|  |
| --- |
| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

|  |
| --- |
| In middle age females with chronic pelvic pain are relaxation techniques [yoga, meditation, breathing techniques] better than pelvic floor physical therapy alone in patient reported reduction or management of pelvic pain? |

**AUTHOR**

|  |  |  |  |
| --- | --- | --- | --- |
| **Prepared by** | Abbie Marrale | **Date** | 11/24/15 |
| **Email address** | abbie\_marrale@med.unc.edu | | |

**CLINICAL SCENARIO**

|  |
| --- |
| Through multiple observation opportunities with pelvic floor physical therapists, I have discussed the impact of chronic pelvic pain with many individuals who suffer with this condition. Some of the main functions that chronic pelvic pain can affect are the ability to sit for prolonged period of time and engage in sexual intercourse. Many people are able to find relief for their pain through physical therapy treatments, which often include internal manual therapy and/or biofeedback. However, pelvic floor physical therapy is generally used for a short duration and does not always address the issue of the chronic nature of this condition. Learning about alternative methods that patients can engage in would benefit the patient in being able to contribute to their own pain management and would help clinicians offer more direction to patients on their home plan.  The goal of yoga, meditation, and/or breathing techniques in this situation is to decrease stress1-2, decrease muscle tension2, specifically pelvic floor muscles, and give the individual techniques they can use anywhere. Considering my interest in pelvic floor physical therapy, the aim of this investigation is to determine if learning yoga, meditation, and/or breathing techniques is an effective tool for chronic pelvic pain reduction or pain management. |

**SUMMARY OF SEARCH**

|  |
| --- |
| * Three electronic databases were searched, 10 articles were identified:   + 7 Randomized controlled trials, 1 retrospective chart review, 2 systematic reviews * Evidence from the three highest quality studies shows that:   + Yoga interventions are beneficial in reducing pain and improving function in populations with various musculoskeletal conditions. Yoga is not more beneficial when compared to therapeutic exercise for function. However, pain reports were significantly reduced by yoga interventions when compared with therapeutic exercise.   + Mensendieck somatocognitive therapy (similar to yoga) demonstrates significantly improved functional motor patterns and reduced pain when compared to standard gynaecological treatment. However, this study did not compare Mensendieck therapy to another active control group.   + Women with pelvic girdle pain during the postpartum period demonstrated significantly lower levels of pain and disability following a physical therapy program with stabilization exercises that remained at 2-years follow-up when compared to a physical therapy program that did not include stabilization exercises. * There were no accessible studies[[1]](#footnote-1) that directly studied relaxation techniques and physical therapy intervention for chronic pelvic pain. Studies that included “yoga-like” interventions were included. |

**CLINICAL BOTTOM LINE**

|  |
| --- |
| Current best evidence suggests that yoga, or a similar movement-based therapy, significantly reduced pain in individuals with chronic musculoskeletal conditions, chronic pelvic pain, and pelvic girdle pain. Some research indicates that movement-based therapies, such as yoga, could be more beneficial than therapeutic exercise alone. Physical therapists could utilize these results for chronic pelvic pain reduction techniques, which could be used in conjunction with physical therapy intervention. |

|  |
| --- |
| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

**SEARCH STRATEGY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Female  Women  Pelvic pain  Pelvic-pain  Chronic pelvic pain  Chronic pelvic-pain  Pelvic girdle pain | Relaxation techniques  Yoga  Meditation  Breathing Techniques  Mindfulness | Pelvic Floor Physical Therapy  Pelvic Floor Manual Therapy  Pelvic Floor Rehabilitation  Pelvic Floor Physiotherapy | Pain\*  Reported pain  Pain management  Pain perception |

**Final search strategy:**

|  |  |  |
| --- | --- | --- |
| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **Pubmed** |  |  |
| Search#1: (female OR women) AND (pelvic pain OR chronic pelvic pain OR pelvic girdle pain) | 14292 | N/A |
| Search #2a: (relaxation techniques OR yoga OR meditation OR mindfulness) | 40471 | N/A |
| Search #2b: (relaxation techniques OR yoga OR meditation OR mindfulness OR diaphragmatic breathing) | 46521 | N/A |
| Search #2c: (relaxation techniques OR yoga OR meditation OR mindfulness OR breathing) | 273732 | N/A |
| Search #3: ((physical therapy OR physiotherapy OR rehabilitation OR manual therapy) AND pelvic floor) | 2071 | N/A |
| Search #4: (pain[MeSH Terms] OR "reported pain" OR "pain management" OR "pain perception") | 346047 | N/A |
| Search #5: #1 AND #2a AND #3 AND #4 | 7 | N/A |
| Search #5: #1 AND #2b AND #3 AND #4 | 9 | N/A |
| Search #5: #1 AND #2c AND #3 AND #4 | 11 | N/A |
| Search #6: #1 AND #2 AND #4 | 15 | English |
| Search #6: #1 AND #2b AND #4 | 59 | English |
| Search #6: #1 AND #2c AND #4 | 91 | English |
| Search #7: #1 AND #3 AND #4 | 116 | English |
| Search #7: #1 AND #3 AND #4 | 54 | Clinical Trial  Review  English  Female |
| **CINHAL** |  |  |
| Search #1: (female OR women) AND (pelvic pain OR chronic pelvic pain OR pelvic girdle pain) | 1743 | N/A |
| Search #2: ((physical therapy OR physiotherapy OR rehabilitation OR manual therapy) AND pelvic floor) | 482 | N/A |
| Search #3: (pain\*[MeSH Terms] OR "reported pain" OR "pain management" OR "pain perception") | 11190 | N/A |
| Search #4: (relaxation techniques OR yoga OR meditation OR mindfulness OR breathing) | 21363 | N/A |
| Search #5: #1 AND #2 AND #3 AND #4 | 0 | N/A |
| Search #6: #1 AND #2 AND #4 | 1 | N/A |
| Search #7: #1 AND #2 | 45 | N/A |
| Search #8: #1 AND #3 AND #4 | 1 | N/A |
| Search #9: #1 AND #4 | 19 | N/A |
| **Cochrane** |  |  |
| Search #1: (female OR women) AND (pelvic pain OR chronic pelvic pain OR pelvic girdle pain) | 977 | N/A |
| Search #2: ((physical therapy OR physiotherapy OR rehabilitation OR manual therapy) AND pelvic floor) | 263 | N/A |
| Search #3: (pain OR "reported pain" OR "pain management" OR "pain perception") | 81706 | N/A |
| Search #4: (relaxation techniques OR yoga OR meditation OR mindfulness OR breathing) | 11352 | N/A |
| Search #5: #1 AND #2 AND #4 | 0 | N/A |
| Search #6: #1 AND #2 AND #3 AND #4 | 0 | N/A |
| Search #7: #1 AND #2 | 17 | N/A |
| Search #8: #1 AND #4 | 7 | N/A |

