Mulligan Concept Intervention for Pregnancy Related Lumbo-Pelvic Pain
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Research Strategy
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Significance

Pregnancy-related pelvic girdle pain (PPGP), whether of the pelvic girdle or the lubopelvic junction, is exceptionally prevalent; reportedly, 45-76% of all pregnant women and 25% of postpartum women suffer from PPGP.[3-8] A major cause of sick leave during pregnancy,[17] PPGP greatly affects activities of daily living and is associated with risk of long-term back pain.[7, 9-10] Women suffering from PPGP typically seek treatment from their primary care physician or obstetrician. Primary care physicians have historically been more responsible for providing pregnancy related care in the Pacific and Inland Northwest regions compared to national averages; however, a marked decline in the provision of pregnancy related care has occurred in Alaska, Idaho, Montana, and Wyoming since 1999.[1, 11]

Maternal health disparities exist in rural communities and are accompanied by poor health outcomes and increased healthcare costs.[11] Consequently, a call has been made for solutions stemming from problems related to diminishing access to care.[1,3] Limited access means that positive and impactful patient outcomes at each visit are even more critical. Giving health care professionals more effective intervention options can help make limited visits more efficient, increase patient outcomes, decrease maternal health disparity in rural communities, as well as help women across the nation.

Researchers and clinicians have theorized PPGP to be caused by a widening of the pelvis in response to hormonal changes during pregnancy, creating instability in the sacroiliac (SI) joints.[3, 12] While the theory is logical, evidence does not support hormone induced ligament laxity having a role in the etiology of PPGP.[6] A more likely cause is mechanical dysfunction, such as malposition of bones in the lumbopelvic region, which has been observed in radiographic and gait analysis studies.[3, 5, 12, 15] Mechanical changes are correlated with failure of the load transfer mechanism of the SI joints, movement dysfunction, and pain.[14] Clinical intervention for PPGP ranges from acupuncture to stabilization exercises to corticosteroid injections, with only mildly positive results because these treatments are not aimed at correcting underlying mechanical and motor control dysfunction.[10]

The Mulligan Concept is a manual therapy paradigm used to correct pain of mechanical origin by using specific joint mobilizations with limb movement to restore functional relationships between joint surfaces. The purported benefits of the Mulligan Concept are an immediate reduction or abolition of pain, immediate restoration of function, and options for self-treatment.[15, 14, 16] The effects of a manual therapy intervention aimed at restoring mechanical and motor control function of the lumbopelvic region have yet to be measured in women with PPGP. The proposed project will improve knowledge surrounding PPGP and create evidence for clinical practice options. If the proposed aims are achieved, we will have a better understanding of the efficacy of the Mulligan Concept for use in the pregnant population, build upon current research associating poor motor control to PPGP, and introduce novel assessment and treatment procedures for women suffering from PPGP.

Innovation

There is growing consensus that the etiology of PPGP is not due to hormonally induced laxity, but a combination of mechanical and motor control dysfunctions.[3, 5, 8, 12] Researchers have identified gait characteristics and joint relationships differences that are unique to patients with PPGP; not found in pregnant women with out PPGP or in patients with simple low back pain.[3, 8, 10] Positional abnormalities (e.g., subluxation of the pubic symphysis), changes in gait (e.g., thoracic and lumbar rotation timing and amplitude), and muscle activation patterns have been associated with the syndrome but

not found in matched healthy subjects.[3, 8,13] Failure of the load transfer mechanism of the sacroiliac joints, specifically, is associated with positional displacements of the joints in pelvic girdle and can cause dysfunctional pelvic girdle movement, loss of motor control, pain and disability.[18-20] Researchers have yet to conduct intervention trials to determine whether these associated dysfunctions can be altered with treatment. A clinician utilizing the Mulligan Concept would aim to simultaneously restore the load transfer mechanism and correct the malpositioning of the joints of the pelvis through mobilizations and patient movement. The concept is novel and has yet to be tested in this population. This application seeks to shift current research toward clinical intervention trials that close the evidence-based medicine gap and aim to inform clinical practice.

Approach

Twenty pregnant volunteers, ages 20-45 years, will be recruited for the study. Participants will be between their 20th-34th week of gestation, with reported pregnancy-related lumbopelvic pain. Participants would be excluded for any of the following criteria:

- orthopaedic or neurological problems with walking (other than PPGP)
- prior surgery of the lumbar spine, pelvis, hip, or knee
- fracture
- known malignancy
- active inflammation in the lumbar spine or pelvis
- ankylosing spondylitis, Scheuermann's kyphosis, active polyarthritis, or severe osteoporosis
- any pulmonary, cardiac, visual, auditory, or cognitive disorders
- any other multi/co-morbidities that limit the volunteers ability to complete a gait and sit-to-stand task

Volunteers will be recruited from Latah County, Idaho and surrounding areas by word of mouth and print and social media. Pregnant women who express interest in the study will be given an informational packet explaining the methods, risks, and benefits of participation. If the women decide to participate they would sign a consent statement and conduct an initial questionnaire, sent via online link. The survey would be used to determine inclusion and exclusion criteria, and group assignment (i.e., intervention group, placebo group). Un-paired t-tests will be conducted to determine whether significant differences exist between intervention and control groups in age, weight, height, as well as gestational week and number of pregnancies. Randomly stratifying the participants in to groups in this manner minimizes the potential confounding variables.

