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Supervised Lower Extremity Strengthening Program to Improve Function in Women Over Fifty with Knee Osteoarthritis: A Time Series Design

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SUPERVISED LOWER EXTREMITY STRENGTHENING PROGRAM TO IMPROVE FUNCTION IN WOMEN OVER FIFTY WITH KNEE OSTEOARTHRITIS: A TIME SERIES DESIGN

By

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A doctoral project submitted in partial fulfillment
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THE GRADUATE COLLEGE

We recommend the doctoral project prepared under our supervision by

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entitled

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Doctor of Physical Therapy
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ABSTRACT

Objective: Develop a simple, self-paced lower extremity strengthening program incorporating functional activities for women over the age of fifty to reduce limitations associated with knee OA.

Study Design: This was a pilot study utilizing a time series design with 8 women aged 55-65 (M $\pm$ SD = 60 $\pm$ 3) meeting the American College of Rheumatology's criteria for clinical diagnosis of knee OA.

Background: Lower extremity weakness in women with knee osteoarthritis is associated with pain and functional limitations.

Methods and Measures: Subjects began the 14-week program with 2 weeks of baseline treadmill walking. The following 12 weeks were divided into 3 phases, 4 weeks each, consisting of a 10 minute walking warm-up, 18 minute stepping protocol and a 10 minute walking cool-down. Step height progressively increased by 2 inches each phase. Outcome measures included Limits of Stability and Sensory Organization Test taken at weeks 1 and 14 on the NeuroCom Smart Equitest®; the Western Ontario and McMaster's University Arthritis Index (WOMAC) and quadriceps strength using a hand-held dynamometer recorded at each change of phase; and pain rating using a visual analogue scale which was scored every session.

Results: A repeated measures ANOVA demonstrated a significant difference between WOMAC means ($F(4,28) = 6.218$, $p<.001$). Additionally, a statistically significant difference was found among the means for bilateral quadriceps strength measurements ($F(4,28) = 36.338$, $p<.0005$). Pair-wise comparisons for bilateral quadriceps strength revealed a statistically significant difference among the means between all treatment times when compared to the post-treatment scores ($ps<.003$).

Conclusions: Subjects demonstrated an increase in quadriceps strength particularly in the final phase of the step program. WOMAC scores revealed significant changes between pre and week 10 treatment functional levels. The gains seen within this subject group in a limited time frame offer preliminary evidence that a strength-training program may benefit women over 50 with knee OA by improving lower extremity strength and function. These results warrant further investigation using more rigorous methodology.

KEY WORDS: knee osteoarthritis, muscle strength, quality of life

INTRODUCTION

Osteoarthritis (OA) is a prevalent and disabling musculoskeletal condition. The knee is the most commonly affected lower extremity joint, and leads to the majority of disability associated with OA.[1-3] Knee OA is estimated to affect nearly 40% of adults in the United States, and prevalence significantly increases with age.[1,3] In addition, clinical symptoms and radiographic evidence appear more frequently in women than in men.[1,3]

Lower extremity muscle weakness, particularly of the quadriceps, is common in the aging population and is associated with clinical symptoms of knee OA.[4] Weakness of the quadriceps can lead to instability in the knee joint which in turn can lead to further degenerative changes, pain, decreased balance and a reduction in physical activity.[4] Individuals affected by symptomatic knee OA experience challenges related to walking, climbing stairs, and rising from sit to stand.[5] Difficulty with specific functional activities that are commonly associated with symptomatic knee OA include standing from a seated position and stair negotiation.[3]