## INCLUSION and EXCLUSION CRITERIA

|  |
| --- |
| **Inclusion Criteria** |
| * Randomized controlled trails * Systematic reviews & Meta-Analyses * Women with chronic pelvic pain, defined as intermittent or constant pain of at least three to six months   + Systematic Reviews for chronic pain due to lack of randomized trials regarding chronic pelvic pain * Pain localized in the abdomen or pelvis, not limited to the period of menstruation or intercourse * Female participants between the ages of 25-50 years of age |
| **Exclusion Criteria** |
| * Trials with pelvic pain due to only endometriosis * Pain due to active chronic pelvic inflammatory disease * Studies involving males or adolescents * Case studies |

**RESULTS OF SEARCH**

**Summary of articles retrieved that met inclusion and exclusion criteria**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Author (Year)** | **Study quality score14-16** | **Level of Evidence17** | **Study design** |
| 1. | Gutke (2010)4 | 7/11 | 2b | Randomized clinical trial |
| 2. | Stuge (2004)5 | 8/11 | 1b | Randomized clinical trial |
| 3. | Sakuma (2012)6 | 8/11 | 1c | Randomized controlled trial |
| 4. | Bedaiwy (2013)7 | 9/29 | 2b | Retrospective chart review |
| 5. | Martins (2014)8 | 7/11 | 2b | Randomized controlled trial |
| 6. | LaCour (2015)9 | 7/11 | 1c | Randomized Controlled intervention study |
| 7. | Haugstad (2006)10 | 7/11 | 1c | Randomized controlled intervention study |
| 8. | Posadzki (2011)11 | 9/11 | 1a | Systematic Review |
| 9. | Carson (2010)12 | 8/11 | 1b | Randomized control study |
| 10. | Ward (2013)13 | 10/11 | 1a | Systematic Review |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

**SUMMARY OF BEST EVIDENCE**

|  |
| --- |
| * Ward L, Stebbings S, Cherkin D, Baxter GD. Yoga for functional ability, pain, and psychological outcomes in musculoskeletal conditions: A systematic review and meta-analysis. Musculoskelet Care. 2013;11:203-217.13   + Though none of the articles reviewed looked at chronic pelvic pain, this systematic review looked at numerous studies of yoga and its effects on different types of chronic pain.   + This was a high quality systematic review and meta-analysis (level 1a) and scored well on quality assessment.   + This review included 17 different studies, with 12/17 studies using some kind of usual care controlled groups, and 12/17 were of good quality * Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. Am J Obstet Gynecol. 2006;194(5):1303-10.10   + Mensendieck Therapy: German movement technique consisting of various movements, where a student learns to consciously relax muscles and release tension. This study did not look at yoga, but had similar components to yoga.   + This study looked at chronic pelvic pain specifically   + Higher-level evidence and scored high on study quality score.   + This study featured a control treatment group (i.e. receiving standard care) * Stuge B, Veirerod MB, Laureum E, Vollestad N. The efficacy of a treatment program focusing on specific stabilizing exercises for pelvic girdle pain after pregnancy: a two-year follow-up of a randomized clinical trial. Spine (Phila Pa 1976). 2004;29(10):E197-203.5   + This article was closest to addressing my PICO question. Although they did not look at yoga, the exercises they performed for the intervention stabilizing exercises are those commonly seen in yoga practice.   + Scored high on level of evidence and study quality score.   + There were a variety of outcomes assess, including pain, QOL, muscle function, and disability. However, looked at lumbopelvic pain, so was not as focused on just pelvic pain. |

