part in this study, you will be asked to take a 10-minute Pretest survey today.

- Pre- test administration of the WOMAC index completed in initial telephone contact with patients. The educational material (Walk with Ease booklet) will be provided once a Participation Release Form and participation Information Survey is obtained from participants as requested by the Arthritis Foundation. The pre-test WOMAC index takes 10-15 minutes to complete. The Participation Release form and Participation Survey takes 10 minutes to complete.
- Intervention / Education – Evidence-based education self-management program of osteoarthritis guidelines provided by student investigator. The information will be simple written English language for ease of retention and reading. Walk with Ease is a community-based walking program developed by the Arthritis Foundation. The evidence-based program is self-paced. The commitment is self paced over 6 weeks time. The guidebook is educational information with a mix of physical activity and managing arthritis educational topics.
- Post-test administration of the WOMAC index will be completed in follow up telephone contact with patients. The post-test WOMAC, in addition to the Participation Evaluation Form should take 15 minutes for the participants to complete. After 6 weeks of self-managed educational intervention, participant's follow up is through telephone contact only. You are not

expected to return to Truman Medical Center, the study investigator will call you by phone for the post –test and evaluation survey.

When you are finished taking part in the study, you can keep the booklet.

Possible Risks or Side Effects of Taking Part in this Study

We will make every possible effort to maintain your privacy. There is a possible risk of breach of confidentiality. Meaning that your personal information such as, your name and phone number, could possibly be seen by people other than the research team.

Possible Benefits for Taking Part in this Study

Benefits of this study are that gained information on your illness. Your osteoarthritis symptoms may improve, and overall improve care. Other people may benefit in the future for the information that comes from the study.

Costs for Taking Part in this Study

There is no monetary cost to the subjects. You will be responsible for your doctor and or hospital cost as usual.

Payment for Taking Part in this Study

There is no payment for taking part in the study.

Alternatives to Study Participation

The alternative is to not take part in the study.

Confidentiality and Access to your Records

The Bar Code at the top of this consent form will be used to link this consent form and your participation in this research study to your Truman Medical Center permanent medical record. If you do not want this consent form or your participation in this study to be a part of your permanent medical record you cannot participate in this research study.

The results of this research may be published or presented for scientific purposes. You will not be named in any reports of the results. Your study or applicable medical records that have your identity in them may be shown to the Institutional Review Board (IRB) (a committee that reviews and approves research studies), or other governing agencies. This is to prove which study procedures you completed and to check the data reported about you. They may also review your

medical records for any treatment you received before you agreed to take part in this study. This is to confirm your medical history and that you meet the requirements to be in this study. The study team will keep all information about you confidential as provided by law, but complete confidentiality cannot be guaranteed.

If you leave the study or are removed from the study, the study data collected before you left may still be used along with other data collected as part of the study. For purposes of follow-up studies and if any unexpected events happen, subject identification will be filed at University of Missouri-Kansas City under appropriate security and with access limited to medical research personnel only.

If you sign this consent form, you are allowing the study team and these other agencies to see your medical records.

In Case of Injury

The University of Missouri-Kansas City appreciates people who help it gain knowledge by being in research studies. It is not the University's policy to pay for or provide medical treatment for persons who participate in studies. If you think you have been harmed because you were in this study, please call the researcher, Dr. Renee Endicott you have any questions about the study.

Contacts for Questions about the Study

You should contact the IRB Administrator of UMKC's Institutional Review Board at 816-235-5927 if you have any questions, concerns or complaints about your rights as a research subject. You may call the researcher Dr. Renee Endicott at you have any questions about this study. You may also call her if any problems come up.

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers, doctors or sponsors may stop the study or take you out of the study at any time

- if they decide that it is in your best interest to do so,
- if you experience a study-related injury,
- if you need additional or different medication/treatment,
- if you no longer meet the study criteria, or
- if you do not comply with the study plan.

They may also remove you from the study for other administrative or medical reasons. You will be told of any important findings developed during the course of this research.

You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling Dr Renee Endicott. By signing this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.