A recent meta-analysis of exercise programs for knee OA reveals that interventions utilizing lower extremity strengthening are effective in increasing function and decreasing pain in adults with knee OA.[6] Many of the studies included in this meta-analysis investigated the individual or combined effects of lower extremity flexibility, balance and/or isolated muscle strengthening on pain and function compared to control groups.[6] Four of the 32 studies included in this analysis incorporated functional activities such as stepping exercises and mini-squats; however, none of them looked at functional strengthening of the lower

extremities in isolation from other interventions such as isometrics, theraband strengthening, and taping.[7-10] There is also limited evidence to support interventions that allow the participant to self-select the pace and number of repetitions for each exercise. An important finding from this meta-analysis was that beneficial functional outcomes for land-based exercise programs are strongly associated with number of directly supervised treatment sessions.[6] Studies that included at least 12 supervised treatment sessions demonstrated better pain and physical function outcomes compared to independent exercise.[6] Scheduling and financial restrictions may make it difficult for a woman affected by knee OA to consistently attend supervised treatment sessions. By incorporating exercises as part of a daily routine, early supervised training that gradually tapers off to an independent home based program may be most effective in yielding long-term results.

As a result of these findings our study aim was to develop a simple, self-paced lower extremity strengthening program based on functional activities, performed both supervised and independently for women over the age of 50 to reduce activity limitations associated with knee OA.

MATERIALS AND METHODS

Subjects

Nine women over the age of 50 (mean=59.71, SD=3.38) who were either medically or self-diagnosed with OA in one or both knees were recruited by convenience sample through University of Nevada, Las Vegas (UNLV) faculty email and the surrounding community. Participants were excluded if they had

experienced a fracture, major trauma or joint replacement in either lower extremity. Subjects were also excluded if they had a history of rheumatoid arthritis and/or osteoporosis. Participants had a Dual Energy X-ray Absorptiometry (DEXA) scan measuring their bone mineral density to verify the absence of osteoporosis. To get an accurate account of knee pain throughout the study, we excluded women who used opioid-based pain relievers or who had corticosteroid injections in the past 30 days. One participant withdrew from the study after the first treatment session and her data were not included the study. The reported results include data from the 8 participants who completed the 14-week protocol.

Upon arriving to the UNLV campus facility, each subject formally consented to treatment under Institutional Review Board approval at UNLV. In addition, each woman was screened with the American College of Rheumatology's (ACR) criteria for the clinical diagnosis of knee osteoarthritis.[12,13] Factors included within the ACR knee OA criteria are knee pain, age over 50, stiffness lasting less than 30 minutes after rest, crepitus, bony enlargement, bony tenderness and no palpable joint warmth.[12] These criteria are 89% specific for women having 4 of the 6 factors outlined.[12] Subjects were excluded if they did not have at least 4 of the 6 factors. Blood pressure (BP) and heart rate (HR) measurements were taken before every session to ensure subjects did not have deleterious cardiovascular function prior to exercise. Participants were asked not to begin any other new exercise programs for the duration of the 14-week study to ensure that any changes in outcome measures could be attributable to the step program.

Study Design

To address quadriceps weakness, a dynamic and functional activity was incorporated into the lower extremity strengthening program. Stair negotiation is a daily activity for most community dwelling adults that requires both concentric and eccentric lower extremity muscle activation. Step exercise incorporates lower extremity muscle strengthening and balance training by mimicking this functional activity performed in daily life. For this reason, our intervention focused on step exercises, utilizing body weight resistance for lower extremity strengthening.

Our 14-week time series design consisted of 2 weeks for baseline testing followed by 12 weeks of intervention (Figure 1). To establish baseline knee pain following ambulation, subjects walked on a treadmill at a self-selected pace without shortness of breath for 10 minutes. Knee pain was rated using the VAS prior to and following treadmill walking. Subjects were also encouraged to engage in conversation during this time to ensure that the walking speed was not too fast. This baseline testing was performed twice weekly for the first two weeks of the study. Subjects were then scheduled for 12 weeks of intervention consisting of two supervised sessions and one at-home session per week.

The 12-week stepping exercise intervention began with 10 minutes of treadmill walking for warm-up followed by the step program consisting of:

- Forward stepping up and down leading with right foot
- Forward stepping up and down leading with left foot
- Mini-squats keeping knees behind toes
- Side-stepping up and down leading with right foot

- Side-stepping up and down leading with left foot
- Heel raises

Each of the 6 steps was performed for 1 minute and subjects cycled through the progression three times for a total of 18 minutes. Subjects completed the stepping exercises at a comfortable pace so as not to cause shortness of breath at any time. Following completion of the stepping sequence subjects walked on the treadmill for a 10 minute cool-down. Each subject received an identical step and copy of the protocol and was instructed to do one additional 38-minute protocol at home for a total of three sessions per week. Subjects were asked at the beginning of each supervised session if they were complying with the home exercise sessions and encouraged to ask questions and discuss any difficulties that arose during their independent sessions. For the first four weeks, the stepping intervention was performed on a 4-inch step, the second four weeks on a 6-inch step, and the final four weeks on an 8-inch step.