Participants will report to the University of Idaho Integrated Sport Medicine and Rehabilitative Therapy Clinic for initial patient reported outcome measures collection and standardized examination. Primary patient reported outcome measures include the Visual Analog Pain Scale, the Pelvic Girdle Questionnaire, the Assessment of Disablement Questionnaire, the Patient Specific Function Scale, and the Short Stress State Questionnaire. The examination will include history, palpation, special tests (e.g., Posterior Pelvic Pain Provocation test, Active Straight Leg Raise), and neurological screen.

Each participant will then perform a walking gait and sit-to-stand task as a baseline, in the University of Idaho Biomechanics Laboratory. An eight-infrared camera optical system (Vicon Motion Systems Ltd., Oxford, UK) and forceplate (AMTI, Watertown, MA, USA) will be used to collect the kinematic and kinetics data during the tasks. In addition, an eight-channel wireless electromyography (EMG) system (Delays, Inc., Natick, MA, USA) will be used to collect muscle activity during the gait and sit-to-

stand tasks, and the active straight leg raise (ASLR) special test. The participants in the treatment group will receive a Mulligan Concept evaluation and treatment administered by a Certified Mulligan Practitioner. The placebo group will undergo only the Mulligan Concept evaluation. The same tasks and ASLR will be repeated. Outcome measures and physical examination will also be repeated.

The study will be conducted under a randomized triple blinded placebo trial design. Neither the participants, the treating clinician, biomechanist, nor researcher collecting outcome measures will know the group designation of the participants. Conducting the trial in this manner will ensure the lowest possibility that any observed effects of the intervention are due to confounding factors.

Statistical Analysis

Sample size calculations were conducted to determine the appropriate number of participants that must be included. A sample size of 17 participants per group is needed to detect differences between groups with 80% power, and an *a priori* alpha of 0.05. Accounting for a reasonable 5% drop out rate, the final recommended number of participants is 36 (18 participants per group).

Specific Aim #1: Determine if Mulligan Concept manual therapy produces immediate changes in pain and self-reported function in women with PPGP.

A series of independent samples t-tests will be used to determine if a difference exists between the mean scores of the intervention and placebo groups on the VAS, PSFS, ADQ, and PGQ.

Specific Aim #2: Determine whether treatment with the Mulligan Concept immediately restores or alters dysfunctional gait characteristics and pelvic girdle motor control in women experiencing PPGP.

The timing and amplitude of lumbar and thoracic spine rotations, as well as muscle activity, will be recorded and compared using descriptive statistics. Between groups analysis will consist of descriptive statistics to compare differences in timing, amplitude, and EMG activity after intervention.

Specific Aim #3: Identify intake factors that predict treatment outcome.

Standard multiple regression and step-wise multiple regression will be used to predict treatment outcome from different factors of interest (e.g., number of pregnancies, week of gestation, initial ADQ score, etc.).

Project Timeline

Preparation for participant recruitment will begin July 15th, 2017. Participant recruitment will take place between December 2017 and March 2018. Data collection will take place over 5-6 days in late March 2018. Data Analysis will take place between April and May 2018. Abstract and manuscript development and preparation for publication and presentation will take place through December 2018.

Interim Milestones

The following interim milestones will be used to hold the PI and research team accountable. These milestones will be shared with the research team and overseen by the PI. When appropriate and if a milestone is not met in a timely fashion, guidance will be sought from the Mentor and a plan for re-establishing the project timeline will be established and implemented.

Phase	Milestone	Timeline
Study Start Up	• IRB Approval • Award Announcement • Preparation • Pre-recruitment planning (e.g., creation of media material)	• Prior to March 1, 2017 • May 31, 2017 • July 15- October 1, 2017 • October 1- December 1, 2017
Study Conduct	• Ready to Recruit • Materials completely distributed • 50% Enrollment Achieved • 100% Enrollment Achieved • Data Collection	• December 1, 2017 • January 15, 2018 • February 20, 2018 • March 15, 2018 • Late March, 2018
Study Close-out	• Attendance at Annual Meeting • Publication within 12 months of study close	• May, 2018 • December, 2018

Plans for developing and submitting future grant applications

This grant application marks continued steps toward becoming an independent and successful researcher. The project will enable the PI to further establish her work in patient-care and manual therapy research, where she has had previous experience in relation to core motor control. Additionally, this project will aid in the PI's professional development by establishing University and community collaborations.

Information gathered from this exploratory trial will greatly inform next steps in a long line of research and allows the PI to collect preliminary data and develop evidence for interventions in an underserved population. For example, if the central hypothesis is confirmed, further investigation into the Mulligan Concept as treatment for PPGP in this population is warranted. A larger-scale multi-site randomized control trial with large sample size and more diverse sample would be the next logical step to create more robust evidence of the technique. Once the efficacy of the treatment protocol is established, exploration of a patient-applied treatment as a home program would be developed. If the kinematic, kinetic, pain and dysfunction effects can be well established, continued research would not necessarily focus on the biomechanical mechanisms, but would be more clinical in nature; a full scale clinical trial, focusing on treatment outcome, comorbidity, predictive factors of treatment outcome, risks, and side effects, etc. Future research will not be equipment heavy, but need funding primarily for participant recruitment, clinician training, and researcher salaries. Exploratory/Developmental research grants such as the NIH R21, or multi-site collaborative grants such as the CTR-IN Multi-Site Research Project Program, would be an ideal funding mechanisms for the next stages of this research line.