Signature (Volunteer Subject) Date

Printed Name (Volunteer Subject)

**Signature (Authorized Consenting Party) Date
Consenting Party)**

Printed Name (Authorized

**Relationship of Authorized Consenting
Party to Subject**

**Signature of Person Obtaining Consent Date
Consent**

Printed Name of Person Obtaining

Appendix L
Statistician Communication

To:
Sent: Thu, Apr 30, 2015 1:00 pm
Subject: ED Study

I am working on a school project through UMKC, researching a specific patient population to improve care. I would like to meet you to discuss further so I have included study information. Can we meet next week? Can you help me determine the sample size for my study and the power enough to detect if statistical significance?

Suggestions always welcomed. Thank you,
Amy Siebes

Appendix M
Descriptive Data Analysis

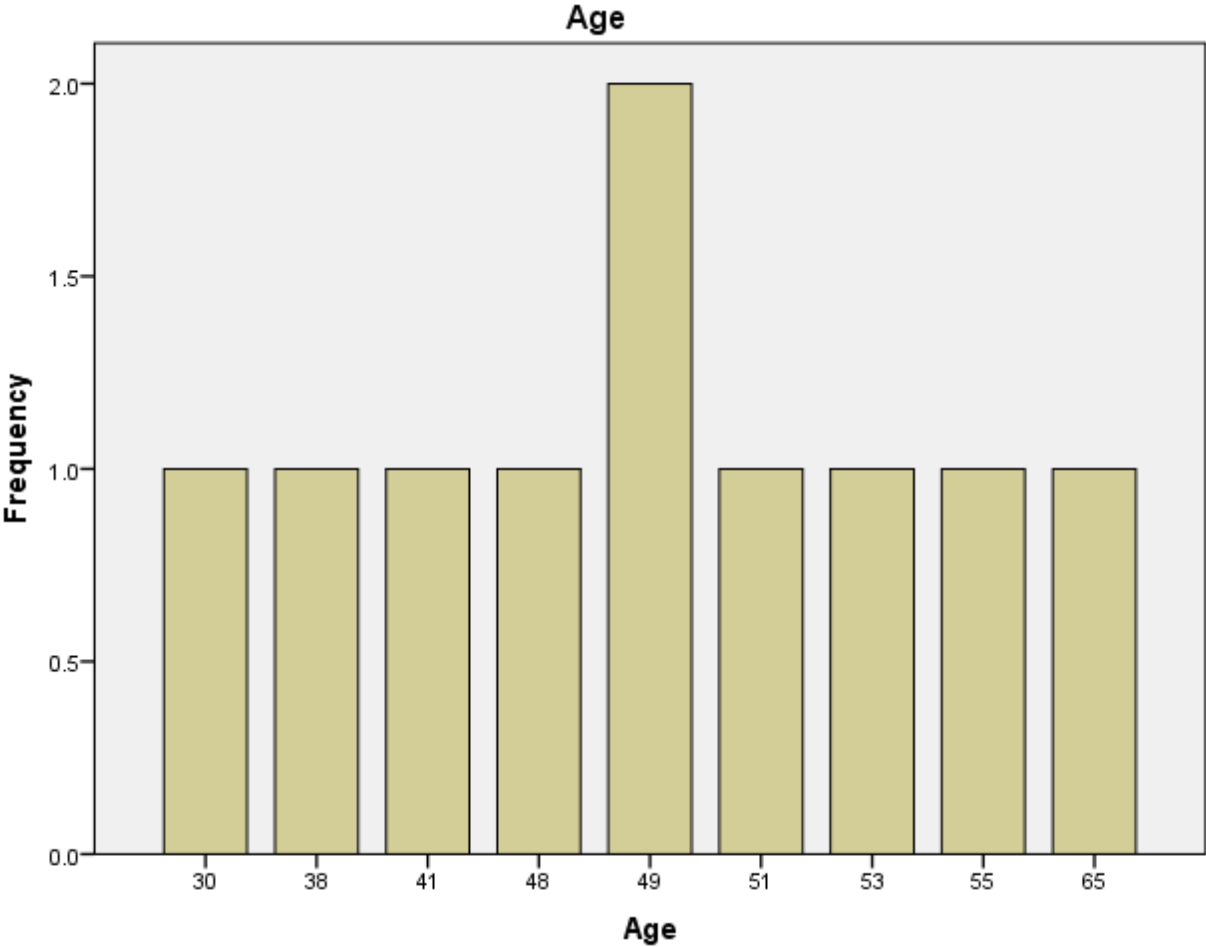
		Statistics			
		Age	Gender	Ethnicity	Health Status
N	Valid	10	10	10	10
Mean		47.90	1.70	2.00	1.60
Median		49.00	2.00	2.00	2.00
Mode		49	2	2	2
Std. Deviation		9.701	.483	1.155	.516
Percentiles	25	40.25	1.00	1.00	1.00
	50	49.00	2.00	2.00	2.00
	75				
Valid	3				
	3				
	4				
	4				
	4	53.50	2.00	2.00	2.00
	5				
	5				
	5				
	6				
	T				
Missing	S				
Total					