Outcome measures

Prior to beginning the 14-week study, balance was measured on the NeuroCom Smart Equitest® which included both the Sensory Organization Test (SOT) and Limits of Stability (LOS). This assessment was incorporated into the design because strength is an important component of balance. These tests have moderate to high reliability (ICC range .78 to .91) and good predictive validity for functional status on activities of daily living.[14,15]

Subjects also completed the Western Ontario and McMaster's University Arthritis Index (WOMAC), which assesses pain, stiffness and function in subjects

with knee OA.[16] Reported test-retest reliability for the WOMAC for pain and physical function subscales are .74 and .92 (ICC), respectively.[16] The WOMAC has moderate to strong construct validity compared to other functional ability scales.[16,17]

Maximum isometric quadriceps strength was measured bilaterally with subjects in short sitting using a hand-held dynamometer[18] placed two inches below the tibial tuberosity.[19] Both inter and intra-rater reliability for testing using this instrument was determined for the purposes of this study. Inter-rater reliability results revealed excellent agreement among the 3 raters: ICC (3,3)=.953 (95% CI: .861 to .987). Similarly, intra-rater reliability results showed excellent agreement (ranging from .934 to .945).

Scores for the WOMAC and quadriceps strength were reassessed when moving to a new step-height and all measures, including the SOT and LOS were reassessed following the conclusion of the 14-week study. In addition, for every on-site session, participants were asked to rate pain in one or both knees prior to and following the intervention using a visual analog scale (VAS). For compliance and comfort, subjects were only allowed to progress to the next phase and subsequent step height if their VAS score remained below 4 out of 10. Studies have shown that in chronic conditions, the level of satisfaction concerning pain management is deemed acceptable by patients when the score falls at or below a 3 on the 10 point VAS.[20-23]

RESULTS

All statistical analyses were performed using the Statistical Package for the Social Sciences for Windows, Version 18.0 (SPSS, Chicago, IL). For all analyses, α was set at .05.

Lower extremity pain and function

A repeated-measures ANOVA, with sphericity assumed and a Bonferroni correction, was used to determine if there was a difference in WOMAC scores throughout the treatment. A statistically significant difference was found in WOMAC scores over time, $F(4,28)=6.218$, $p<.001$ (Table 2). Pair-wise comparisons revealed a significant difference for the treatment means between pre-treatment scores and those at the beginning of week 10 ($p=.03$).

Lower extremity strength

Similarly, a repeated-measures ANOVA, with sphericity assumed and a Bonferroni correction, was performed for bilateral quadriceps strength measured using a hand-held dynamometer. There was a statistically significant difference among the means, $F(4,28)=36.338$, $p<.0005$. Pairwise comparisons revealed that there was a significant difference between all strength values when compared to post-treatment scores ($ps\leq.005$).

Balance

Composite scores on the NeuroCom® were analyzed using paired samples *t*-tests. No statistically significant differences were found between pre and post treatment scores for the composite measurements taken during the NeuroCom® tests of balance (Table 3).

COMMENT

The purpose of this study was to determine the effect of a supervised step program on improving lower extremity strength as well as functional ability in women over 50 with knee osteoarthritis. The results of this study suggest that the outlined intervention improves strength in the quadriceps muscle group in women with knee OA. As the intervention progressed, increases in strength and decreases in pain and functional activity limitations were noted. Compliance by the participants was exceptional, indicating subject enjoyment and dedication to the study. Quadriceps strength showed the greatest change of all measurements taken during the 14-week step program. The final phase of the program incorporated a step height increase to 8 inches, which is the standard step height for stairs in the community. During this phase, the subjects demonstrated the greatest increases in quadriceps strength. Extension of this final phase may be beneficial and lead to greater gains in strength and WOMAC scores as daily functional activities become easier. According to one study, the suggested MCID for quadriceps strength is a 43% change in knee extension force (N).[24] All study subjects exceeded the MCID for quadriceps strength from pre to post measurements.

