Hydrotherapy in the management of persistent pelvic pain: A pilot randomised controlled trial

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1. Background

Pelvic pain is estimated to occur in up to 24% of women of both pre and post-menopausal status (1). Many conditions are associated with pelvic pain such as endometriosis, pudendal neuralgia, proctalgia and pelvic floor pain and dysfunction (2). As outlined in the Pelvic Pain Report (2), the $6billion woman refers to the estimated direct cost per annum of medical and surgical treatments for women with endometriosis in Australia. This figure does not include other conditions causing pelvic pain, indirect costs or adolescent girls. A study conducted in Canada highlighted that chronic pelvic pain costs their health care system approximately $25 million per annum in hospital admissions (3). In addition, endometriosis, (i.e. a disorder in which tissue that normally grows within the uterus in found in an abnormal anatomical location outside the uterus), alone causes afflicted women to lose 11 working hours per week in both absenteeism (absent from work due to pain) and presenteeism (working less effectively due to pain) (2).

Patients with pelvic pain of all aetiologies are often referred to physiotherapy for conservative management (4). A comprehensive physiotherapy examination often reveals muscular spasm in varying sites (both internal and external), decreased ability to relax the pelvic floor musculature, elevated resting pelvic floor tone, and pain in the pelvic floor muscles on palpation (5, 6). Physiotherapy has been shown to be successful in the reduction of pelvic pain in up to 59% of cases (7). For example, a study by Eman et al. (8) found that eight weeks of a guided exercise program was effective in decreasing pain and postural abnormalities associated with endometriosis and pelvic pain. Physiotherapy treatment of these symptoms are often multimodal and can include interventions such as pelvic floor relaxation, myofascial release, biofeedback, electrical stimulation, vaginal dilators, and manual therapy techniques, such as deep tissue release of pelvic floor (5-7, 9-12). While individual physiotherapy appointments have been shown to be effective in the management of pelvic pain (5-7, 9-17), they require high resource utilisation, and as such are impacting the ability to manage the growing waitlist for this patient population within the public health sector.

It is hypothesised that hydrotherapy (i.e. targeted exercise in warm water) may assist in decreasing pain for this patient population. Systematic reviews have shown hydrotherapy to be effective in the improvement of pain and function for individuals with chronic pain conditions such as fibromyalgia and osteoarthritis (18-20). Preliminary findings from a feasibility RCT also demonstrated the clinical benefits of hydrotherapy for women with pregnancy-related pelvic girdle pain (21). A comprehensive search of electronic databases (i.e. Pubmed, Medline, and CINAHL) using the search terms (Hydrotherapy OR Baleonotherapy or Aquatic therapy) AND (Pelvic pain OR endometriosis) however revealed no controlled studies investigating the effect of hydrotherapy in a persistent pelvic pain (PPP) population. Therefore, with evidence demonstrating the clinical benefits of hydrotherapy in a general chronic pain population it was considered timely to undertake a controlled clinical trial investigating the effect of hydrotherapy as an additional modality for the physiotherapy management of patients with persistent pelvic pain specifically diagnosed as endometriosis.

2. RESEARCH AIMS & OBJECTIVES:

2.1 TRIAL AIM AND PURPOSE

The primary aim of this research is to investigate whether a course of hydrotherapy, in addition to usual care, improves pain and quality of life in patients with Persistent Pelvic Pain (PPP) due to endometriosis when compared to usual care alone.

Secondary aims will include:

- To evaluate feasibility including patient-related experiences, completion rate, acceptability and satisfaction towards participating in a hydrotherapy program in addition to usual care.
- To evaluate service utilisation by participants and the associated costs (from the perspective of the RBWH Physiotherapy Department) when offering hydrotherapy as an additional treatment intervention.

2.2 HYPOTHESIS

Null Hypothesis: Hydrotherapy in addition to usual care will not have a beneficial effect on pain or quality of life compared to usual care alone for women with PPP due to endometriosis.

2.3 OBJECTIVES

Main Objectives

The primary objective of this research is to investigate whether a course of hydrotherapy in addition to usual care improves pain severity and quality of life in patients with PPP due to endometriosis when compared to usual care alone.

Specific Objectives

Specific Objectives will be to investigate whether this intervention:

- The trial methodology will be feasible with regards to completion rate and acceptability;
- Leads to improvements in health-related quality of life and pain severity that is significantly greater than that achieved by usual care alone;
- Results in high patient satisfaction and acceptability towards participating in the intervention and the clinical outcomes experienced;
- Results in high service utilisation (attendance rates) and completion rates throughout the intervention period; and
- Results in a neutral net financial position (from the perspective of the RBWH Physiotherapy Department) with the addition of the hydrotherapy intervention.

2.4 RESEARCH QUESTION

Does a course of hydrotherapy in addition to usual care improve pain severity and quality of life in patients with persistent pelvic pain due to endometriosis?

3. METHODS:

3.1 STUDY DESIGN

This is a prospective, single blinded pilot randomised controlled trial based on CONSORT guidelines (22) with concealed allocation, blinded assessors and intention to treat analysis. The healthcare professionals involved in providing the treatment interventions cannot be blinded. However, the specific personnel recording the outcome measures will be blinded. however they will not be specifically involved in the collection of outcome measures. Participants will be unable to be blinded to the intervention that they receive. The trial will be registered on the clinical trials website.

3.2 SELECTION OF PARTICIPANTS

Inclusion criteria

Patients included will be female, minimum age 18 years (at the time of study recruitment), have a formal diagnosis of endometriosis following a laparoscopic procedure undertaken at least 6 months prior to study recruitment; and have been referred to the RBWH Physiotherapy Department for management of their PPP condition. Patients will be screened for inclusion criteria at the time of their initial Physiotherapy appointment.