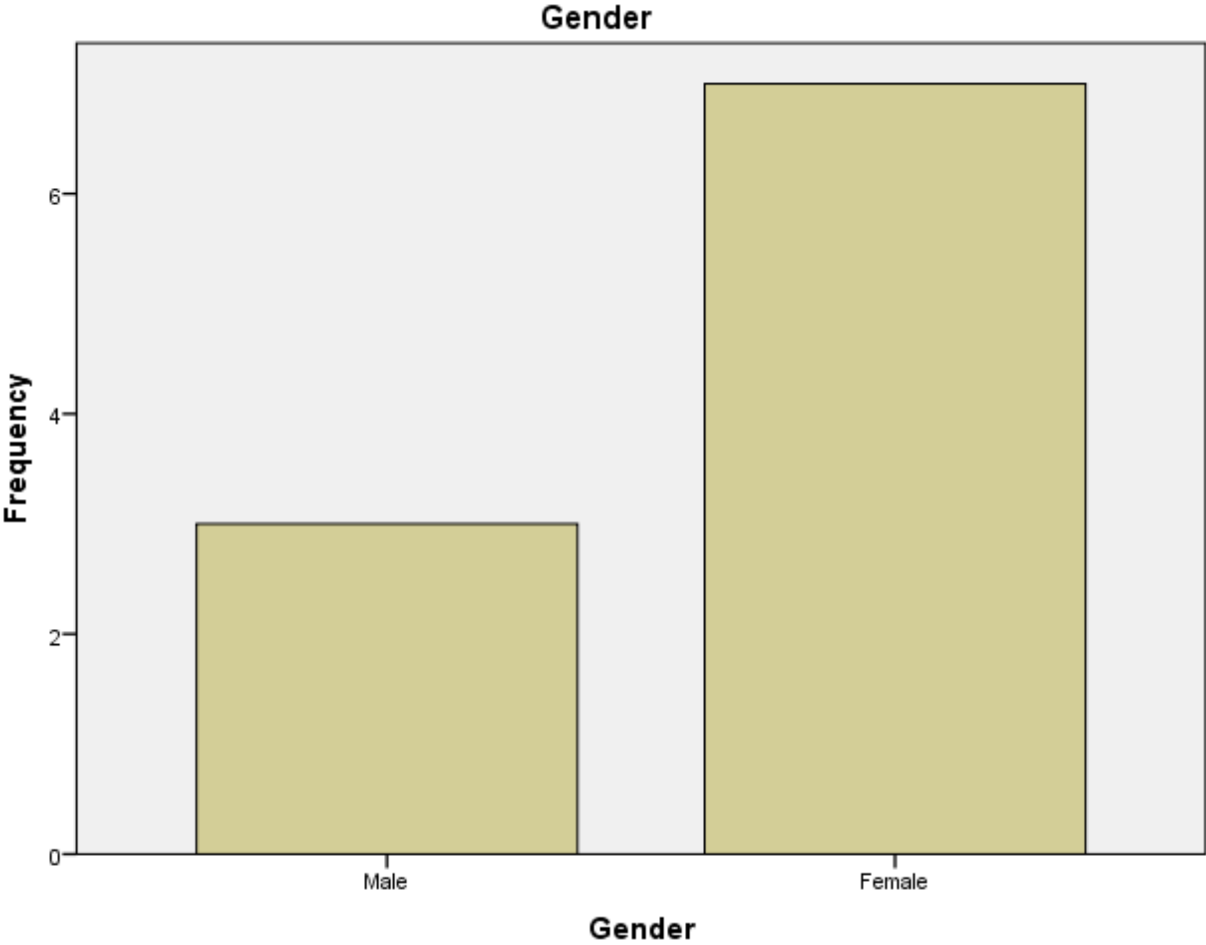
Frequency Table

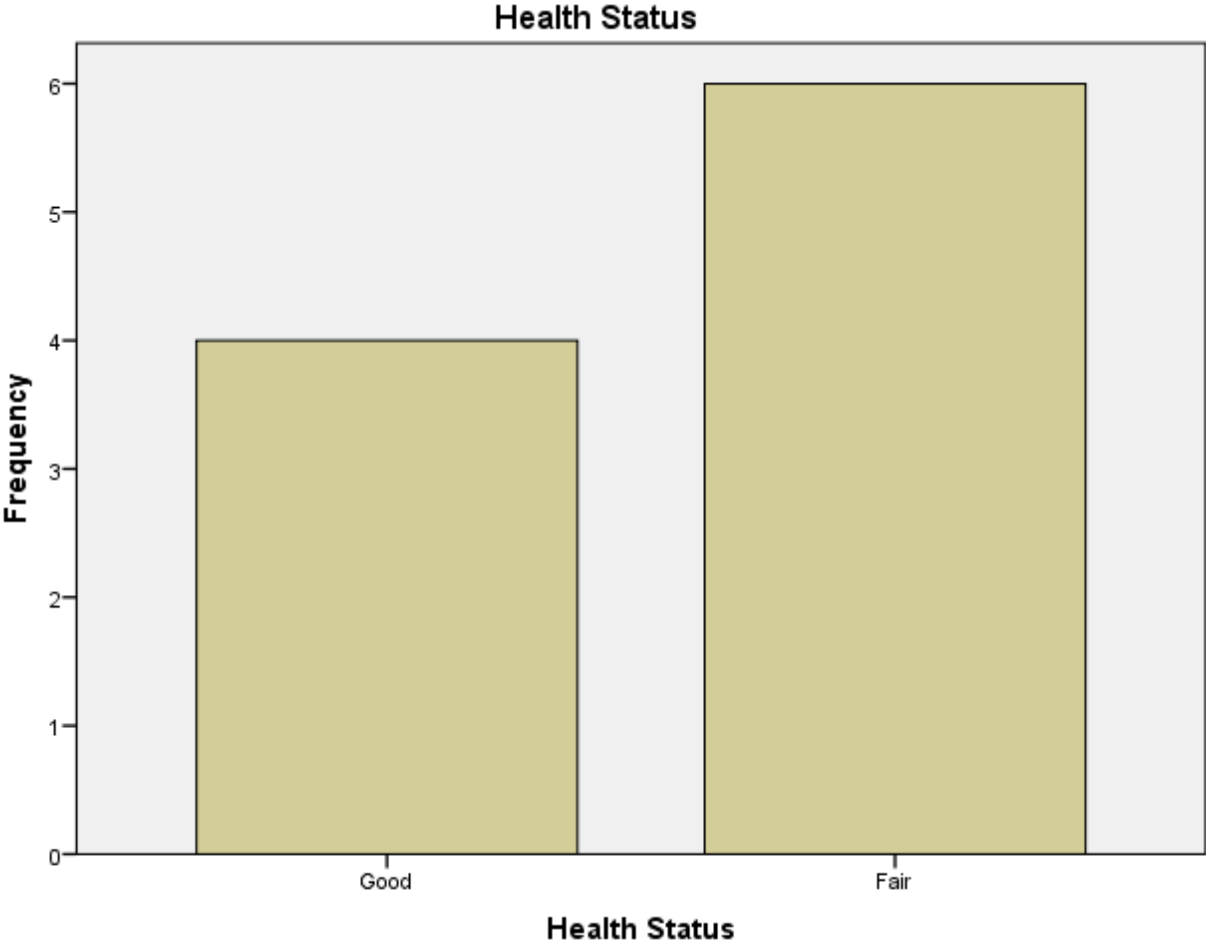
		Gender			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Male	3	7.3	30.0	30.0
	Female	7	17.1	70.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