**(1) Description and appraisal of Yoga for Functional Ability, Pain and Psychosocial Outcomes in Musculoskeletal Conditions: A Systematic Review and Meta-Analysis by Ward et al13 (2013).**

|  |
| --- |
| **Aim/Objective of the Study/Systematic Review:** |
| The objective of this systematic review/meta-analysis was to determine the effectiveness of yoga on functional ability, pain, and psychosocial outcomes in people with musculoskeletal conditions. This paper also aimed to conduct a conservative meta-analysis on the effects of yoga on pain and functional outcomes in good quality studies. |
| **Study Design** |
| Search Strategy   * Systematic review of multiple databases (20) for relevant randomized controlled trials. Articles were rated for methodological quality and risk of bias. Good-quality articles were included in a conservative meta-analysis. * 20 relevant databases were searched from their inception until December 31, 2011 *[AMED, BioMedCentral, CINAHL, Cochrane Central Register of Controlled Trials, EMBASE, Medline, Google Scholar, IndMED, IJYT, NAHCC, NZ Theses, PEDro, Proquest, Proquest Dissertations and Theses, PsychInfo, PubMed, Science Direct, Scopus, SPORT Discus, Web of Science]* * A senior faculty librarian assisted in the formation of search strategies. They developed database specific search strategies based on the terms ‘yoga’, ‘musculoskeletal’, and ‘random’ combined with the keywords ‘back pain’ and ‘arthritis. A full search strategy was not provided.   Selection Criteria   * Yoga was the primary intervention with no restriction to the type of comparison group, the study just needed to be designed as an RCT. * Participants had clinical diagnosis of a musculoskeletal condition (all types were accepted, however the article included had MSK diagnoses of low back pain, rheumatoid arthritis, osteoarthritis, fibromyalgia, and kyphosis). * Participants were over age 18 * Study was designed as a randomized controlled trial * Article was published in peer reviewed journal * The article was available in full text (authors were contacted when appropriate) * Outcomes measured were not part of selection criteria   Methods   * Two independent reviewers assessed which articles met inclusion criteria, methodological quality, and risk of bias. Disagreements were resolved by consensus. This study adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), assessed methodological quality via the ten-item PEDro and 19-item van Tulder scales, and assessed risk of bias via the seven-domain Cochrane Collaboration tool. Cut-offs for high/low quality and high-risk/low-risk of bias were set at 50% for all scales. * All studies that scored >50% on the van Tulder scale were included in a conservative meta-analysis, except for studies with primary psychosocial outcomes due to the small number of those that met the criteria. Only published data was included in analysis. Statistical cut-offs were as follows:   + Heterogeneity: *priori* level of I2 >50%   + Standard Mean Difference (SMD) less than 0 favoured yoga intervention     - Medium effect size: SMD<-0.50     - Large effect size: SMD <-0.80 |
| **Setting** |
| The 17 eligible studies were conducted between 1994 and 2011 in the USA, India, and the UK. Most studies were conducted in a single outpatient setting with the exception of 2 studies conducted in the residential settings (retreats) and 2 conducted at multiple outpatient settings. |
| **Participants** |
| 17 studies met the inclusion criteria and were included in the systematic review, 8 studies were included in the meta-analysis (only studies with pain and functional outcome primary results). A total number of 1,626 participants were included (studies ranged from 12-313 participants per study) in the systematic review. Participants in the 17 studies were predominantly female (72%), ranged from 23-90 years of age, and consisted of five different musculoskeletal conditions: low back pain (LBP), kyphosis, osteoarthritis (OA), rheumatoid arthritis (RA), and fibromyalgia (FM). Average duration of the musculoskeletal condition was >10 years and had a clinical diagnosis. Overall severity of the pain or condition was generally mild to moderate, with the exception of two studies that examined patients with moderate to severe pain or condition. Eleven studies assessed primary functional outcome, six assessed primary pain outcome, and three studies assessed primary psychosocial outcomes. |
| **Intervention Investigated** |
| *Control (number of studies)* |
| The comparison groups in the 17 studies varied, but included:   * Conventional stretching (k=1) * Physical Therapy Exercise (k=4) * Usual Care/Wait List (k=8) * Education/Self-Care Book (k=4) * Not Reported (k=1) * Social Environment (k=1) |
| *Experimental* |
| The experimental intervention was yoga, but the studies differed in terms of style, frequency and duration of treatment, summarized as follows:   * Styles of yoga included: Iyengar, Hatha, integrated yoga therapy, Viniyoga, integrated approach to yoga therapy, yoga awareness, and style was not reported in two studies * Duration of yoga sessions ranged from 40 minutes to 480 minutes per day. Most studies ranged from 60 minutes to 90 minutes. * Participants had 1-56 hours of yoga per week, with most studies averaging <3 hours of yoga per week. * Frequency ranged from 1 times to 7 times per week. * Intervention duration ranged from 40 days to 24 weeks * 10/17 studies encouraged a home practice in addition to the intervention |
| **Outcome Measures** (Primary and Secondary) |
| This systematic review and meta-analysis chose studies with primary outcome measures for functional outcome, pain, and psychosocial outcomes. This CAP/CAT will focus primarily on the results for the primary pain and functional outcomes.  Pain   * Simple Descriptive Pain Intensity Scale * Visual Analogue Scale: 10 cm scale with MDC of 13 mm & MCID of 30 mm * Numeric Rating Scale   Functional Outcomes   * Fibromyalgia Impact Questionnaire Revised * Functional Reach * Functional Rating Index * Oswestry Disability Index * Roland-Morris Disability Questionnaire * Range of Motion * Short form 36 Health Survey Questionnaire * Straight Leg Raise * Timed Chair Stand * Walking Speed * Pain Disability Index |