While there were significant positive changes in subject WOMAC scores from pre-treatment to week 10, additional gains may have been limited by outside factors that were beyond the control of the researchers. Knee osteoarthritis is particularly sensitive to weather and humidity changes. Some patients reported the use of pain medication, and although not opioid-based, this may have resulted in fluctuations of perceived pain. In future studies, recording the pain medication used and/or

analyzing it as a covariate would help to determine the direct gains measured by the WOMAC. During the first two weeks of the final phase of the program, delayed onset muscle soreness (DOMS) also affected subjects' ability to participate fully in normal activities of daily living. Extending the time spent in the final phase to allow for muscle soreness to resolve may result in a significant change in WOMAC scores over time. Modification of the program could include additional training time at the 8-inch step height where significant gains in strength were most apparent.

In the last phase of the study, the subjects' quadriceps strength measures and self-reported functional levels improved. Previous studies have shown that resistance training, specifically of the quadriceps muscles, decreases pain and disability in subjects with knee OA.[25,26] When strengthening a muscle or muscle group, a broad spectrum of approaches exists. In a study by Gur et al it was demonstrated that high volume concentric and eccentric contractions of the lower extremities were safe, effective and well-tolerated in patients with knee OA.[27] A high-intensity home-based program involving squats, stepping and isokinetic knee exercises with ankle weights was shown to improve strength, pain, physical function and quality of life.[8] The specific stepping protocol developed for this research incorporated all of the aforementioned components by strengthening the quadriceps muscles and utilizing concentric and eccentric contractions, with an element to be completed in the home. Beyond that which research previously supported, two of the three sessions each week were therapist directed, and each exercise session involved nothing further than a warm-up, stepping exercises, and a

cool-down. This step program was inexpensive and an efficient exercise routine that most women could perform in a small area of their home.

Our initial hypothesis included expected changes in balance, due to the single leg stance component of the step program and the strengthening of the quadriceps. Contradictory to this hypothesis, improvements in balance were not seen following completion of the step program. This is likely because the intervention did not specifically focus on techniques to challenge balance, but could also be the result of a ceiling effect. In a previous case study, incorporation of agility drills and perturbation training was shown to be effective in improving balance in this specific population.[28] Based on the principle of specificity of training, inclusion of balance exercises and challenges to core stabilizers in addition to the lower extremity strengthening would be a beneficial modification to the stepping program.

Limitations of this study include a lack of randomization, no control group, utilization of a sample of convenience from a limited population, learning effect, maturation effect, and potential effects from pain medications not in our exclusion criteria. Additionally, comorbidities were considered only as exclusion criteria for our study. Therefore, the results may not be generalizable to the larger population of women over 50 with knee OA. Another limitation of the study is that strength changes were measured for the quadriceps muscle group only and did not include other lower extremity strength gains. Functional outcome tools such as the timed stair-climb or 30 second sit-to-stand may yield more complete and objective lower extremity strength measurements. Obtaining a measure of aerobic improvements gained through the study may also be of interest in future research.

CONCLUSION

The women in our study demonstrated a significant increase in quadriceps strength in the final phase of the step program when the step height was raised to 8 inches. According to our data, the 4-inch and 6-inch step heights were not sufficient to drive strength changes in our subjects. WOMAC scores revealed significant changes between initial measures and scores at week 10. An extension of the final phase in future studies may maintain improvements in WOMAC scores. Additionally, comparison of pre and post NeuroCom® scores showed no change in balance, suggesting subjects' balance was not affected by the strength training protocol used in this study.

The strength gains seen within the subject group in this limited time frame show potential benefits for developing a long-term experimental study utilizing a similar exercise program. With knee OA being a prevalent and functionally limiting disease, a simple step-protocol incorporating both supervised and independent home programs, focusing on lower extremity strengthening, may be a valuable exercise tool for this population.