		Health Status			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Good	4	9.8	40.0	40.0
	Fair	6	14.6	60.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

Bar Chart





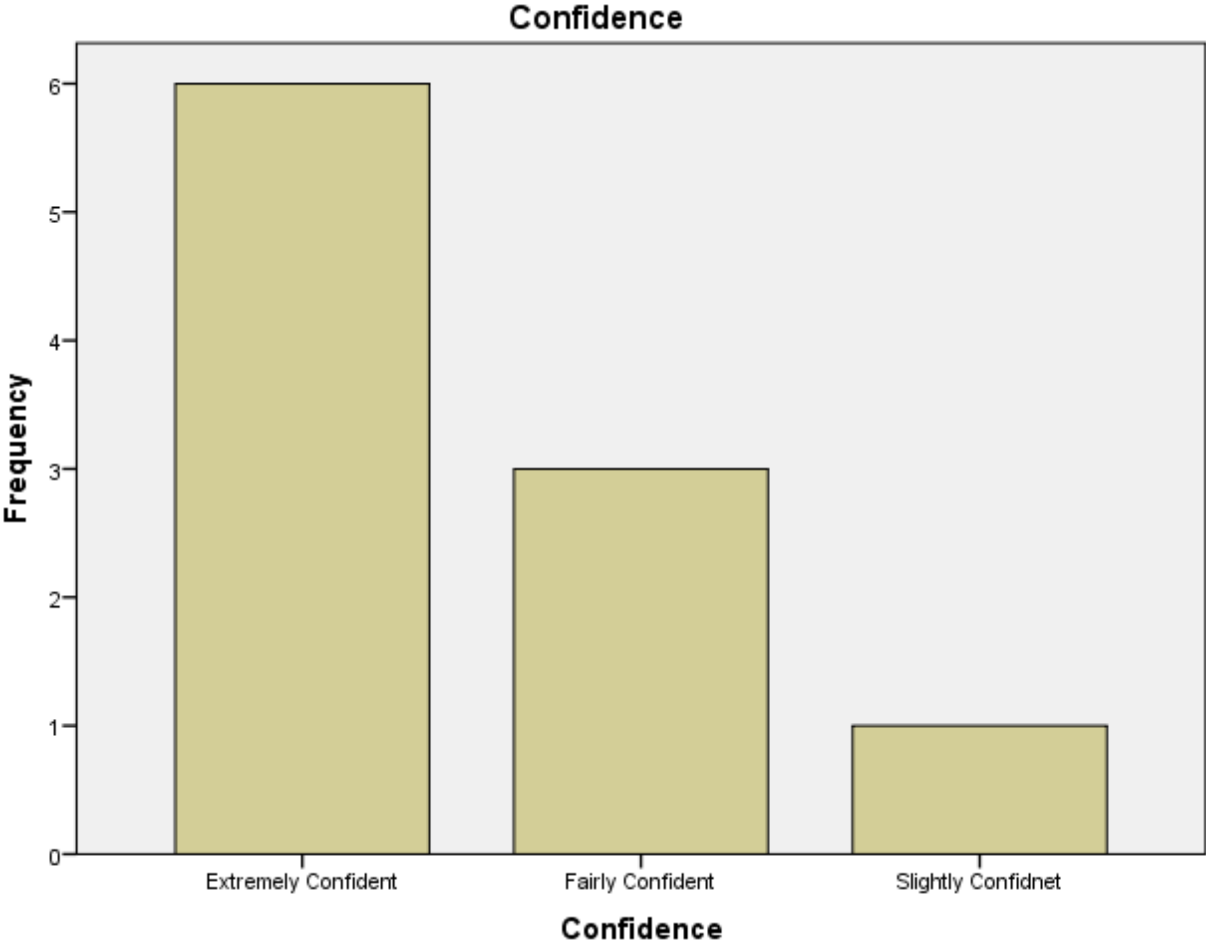


Frequency Table

		Confidence			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Extremely Confident	6	14.6	60.0	60.0
	Fairly Confident	3	7.3	30.0	90.0
	Slightly Confident	1	2.4	10.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