| **Main Findings** |
| A meta-analysis of 8 good-quality studies was included for papers looking at pain and functional outcomes. Psychosocial outcomes were not included as not enough good-quality articles were found.  Four studies were included on the meta-analysis of pain, and were found to favour the yoga intervention when compared to the control group as shown by a moderate effect size of -0.61 (95% CI -0.97 to -0.26; p=0.0007). With two two-arm and two three-arm studies, there were four passive control groups and two active control groups and a sub-analysis of the passive control interventions increased the treatment effect to -0.84 (95% CI -1.24 to -0.44; p<0.0001).  All eight studies were included in the meta-analysis of functional outcomes, and included studies on LBP and fibromyalgia. These studies included ten yoga-control group comparisons, with seven passive and three active controls. An overall moderate effect size of -0.64 (95% CI -0.89 to -0.39; p<0.0001) was found for functional outcomes favouring yoga intervention compared to controls. The effect size remained unchanged with sub analysis of passive controls [SMD -0.60 (95% CI -0.76 to -0.43; p<0.0001)], however became non-significant when a sub analysis of active controls was conducted [SMD -0.56 (95% CI -1.37 to 0.24; p=0.17). |
| **Original Authors’ Conclusions** |
| “A conservative analysis of high-quality studies suggests that yoga interventions produce clinically meaningful improvements in pain and functional outcomes across a range of MSCs. This effect of yoga is stronger when yoga is compared with passive rather than active control interventions.” (pg. 214) |
| **Critical Appraisal** |
| **Validity** |
| Ward et al conducted a well-researched, well-conducted systematic review and meta-analysis (level of evidence, Ia). According to the AMSTAR guideline this systematic review scored 10/11 points, missing only assessment of the likelihood of publication bias.  Strengths:  Ward et al created a well thought out search strategy and methods for article evaluation (methodological quality and risk of bias was assessed) and for meta-analysis. *A priori* was conducted and established cut-off scores, measurement plan for heterogeneity of studies, and standard mean difference ranges. The methodological quality of the individual studies was assessed using two separate scores (PEDro and van Tulder scale), and only good quality evidence was included in the meta-analysis. The sensitivity analysis comparing the treatment effects separately for passive controls was also a good feature, I think. Do you agree? It provided additional information about the effect size.  Limitations:  The likelihood of publication bias was not assessed, although studies with no statistically significant effects were included in the paper. The authors included all types of MSK conditions, so treatment effects of specific conditions cannot be ascertained from this analysis. Several studies included in the systematic review and meta-analysis were small pilot studies, which later become larger studies (that were also included in the systematic review and meta-analysis). One other limitation was lack of a third party reviewer to help settle disagreements between the two independent reviewers.  This systematic review and meta-analysis seems to hold up to its validity being critically appraised. It met almost all AMSTAR guidelines, with partial mention of publication bias. *A priori* was performed and clearly stated, and all included studies were held to the pre-determined standards. There were some limitations to this article including a musculoskeletal bias, progressive studies published by the same author, and not having a third party to settle disparities between the independent reviewers. However, the limitations do not offer any large warning of bias. The strengths clearly outweigh the limitations in this review, with the authors not only just having conducted a well organized systematic review and meta-analysis, but also generating a comprehensive article with their results. |
| **Interpretation of Results** |
| This systematic review and meta-analysis found that yoga is an effective method to improve functional outcomes and pain outcomes in participants with chronic musculoskeletal conditions. The review found that individuals with mild to moderate functional status and/or pain saw significant improvements when compared with passive controls, however there were no significant differences between the yoga group and active controls (those receiving a different type of treatment/usual care).  The meta-analysis found a statistically significant, moderate effect size in favour of yoga interventions on pain outcomes for studies compared to both passive and active controls, with only a slight increase in effect size when looking exclusively at passive controls. This slightly challenges the review findings in that active control interventions may have been significantly different than the yoga treatment. There was also a statistically significant moderate effect size in favour of yoga interventions on functional outcomes compared to studies with both passive and active controls. However, a sub-analysis comparing yoga to active controls found the effect size to be no longer significant, indicating that yoga is better than no treatment and on par with other types of treatment.  Based on the critically appraised validity of the article (above) it can be assumed these results are sound, and do not demonstrate large sources of bias. This being said, the meta-analysis indicated heterogeneity of studies making it more difficult to completely accept and generalize the results. A random-effects model was utilized, however this is still a factor to be considered.  Per the predetermined threshold for effect size, a standard mean difference <-0.50 indicated a medium effects size with potential clinical relevance. Indicating that yoga intervention presents a potential clinical relevance for both pain and functional outcomes when compared with both passive and active controls. |