Figure 1. Study Design Flowchart

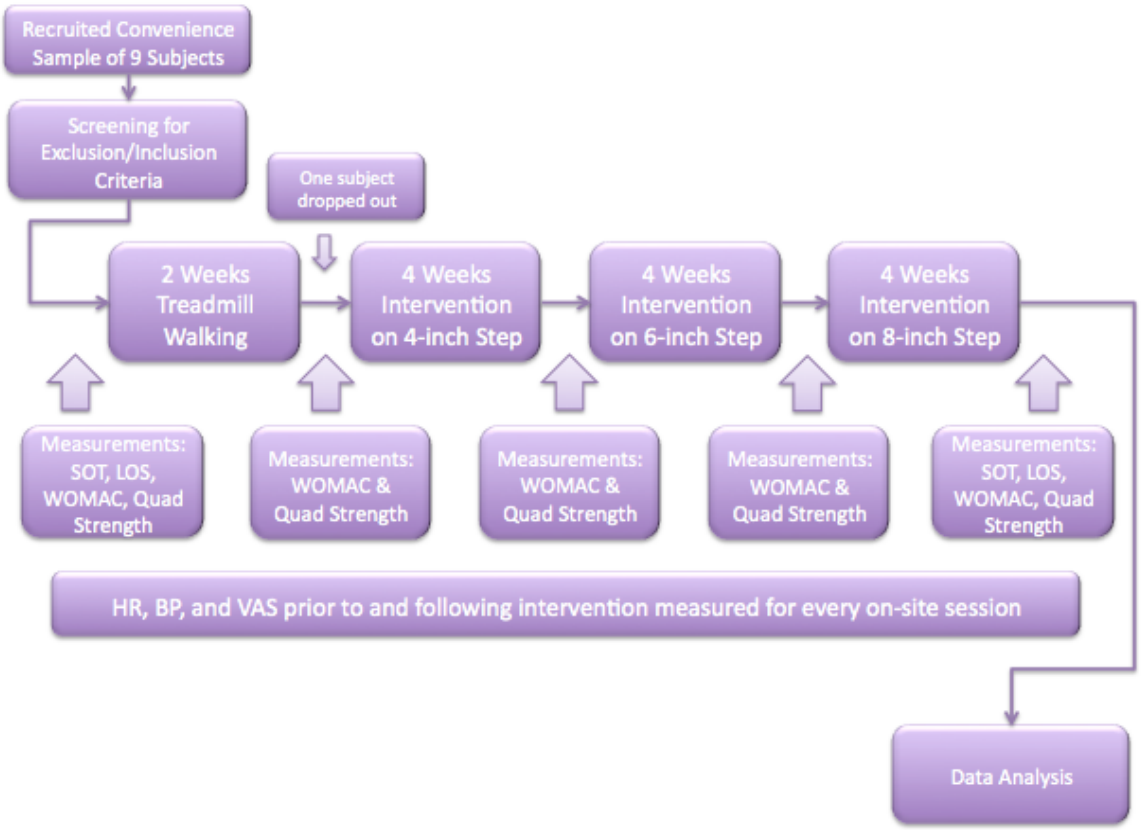

Figure 2. Change in WOMAC Scores and Quadriceps Strength Over Time

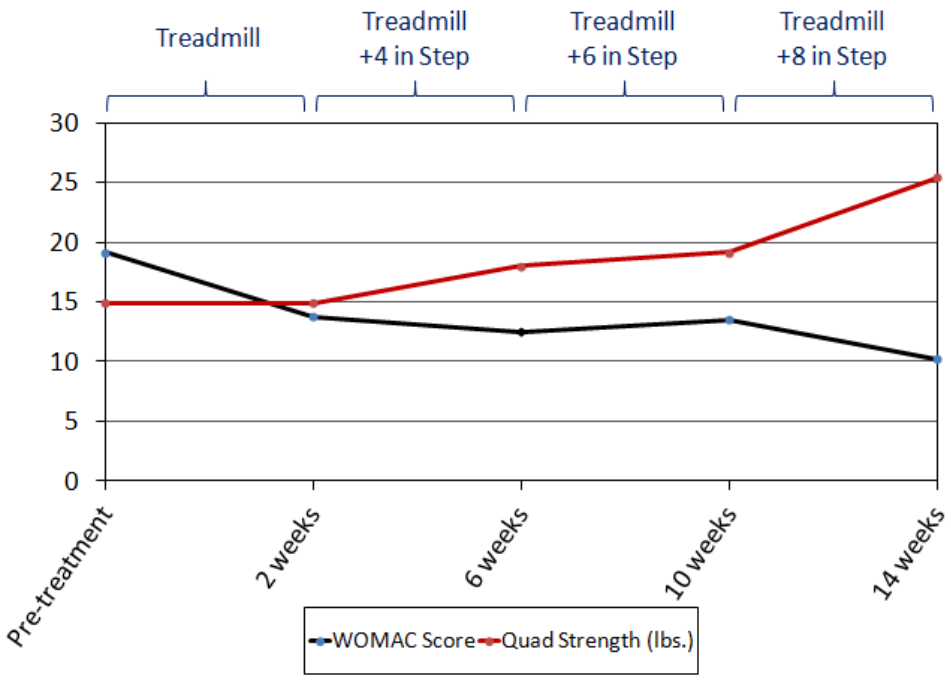

Table 1. Subject Demographics

Subject	1	2	3	4	5	6	7	8	**Mean (N=8)**	**SD (N=8)**
Age	60.8	62.8	58.3	55.1	59.1	61.1	55.6	64.9	59.7125	3.38291
Weight (pounds)	163	136	199	191	144	195	131	223	172.7500	33.92744
Height (inches)	62	62	66	64	69	66	63	67	64.8750	2.53194
Body Mass Index (BMI) (kg/m^2)	29.8	24.9	32.1	32.8	21.3	31.5	23.2	34.9	28.8125	5.00298

Table 2. Average Values and Standard Deviations for the WOMAC Results

WOMAC	Mean	SD	N
Pre treatment	19.125	9.56836	8
2 weeks	13.750	9.63253	8
6 weeks	12.500	7.09124	8
10 weeks	13.500	7.54037	8
14 weeks (post-treatment)	10.250	7.10634	8

Table 3. Average Values and Standard Deviations for the Quadriceps Strength Dynamometry Results

Bilateral Quadriceps Strength	Mean	SD	N	p value compared to post treatment
Pre treatment	14.8750	2.79987	8	.001
2 weeks	14.8750	2.64237	8	.002
6 weeks	18.0000	1.43925	8	.003
10 weeks	19.1250	2.08310	8	.002
14 weeks (post-treatment)	25.4375	3.67848	8	1.000