		Satisfaction			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very well satisfied	5	12.2	50.0	50.0
	Satisfied	5	12.2	50.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

Bar Chart





Statistics

	Confidence	Satisfaction
Missing	31	31
Mean	1.50	1.50
Median	1.00	1.50
Mode	1	1 ^a
Std. Deviation	.707	.527
Percentiles		
25	1.00	1.00
50	1.00	1.50
75	2.00	2.00

a. Multiple modes exist. The smallest value is shown

Frequency Table

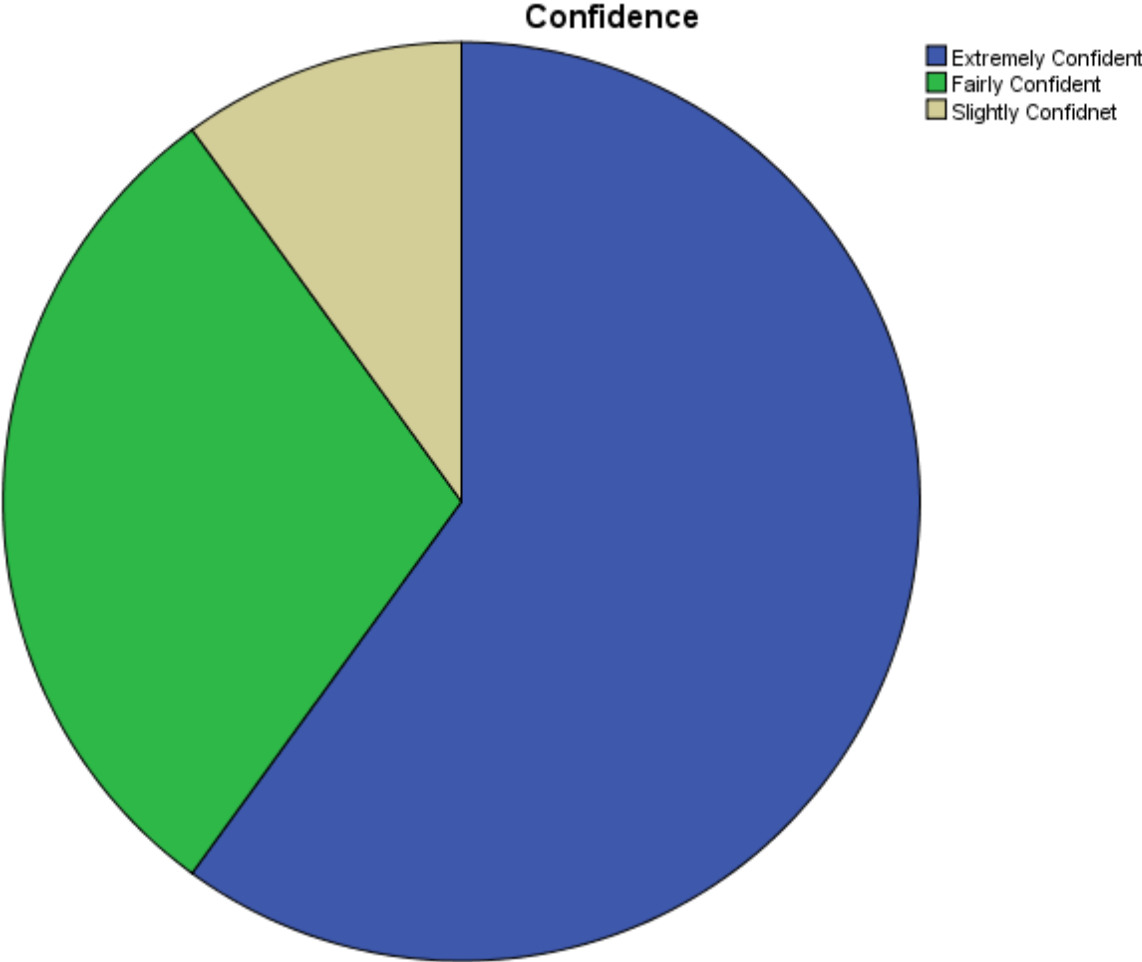