**(2) Description and appraisal of Mensendieck somatocognitive therapy as treatment approach for chronic pelvic pain: Results of a randomized controlled intervention study by Haugstad et al10 (2006).**

|  |
| --- |
| **Aim/Objective of the Study/Systematic Review:** |
| The purpose of this study was to examine whether Mensendieck somatocognitive therapy has beneficial effects on motor behaviour and experienced pain in women with chronic pelvic pain. |
| **Study Design** |
| This study was a randomized controlled intervention trial. Patients were randomized into 1) standard gynaecological treatment or 2) standard gynaecological treatment + Mensendieck somatocognitive therapy groups by drawing a folded piece of paper with the patient’s name from a jar, thereby allocating the name to a previously chosen treatment group. The treatment period was 3 months and outcomes were measured at baseline and at the 3-month mark (90 days) following treatment. Participants were video taped during baseline and 3 month standardized testing (while completing the Mensendieck examination), and evaluations were completed by one Mensendieck physical therapist. The videos were evaluated by a different Mensendieck physical therapist that did not know the allocation of the participants, thus the study was evaluator-blinded. |
| **Setting** |
| Patients were recruited from the gynaecologic outpatient department of a tertiary care university hospital, Rikshospitalet, the National Hospital in Olso, Norway. |
| **Participants** |
| Forty women with chronic pelvic pain were included in the study and randomized into the two treatment groups via pulling a folded piece of paper out of a jar with a name on it and allocating it to a predetermined group. They were recruited from an outpatient gynaecologic department of Rikshospitalet (Oslo, Norway).  Mean age was 33.3 years old with pain duration averaging about 6 years. Each woman had an average of 1 child, and 32% of the women were living alone. Most women had completed high school level education (n=17), only a handful received a college education (n=7), and the rest received only elementary school education (n=15). Commonly reported symptoms were dyspareunia (n=30), dysphoria (n=5), and anxiety (n=7). Other present and former diagnoses in addition to chronic pelvic pain included urinary tract infection (n=7), salgingitis\* (n=17), irritable bowel syndrome (n=10), abdominal surgery (n=8), conditions in legs/low back (n=15), muscle and joint pains (n=17), respiratory tract (n=23), headache/brain disorders (n=7), cardiovascular and endocrinology disorders (n=7), dermatologic conditions (n=2), and lactose or gluten intolerance (n=1).  Per the tables provided in the article, the patients appear to be similar at baseline overall. However, the authors did not conduct a between-group analysis for baseline characteristics. There are some differences between the groups (i.e. college education, high school education, respiratory tract issues, salpingitis), however without analysis it is difficult to determine if these differences are significant or not.  Baseline pain (VAS) was assessed for the control (6.68cm) and treatment (5.60cm) groups. However, between-group analysis was, again, not completed.  \*Inflammation of the fallopian tubes |
| **Intervention Investigated** |
| *Control* |
| The control group received standard gynaecological treatment at baseline and midway through the study. This included oral contraceptive treatment, progestagens, or gonadotropin-releasing hormone analogs if the pain was cyclic, related to endometriosis, or the patient had a history of painful functional cysts. Analgesics were prescribed as necessary and consisted of NSAIDS, acetaminophen, or a combination of the two. Other standard treatment included reducing anxiety, dietary advice, and intercourse advice. |
| *Experimental* |
| The intervention group received the same gynaecological treatment as the controls at baseline and midway through the study. They additionally received 10 treatment sessions with the Mensendieck therapist for 1 hour’s duration over 90 days. The therapist who conducted the sessions was not the same one who evaluated the video, making this a single-blind study. |
| **Outcome Measures** (Primary and Secondary) |
| Primary Outcomes  Motor Function: Each participant completed the Standardized Mensendieck Test,18 which was video taped, at baseline and after the 90-day study. Performance scores were given for posture, gait, movement, sitting posture, and respiration on a scale from 0 to 7, 7 representing optimal function. Each main score had a set of several sub scores. One therapist (not the one who administered the intervention) evaluated the video recordings and provided scores.  Pain was assessed via Visual Analogue Scale (VAS) scores: VAS scores were obtained at baseline, and then they were asked to assess each day during the first week of the study prior to the start of their treatment. The average score of this first week was taken as baseline value. The same procedure was repeated after the 90-day intervention. This scale consists of a 100mm straight lined between 0 and 10, where 0 represents no pain and 10 represents a maximum pain experience. The minimal detectable change is 2 points (or 20mm) for low back pain,19 the minimally clinically important difference for chronic musculoskeletal pain is 1 point (10mm or 15% change)20 and for chronic pain is 1.7 points (17mm or 27.9%).21 Test-retest reliability and internal consistency has been found to be excellent in chronic pain populations.22 |
| **Main Findings** |
| The control group had no significant change in performance scores (final average ± SEM) for posture (4.15 ± 0.14), movement (3.52 ± 0.20), gait (3.74 ± 0.21), sitting posture (3.74 ± 0.21), or respiration (3.35 ± 0.22) after the 3-month intervention. Although it appeared that statistical measures had been run on the motor function, there were no reports of p-value for non-significant results. VAS scores for the control group were not significant from baseline to the end of the 3-month intervention (p=0.07).  The intervention group receiving the Mensendieck somatocognitive therapy had significant changes in all performance scores (final average ± SEM): posture (4.37 ± 0.38; p<0.01), movement (4.30 ± 0.38; p<0.01), gait (4.13 ± 0.39; p<0.01), sitting posture (4.67 ± 0.36; p<0.01), and respiration (4.72 ± 0.37; p<0.01) after the 3-month intervention. VAS scores for the intervention group were significantly different between baseline and the end of the 3-month intervention (p<0.000).  There were no between group assessments done for baseline characteristics, baseline objective measures, or final outcomes. |
| **Original Authors’ Conclusions** |
| The authors concluded that 90-days of Mensendieck therapy significantly improved scores in all subtests, with the best treatment response found in respiration. The control group had no significant changes found in motor function or pain. They stated, “from a point of view of average motor functions, almost total remission of symptoms occurred after 3 months of Mensendieck treatment” (p. 1307). |
| **Critical Appraisal** |
| **Validity** |
| Validity:  This study scored a 7/11 on the PEDro scale. However, some of the points missed were important items and could potentially compromise the effects of this study. It is unknown if groups were similar at baseline as no analysis was conducted. There were also no between-group statistical comparisons reported for any outcome at any time point.  Strengths:  This study was assessor blinded, which strengthened the findings of this study. This was the first study to look at the effects of Mensendieck therapy on chronic pelvic pain. This study also appeared to have retained 100% of its participants.  Weaknesses:  This study did not conduct between group analyses at any point in this study, making many of their findings questionable. There are a few places where the groups may have been statistically different at the beginning of the study, and this is not accounted for. Only one therapist evaluated the films, and as the motor function assessment is subjective in nature it would have been beneficial to have another therapist assessing the videos to improve reliability. This study was a short-term study and was not able to provided data on long-term outcomes. |
| **Interpretation of Results** |
| Considering the severity of the limitations of this study, any truth to the significance of their results has been compromised. Because no between-group analyses were conducted it is difficult to say that Mensendieck therapy was better than standard gynaecological treatment. The VAS analysis, however, did offer some promising results with a nearly 3-point (30 mm) decrease in reported pain for the treatment group, which is well over the MCID. The control group had only a 0.5-point (5 mm) decrease in reported pain. The VAS effect size was not reported, however the control group had a 7.8% reduction in pain compared with the 48.4% reduction in pain for the Mensendieck therapy group.  There were some other concerning aspects about this study that were unrelated to statistical concerns. A power analysis determined that 20 participants per group were needed, and the authors recruited only 40 participants total and did not lose a single participant. It is surprising considering most studies account for potential ‘lost to follow up’ participants, and most studies do lose a few participants. This is very unusual, though possible.  It was also difficult to determine the actual change in motor function considering the measure used was largely subjective. It would have been beneficial to have another, more concrete, functional assessment to compare to the video evaluation.  Finally, the movement scores were assessed by a single evaluator. For an evaluation tool that heavily relies on observation and experience, it would have been beneficial to have at least one other evaluator look and score the videos for increased reliability.  Ultimately, this study offers some promising results. However, there were many large holes in this study that raise questions as to the validity and reliability of this source. There are several concerns that, had they been addressed, would have made this study much more sturdy and believable. The poor quality of this paper makes the “rigorous design” of the study very questionable. |