Table 4. Average Values and Standard Deviations for Combined Values of the 8 subjects' NeuroCom Smart Equitest® Results

Composite TEST Score	**Pre Treatment Mean**	**Post Treatment Mean**	**Pre treatment SD**	**Post-Treatment SD**	**Significance (2-tailed)**
SOT Score (%)	71.5000	73.5000	6.56832	6.54654	.086
LOS Reaction Time (sec)	.9413	.8025	.17964	.09223	.062
LOS Movement Velocity(deg/sec)	3.2250	3.3875	.74785	.63118	.363
LOS Endpoint Excursion (%)	62.3750	66.5000	5.39676	11.27576	.191
LOS Max Excursion (%)	78.2500	80.5000	8.06669	9.18073	.430
LOS Directional Control (%)	78.3750	79.3750	10.04188	4.95516	.685

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Education

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Physical Therapy Clinical Experience

- Saint Luke's East Hospital, Lee's Summit Missouri: Jan 9,2012-Mar 30, 2012
    - Inpatient Acute Care
- HealthSouth Rehab Hospital, Las Vegas Nevada: Oct 3, 2011-Dec 14, 2011
    - Inpatient Rehabilitation Hospital
- Physiotherapy Associates, Boulder Colorado: Jul 11, 2011-Sep 23, 2011
    - Outpatient Orthopedic Clinic
- Coronado Naval Base, San Diego California: Jun 19, 2010-Jul 31, 2010
    - Outpatient Orthopedic Clinic