Confidence

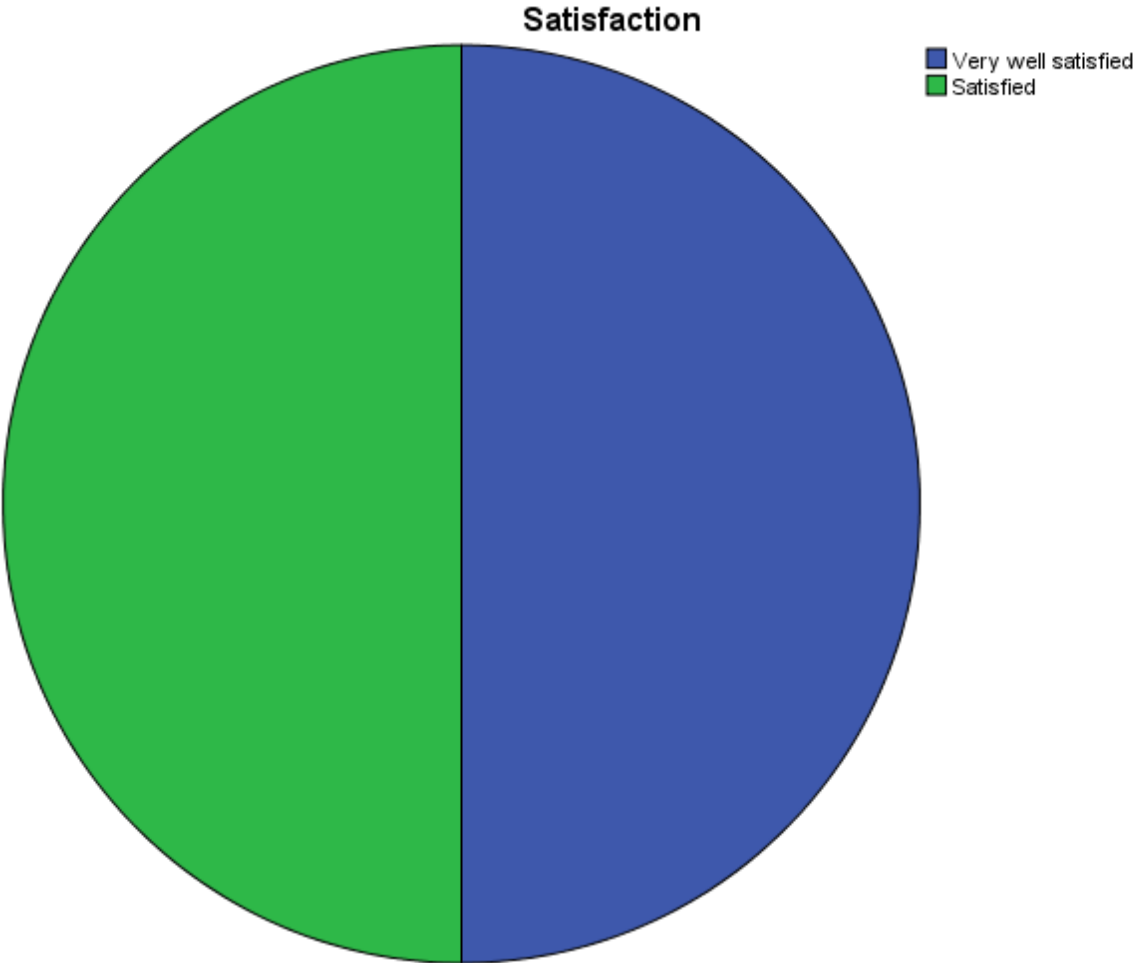
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Extremely Confident	6	14.6	60.0	60.0
	Fairly Confident	3	7.3	30.0	90.0
	Slightly Confident	1	2.4	10.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

Satisfaction

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Very well satisfied	5	12.2	50.0	50.0
	Satisfied	5	12.2	50.0	100.0
	Total	10	24.4	100.0	
Missing	System	31	75.6		
Total		41	100.0		