**(3) Description and appraisal of The Efficacy of a Treatment Program Focusing on Specific Stabilizing Exercises for Pelvic Girdle Pain After Pregnancy: A Two-Year Follow-up of a Randomized Clinical Trial by Stuge et al5 (2004).**

|  |
| --- |
| **Aim/Objective of the Study/Systematic Review:** |
| The aim of this study was to investigate whether the significant differences between the 2-comparison groups one year after delivery persisted at the 2-year follow-up. The authors also wanted to examine whether the women in the group that did not incorporate stabilization exercises had reached a stable condition and whether the improvements in the stabilization exercise group persisted. |
| **Study Design** |
| This was a prospective, randomized, clinical trial with 2 treatment groups and a stratified group design: physical therapy with specific stabilizing exercises and physical therapy without specific stabilizing exercises. Randomization took place after baseline examination was completed and the participant was deemed eligible. A person independent of the study administered pre-coded identical containers to assign the study participants to the intervention groups. |
| **Setting** |
| Unknown location. The original article states that participants were recruited from health practitioners (physicians, midwifes, nurses) following an advertisement to health professionals that gave information about the study and the requirements for participation. It is assumed that this study took place in Oslo, Norway as all the authors are affiliated with universities or medical centres in that area. |
| **Participants** |
| Eighty-one postpartum women with pelvic girdle pain were included for stratified randomization. Forty patients were allocated to the stabilization group and forty-one to the standard PT group. At baseline patients had no significant differences in age (mean age 33 years), weight (mean weight 68 kg), height (mean 167 cm), education (mean 16 years at school), low back pain prior to pregnancy (50%), and regular physical activity (74% of participants). Patients were also similar at baseline regarding the ODI (p=0.16), morning pain (p=0.31), and evening pain (p=0.19). Scores for the SF-36 did not start until the 1-year and 2-year follow-up. |
| **Intervention Investigated** |
| *Control* |
| All patients were treated by 1 of 6 experienced physical therapists over a period of 20 weeks. Individual treatment programs were based on a clinical examination with attention paid to information and coping strategies, body awareness, and ergonomic advice in specific, real-life situations. Patients in the control group received physical therapy methods including massage, relaxation, joint mobilization, manipulation, electrotherapy, hot packs, mobilizing and strengthening exercises. Specific stabilizing exercises were not instructed. |
| *Experimental* |
| All patients were treated by 1 of 6 experienced physical therapists over a period of 20 weeks. Individual treatment programs were based on a clinical examination with attention paid to information and coping strategies, body awareness, and ergonomic advice in specific, real-life situations. However, in the stabilization group, the main focus was exercises and training. The specific stabilizing exercises were base on training of the deep local muscles (transverse abdominus & lumbar multifidus), and training of the superficial, global muscles (gluteus maximus, latissimus dorsi, oblique abdominal muscles, erector spinae, quadratus lumborum, and hip adductors/abductors). Initial focus was on the transverse abdominus, and then was progressed to include all muscle groups. |
| **Outcome Measures** (Primary and Secondary) |
| Primary Outcome  Pain via Visual Analogue Scale (VAS 0-100mm): This scale consists of a 100mm straight lined between 0 and 10, where 0 represents no pain and 10 represents a maximum pain experience. The minimal detectable change is 2 points (or 20mm) for low back pain,19 the minimally clinically important difference for chronic musculoskeletal pain is 1 point (10mm or 15% change)20 and for chronic pain is 1.7 points (17mm or 27.9%).21 Test-retest reliability and internal consistency has been found to be excellent in chronic pain populations.22  Functional Status via Oswestry LBP Disability Questionnaire & Disability Rating Index: This questionnaire consists of 10 items: pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex, social, and travel. Each item consists of six statements correlating to scores of 0 through 5. Scores of 0 indicated the least disability and scores of 5 represent the greatest disability. Total scores range from 0-50 points, with higher scores indicating higher disability level. Minimal detectible change is between 10-15 points, and the minimally clinically important difference is 12.8 points according to one study.23-24  Secondary Outcome  Health-related quality of life via SF-36 Health Survey |
| **Main Findings** |
| The intervention group made significant improvements in ODI scores at 1-year follow up (p<0.001) and in morning/evening pain (p<0.001). These improvements were maintained at 2-years follow-up for the ODI (from baseline p=0.001; change in score from 1-2 years p=0.03), morning pain (from baseline p=0.001; change in score from 1-2 years p=0.18), and evening pain (from baseline p=0.001; change in score from 1-2 years p=0.73). Significant differences in functional status, evening pain, and morning pain between groups were maintained 2-years after delivery (p<0.05). In the control group, statistically and clinically significant improvements were made in functional status at the 2-year follow up (p<0.001), but not for pain intensities (p>0.12). Specifically for the ODI, women in the stabilization group scored an average of 85% (minimal disability) at 2-years compared to 47% (moderate disability) in the control group. |
| **Original Authors’ Conclusions** |
| “The benefits of the specific stabilizing exercise program, previously reported after 1 year,25 persisted at the 2-year follow-up. Disability was still significantly lower in the SSEG [specific stabilization exercise group] than in the CG [control group], and the average pain intensity was much higher in the CG 2 years after delivery than in the SSEG immediately after the intervention period.” (pg. E200) |
| **Critical Appraisal** |
| **Validity** |
| This study scored a 9/11 on the PEDro scale, missing points only for blinding of subjects and blinding of therapists who administered the therapy. Both of the points are nearly impossible to meet in physical therapy intervention studies. This study scores extremely well on validity, and remarkably had returned questionnaires for all 81 participants at the 1-year and 2-year follow-up (however 14 women were excluded at the 2-year follow-up due to subsequent pregnancies, 1 excluded due to hospitalization, and 1 was not willing to fill out questionnaire).  Strengths  This study had a remarkable attrition rate, and was able to collect data on all 81 participants (though 16 were excluded for various reasons at the 2-year follo-up). Additionally, it looks at the long-term effects of a 20-week physical therapy intervention. The comparison group also received treatment, which adds more credibility to results indicating stability exercises being more effective.  Limitations  There was not a non-treatment control group by which to measure the natural progression of recovery following delivery. The 2-year follow-up was questionnaire based, and did not include and element of clinical assessment.  Ultimately, this study scored very well on validity and took appropriate steps to limit potential sources of bias. The overall quality of the study and the article was also high, and the level of evidence was 1b. The questionnaires were an appropriate measure of their primary and secondary outcomes, however it would have been nice to have some clinical-based results as well. This was a high-quality article that looks at both short- and long-term outcomes of a physical therapy program focused on stability for postpartum mothers with pelvic girdle pain. |
| **Interpretation of Results** |
| Based on the high quality of the study and its validity score, the findings appear to be reputable. Per Stuge’s original study,25 a 20-week physical therapy program that focused on stabilizing exercises for postpartum women with pelvic girdle pain demonstrated significant improvements in function and pain measures at 6- and 12-months. The study reviewed looked at the same study population at the 2-year follow-up mark and found that the differences between the stability group and the standard physical therapy group remained at 2-years after the intervention.  The control group did make some gains in both function and pain at the 2-year follow-up, indicating the effects of standard (non-stability based) physical therapy was also beneficial. The control group made significant improvements in functional status at the 2-year mark however made no significant improvements in pain. This study clearly demonstrates that stability exercises are significantly more helpful for functional status and pain at both the 1- and 2-year time points than not incorporating stability exercises. |