Other Experience

- Graduate Assistant to Dr. Sue Schuerman, Department of Physical Therapy
    - Assist in continued development of clinical affiliation database and placement of physical therapy students
- Physical Therapy Aide, Northwest Rehabilitation Associates, Salem Oregon
    - Assist with outpatient orthopedic and neurological rehab, scheduling

Research Experience

June 2010-May 2012: Pilot study performed under the principal investigator Dr. Sue Schuerman, "Supervised lower extremity strengthening program to improve function in women over fifty with knee osteoarthritis: a time series design"

Activities

- American Physical Therapy Association member since 2009
- CPR AED Certified, International CPR Institute, May 2012 – May 2014
- Attended CSM, February 2010, San Diego
- Attended and presented research at CSM February 2012, Chicago
- Transforming Relationships: Training and Injury Prevention Presentation, Kansas City
- AARP Balance Assessments, Relay for Life, Arthritis Walk, Las Vegas

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Physical Therapy Clinical Experience

- Southern Hills Hospital: Jan 9,2012-March 30, 2012
    - Inpatient Acute care with emphasis on wound care
- Children's Physiotherapy Associates: October 3, 2011-December 14, 2011
    - Pediatric Outpatient Clinic
- St. Rose Dominican Hospital: July 11, 2011-September 23, 2011
    - Inpatient Rehabilitation Hospital
- Physiotherapy Associates: June 19, 2010-July 31, 2010
    - Adult Orthopedic Outpatient clinic

High School Science Teacher Experience

- Lakenheath High School, United Kingdom, April 2000-June 2002
    - Taught Human Anatomy and Physiology and Sophomore Biology
    - Girls Volleyball Coach and Girls Basketball Coach
- Crestview High School, Crestview, FL, August 1998-December 1999
    - Taught Freshmen Biology, Physical Science, and Chemistry
    - Girls Volleyball Coach and Girls Basketball Coach

Research Experience

June 2010-May 2012, presented to Southern Nevada APTA members and UNLV faculty as a requirement for graduation from DPT program, poster board presentation at CSM 2012, under submission to Journal of Women's Health Physical Therapy. Pilot study performed under the principal investigator Dr. Sue Schuerman, "Supervised lower extremity strengthening program to improve function in women over fifty with knee osteoarthritis: a time series design. "

Activities

- APTA member since 2009, pediatric, acute care orthopaedic and neurology section member
- Attended CSM, February 2010, San Diego, CA
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- Family and Sports Physical Therapy: Jan 9,2012-March 30, 2012
    - Outpatient orthopedic setting
- St. Rose Dominican Hospital: October 3, 2011-December 14, 2011
    - Inpatient acute care with emphasis on negative pressure wound therapy
- Kindred Transitional Care and Rehabilitation: July 11, 2011-September 23, 2011
    - Long-term acute care hospital
- North Bend Physical Therapy: June 19, 2010-July 31, 2010
    - Outpatient orthopedic setting

Volunteer Experience

- Self Help Centre for Cerebral Palsy, Kathmandu, Nepal: September – December 2007
    - Projects Abroad Physical Therapy Volunteer
- University of Washington Medical Center, Seattle, WA April – August 2005
    - Hospital Volunteer in Physical Therapy Department

Research Experience

Student Researcher, University of Nevada, Las Vegas, NV. Mar 2010 – Present.
Research Advisor Dr. Sue Schuerman PT, PhD, GCS. Supervised lower extremity strengthening program to improve function in women over fifty with knee osteoarthritis: a time series design.

Activities and Certification

- Student member of the American Physical Therapy Association, Nevada Chapter June 2009 – Present
- CPR and AED program certified, American Heart Association. May 2010 – May 2012
- Attended Combined Sections Meeting, February 2010, San Diego, CA
- Attended and presented research at Combined Sections Meeting February 2012, Chicago, IL