Pie Chart





|

Statistical Data Analysis

Wilcoxon Signed Ranks Test WOMAC

Ranks

		N	Mean Rank	Sum of Ranks
Womac 6 weeks - Womac Baseline	Negative Ranks	8 ^a	5.25	42.00
	Positive Ranks	1 ^b	3.00	3.00
	Ties	1 ^c		
	Total	10		

- a. Womac 6 weeks < Womac Baseline
- b. Womac 6 weeks > Womac Baseline
- c. Womac 6 weeks = Womac Baseline

Test Statistics^a

	Womac 6 weeks - Womac Baseline
Z	-2.310 ^b
Asymp. Sig. (2-tailed)	.021

- a. Wilcoxon Signed Ranks Test
- b. Based on positive ranks.

Wilcoxon Signed Ranks Test PAIN

		Ranks		
		N	Mean Rank	Sum of Ranks
Pain 6 weeks - Pain Baseline	Negative Ranks	6 ^a	4.25	25.50
	Positive Ranks	1 ^b	2.50	2.50
Ties		3 ^c		
Total		10		

- a. Pain 6 weeks < Pain Baseline
- b. Pain 6 weeks > Pain Baseline
- c. Pain 6 weeks = Pain Baseline

Test Statistics ^a	
	Pain 6 weeks - Pain Baseline
Z	-1.947 ^b
Asymp. Sig. (2-tailed)	.051

- a. Wilcoxon Signed Ranks Test
- b. Based on positive ranks.

Wilcoxon Signed Ranks Test STIFFNESS

Ranks			N	Mean Rank	Sum of Ranks
Stiffness 6 weeks - Stiffness Baseline	Negative Ranks		5 ^a	5.10	25.50
	Positive Ranks		3 ^b	3.50	10.50
	Ties		2 ^c		
	Total		10		

- a. Stiffness 6 weeks < Stiffness Baseline
- b. Stiffness 6 weeks > Stiffness Baseline
- c. Stiffness 6 weeks = Stiffness Baseline

Test Statistics ^a	
	Stiffness 6 weeks - Stiffness Baseline
Z	-1.065 ^b
Asymp. Sig. (2-tailed)	.287

- a. Wilcoxon Signed Ranks Test
- b. Based on positive ranks.

Wilcoxon Signed Ranks Test FUNCTION

Ranks			
	N	Mean Rank	Sum of Ranks
Function 6 weeks - Function Baseline	7 ^a	6.86	48.00
Negative Ranks			
Positive Ranks	3 ^b	2.33	7.00
Ties	0 ^c		
Total	10		

- a. Function 6 weeks < Function Baseline
- b. Function 6 weeks > Function Baseline
- c. Function 6 weeks = Function Baseline

Test Statistics ^a	
	Function 6 weeks - Function Baseline
Z	-2.090 ^b
Asymp. Sig. (2-tailed)	.037

- a. Wilcoxon Signed Ranks Test
- b. Based on positive ranks.

Wilcoxon Signed Ranks Test Physical Activity

		Ranks		
		N	Mean Rank	Sum of Ranks
PA 6 weeks - PA Baseline	Negative Ranks	2 ^a	6.50	13.00
	Positive Ranks	6 ^b	3.83	23.00
	Ties	2 ^c		
	Total	10		

- a. PA 6 weeks < PA Baseline
- b. PA 6 weeks > PA Baseline
- c. PA 6 weeks = PA Baseline

Test Statistics ^a	
	PA 6 weeks - PA Baseline
Z	-.700 ^b
Asymp. Sig. (2-tailed)	.484

- a. Wilcoxon Signed Ranks Test
- b. Based on negative ranks.

NPAR TESTS

/WILCOXON=PAB WITH PA6 (PAIRED)
 /MISSING ANALYSIS
 /METHOD=EXACT TIMER(5).

Wilcoxon Signed Ranks Test

Frequencies

		Statistics	
		Pain Baseline	Pain 6 weeks
N	Valid	10	10
Mean		13.10	9.00
Median		14.50	8.50
Mode		8	8 ^a
Std. Deviation		4.508	5.249
Percentiles	25	8.00	5.75
	50	14.50	8.50
	75	16.50	12.00

a. Multiple modes exist. The smallest value is shown