**EVIDENCE SYNTHESIS AND IMPLICATIONS**

|  |
| --- |
| The most salient findings turned out to be an eclectic mix of interventions ranging from typical yoga practice to Mensendieck therapy18 (a German therapeutic movement pattern founded in the early 1900’s). The interventions themselves focused on stretching, stabilizing core musculature, posture, and some had a breathing component as well. For individuals with chronic MSK conditions or chronic pain, yoga (and similar movement therapies) was more beneficial than no intervention for functional outcomes.13 However, they were not better than other active interventions including physical therapy exercises, therapeutic exercises, and conventional stretching on functional outcomes.13 Interestingly, yoga and similar movement-based therapies found that yoga significantly decreased pain levels, even when compared to conventional physical therapy.5,13  It appears that the focus of physical therapy intervention plays an important role in both the short- and long-term effects on function and pain.5 Physical therapy intervention that specifically focuses on stability exercises for postpartum women with pelvic girdle pain was more effective in improvements in pain and functional status.5 This is an important consideration when discussing whether yoga or physical therapy is a better intervention technique. Yoga innately focuses on core stability through various postures and moving into and out of those postures. It is possible that yoga may be more beneficial than a physical therapy program that does not incorporate stability exercises, but no better than a physical therapy program that does. However, there is no definitive research on this specific topic at this time. One specifically interesting point from Stuge et al5 was that although both physical therapy groups ultimately made significant gains in functional status at the 2-year follow-up, only the stability group had significant reduction in pain. This agrees with the systematic review/meta-analysis’ findings that yoga interventions, when compared with active controls, had significantly decreased pain levels.13  One caveat to these findings is that much of the research was focused on the effects of physical movement [yoga postures, Mensendieck movement patterns, stabilization exercises] and not on breathing exercises, relaxation techniques, and mindfulness. As many of these movement-base therapies incorporate aspects of these relaxation techniques, it is important to look at the different aspect of movement-based therapies separately [physical & mental aspects]. Mindfulness and meditation have been found to be useful tools for pain management and pain reduction,9 it would be beneficial for additional research focused on the ‘relaxation’ side of yoga and chronic pain management.  Unfortunately, there is not much research on yoga for pelvic pain. Many of the studies focus on musculoskeletal conditions that encompass pelvic pain, but are not specifically focused on pelvic pain. The level of evidence ranges from low to high, with most of the evidence being mid-level quality. There was one pilot study3 that specifically looked at yoga for chronic pelvic pain, however the full article was not accessible. There are many different practices of yoga as well, making it more difficult to generalize the results of ‘yoga’ without knowing the specific type being practiced. More research specifically comparing yoga to physical therapy (specifically pelvic floor physical therapy) in patients with chronic pelvic pain is needed.  In regards to middle age women with chronic pelvic pain, research suggests that yoga and other movement-based therapies may be beneficial in reducing pain. It is not conclusive that this is a better option than physical therapy, however it has been shown that yoga may significantly increase pain reduction. Recommendations based on this literature would suggest that physical therapists recommend yoga in conjunction with, although perhaps not in lieu of, physical therapy treatment for pain management. |

**REFERENCES**

|  |
| --- |
| 1. Nosaka M, Okamura H. A single session of an integrated yoga program as a stress management tool for school employees: comparison of daily practice and nondaily practice of a yoga therapy program. *J Altern Complement Med*. 2015.21(7):444-9. 2. Hassed C. Mind-Body therapies – use in chronic pain management. *Aust Fam Physician*. 2013.42(3).112-7. 3. Fox SD, Flynn E, Allen RH. Mindfulness meditation for women with chronic pelvic pain: a pilot study. *J Reprod Med*. 2011;56(3-4):158-62. 4. Gutke A, Sjodahl J, Oberg B. Specific muscle stabilizing as home exercises for persistent pelvic girdle pain after pregnancy: a randomized, controlled clinical trail. *J Rehabil Med*. 2010;42(10):929-35. doi: 10.2340/16501977-0615. 5. Stuge B, Veirerod MB, Laureum E, Vollestad N. The efficacy of a treatment program focusing on specific stabilizing exercises for pelvic girdle pain after pregnancy: a two-year follow-up of a randomized clinical trial. *Spine (Phila Pa 1976)*. 2004;29(10):E197-203. 6. Sakuma Y, Sasaki-Otomaru A, Ishinda S, et al. Effect of a home-based simple yoga program in child-care workers: a randomized controlled trial. *J Altern Complement Med*. 2012;18)8):769-76. Doi: 10.1089/acm.2011.0080. 7. Bedaiwy MA, Patterson B, Mahajan S. Prevalence of myofascial chronic pain and the effectiveness of pelvic floor physical therapy. *J Reprod Med*. 2013:58(11-12):504-10. 8. Martins RF, Pinto e Silva JL. Treatment of pregnancy-related lumbar and pelvic girdle pain by the yoga method: a randomized controlled study. *J Altern Compliment Med*. 2014;20(1):2-31. Doi:10.1098/acm.2012.0715. 9. la Cour P, Petersen M. Effects of mindfulness meditation on chronic pain: a randomized controlled trial. *Pain Med*. 2015;16(4):641-52. Doi: 10.1111/pme.12605. 10. Haugstad GK, Haugstad TS, Kirste UM, Leganger S, Klemmetsen I, Malt UF. Mensendieck somatocognitive therapy as treatment approach to chronic pelvic pain: results of a randomized controlled intervention study. *Am J Obstet Gynecol*. 2006;194(5):1303-10. 11. Posadzki P, Ernst E, Terry R, Lee MS. Is yoga effective for pain? A systematic review of randomized clinical trials*. Complementary Therapies in Medicine*. 2011;19:281-287. 12. Carson JW, Carson JM, Jones KD, Bennett RM, Wright CL, Mist SD. A pilot randomized controlled trail of the Yoga of Awareness program in the management of fibromyalgia. *Pain*. 2010;151:530-539. 13. Ward L, Stebbings S, Cherkin D, Baxter GD. Yoga for functional ability, pain, and psychological outcomes in musculoskeletal conditions: A systematic review and meta-analysis. *Musculoskelet Care*. 2013;11:203-217. 14. PEDro Physiotherapy Evidence Database. PEDro Scale. <http://www.pedro.org.au/english/downloads/pedro-scale/>. Updated: June 21, 1999. Accesses: November 1, 2015. 15. Shea et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology*. 2007;7:10. doi:10.1186/1471-2288-7-10 16. Downs SH, & Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomized and non-randomized studies of health care interventions. *Journal of Epidemiology Community Health.* 1998;*52*:377-384. 17. CEMB. Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009). Accessed at: <http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/> Accessed on: September 30, 2015. 18. Haugstad GK, Haugstad TS, Kirste U, et al. Reliability and validity of a standardized Mensendieck physiotherapy test (SMT). *Physiother Theory Pract*. 2006;22(4):189-205. 19. Childs JD, Piva SR, et al. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine (Phila Pa 1976).* 2005:30(11): 1331-1334. 20. Salaffi F, Stancati A, et al. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain*. 2004;8(4): 283-291 21. Farrar JT, Young JP Jr., et al. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*. 2001;94(2): 149-158. 22. Rehab Measures Database. Rehab Measures: Numeric Pain Rating Scale. <http://www.rehabmeasures.org/Lists/RehabMeasures/DispForm.aspx?ID=891>. Published: October 30, 2010. Updated: August 29, 2014. Accessed: November 17, 2015. 23. Copay AG, Glassman SD, et al Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and pain scales. *Spine J*. 2008;8(6): 968-974. 24. Rehab Measures Database. Rehab Measures: Oswestry Disability Index. <http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=1114>. Published: 2010. Accessed: November 17, 2015. 25. Stuge B, Lærum E, Kirkesola G, et al. The efficacy of specific stabilizing exercises for pelvic girdle pain after pregnancy. A randomized controlled trial. *Spine*. 2004;29(4):351-9. |

1. One pilot study3 was found that compared meditation and physical therapy for chronic pelvic pain. However, the article could not be received. [↑](#footnote-ref-1)