Exclusion criteria

Patients with the following criteria will be excluded from the study:

- General contraindications to hydrotherapy (see attached RBWH Physiotherapy Department Hydrotherapy Referral Form for contraindications)
- Physiotherapy treatment for the same condition within the last 6 months
- Severe psychiatric history where it is judged that safety during hydrotherapy may be compromised
- Non-English speaking background where an accredited interpreter is required to be present
- Concomitant diagnosis of Fibromyalgia
- Unable to commit to the 8-week intervention period
- Post-menopausal (as defined by absence of menses for 12 months without a pathological cause. The average age at which this occurs is 51.4 years) (23)

3.3 ENROLMENT

Patients who appear to fulfil the eligibility criteria will be approached by their RBWH Physiotherapist at the time of their initial appointment with the service to discuss the study. If agreeable, patients will be provided with a Participant Information Sheet (see attached 'Participant Information and Consent Form') providing further details about the study. As part of the screening for eligibility, a subjective examination and history will be taken in the initial appointment. No pelvic floor examination will be performed at this time. The patients will be given time (up to two weeks) to consider participation in the study and return the signed consent form. Once written consent is obtained, the patient will be randomised to one of two groups using sealed opaque envelopes. The researcher involved in the randomisation process will inform the patient to which group they have been assigned.

Patients will be recruited until at least 10 patients are assigned to each cohort. This is expected to take 2 years based on the eligibility criteria, current referral numbers and an anticipated recruitment rate of 50%.

3.4 RANDOMISATON AND GROUP ALLOCATION

Patients will be consented and randomised to one of two groups following their initial Physiotherapy appointment. The randomization sequence will be concealed from consent designee staff.

3.5 INTERVENTION

Control group: The control group will be provided with usual care interventions for those patients referred to the RBWH Physiotherapy Department for PPP due to endometriosis. Referrals are received from various services including the Pain Management Service, Gynaecology, General Practitioners, Urology, Urogynaecology, Colorectal and from other Physiotherapists (both internal and external to the RBWH). Usual care is a multimodal approach where treatment interventions are based on a comprehensive assessment that is undertaken at the time of the patient's initial appointment with the service. A broad overview of the interventions that may be undertaken during a patient's episode of care with the service include:

- Pelvic Floor relaxation exercises
- Visualisation techniques
- Deep Tissue Release of the Pelvic Floor
- Contract – relax techniques
- Avoidance of maximal pelvic floor exercises
- Pressure Biofeedback using devices such as the Peritron Plus or Pelvic Floor Educator
- EMG Biofeedback using devices such as the Neurotrac or Peritone
- Dry needling
- General exercise regimes
- Dietary advice specific to Physiotherapy management of Persistent Pelvic Pain.

Treatment will be provided by Physiotherapists, who as part of their standard clinical role, have the ability and expertise to provide the aforementioned interventions. Participants will be asked to attend individual outpatient appointments once a fortnight for 8 weeks.

Intervention group: In addition to usual care, the participants will be invited to attend a group-based, weekly hydrotherapy class supervised by a Physiotherapist.

All hydrotherapy sessions will be a maximum of one hour in duration, however participants will be asked to allow for 1.5 to 2 hours for each session to include transport and preparation time. All hydrotherapy sessions will take place within the Physiotherapy Department at the RBWH. The structure of the hydrotherapy sessions will include a warm up, targeted exercises and cool down sections. Slight modifications to the specific exercise regime will be based on the patient's clinical presentation and abilities (see attached 'Hydrotherapy Exercise Program' document).

As per standard practice within the RBWH Physiotherapy Department, patients will be cleared for safe exercise in water prior to consenting to the study (see attached 'RBWH Physiotherapy Department Hydrotherapy Referral Form'). Participants who miss a session during their 8-week period will not be offered make up sessions after the 8-week period has elapsed.

Regardless of intervention group, intervention time period for both cohorts will be a total eight weeks in duration. After the 8-week intervention period, patients will continue to be offered standard care by the RBWH Physiotherapy Department.

3.6 OUTCOME MEASURES

Demographic Information: The following demographic data will be collected for all participants: date of birth, duration of PPP symptoms, recent management, urinary function, anorectal function, vaginal symptoms, sexual symptoms, medical history including other uro-gynaecological comorbidities, menopausal status, obstetric history, surgical history (including date of endometriosis laparoscopic surgery), social history including employment status,

usual exercise or sport. All information will be collected from the 'Physiotherapy Pelvic Pain Assessment' form (see attached) which is completed as per standard practice at the time of the patient's initial

.

Clinical Outcome Measures:

Outcome measures to be recorded to address the primary aim of the study will include the pain Visual Analogue Scale (VAS), the Pelvic Pain Impact Questionnaire (PPIQ), EQ-5D-5L and the Australian Pelvic Floor Questionnaire (APFQ). These measures will be collected by a blinded assessor at baseline and the 8-week follow-up (see attached 'Patient Questionnaires' document).

The Pain Visual Analogue Scale (VAS) is a validated, subjective measurement instrument that measures perceived pain (24-26). It consists of a straight line with the endpoints defining extreme limits such as "no pain at all" and "pain as bad as it could be". Scores are recorded by making a handwritten mark on a 100mm line on this continuum.

The EQ-5D-5L is a health questionnaire covering 5 health parameters (mobility, personal care, usual activities, pain/discomfort, and anxiety/depression. It also includes a 100-point sliding scale for participants to rate their self-perception of their health on the day. The EQ-5D-5L has been validated in a diverse array of clinical populations (27-29).

The PPIQ is a ten-question validated tool that measures the life impact of pelvic pain in women. It is simple to administer and has strong utility for detecting a treatment response. It is specific for pelvic pain conditions and identifies the impact of pelvic pain specific aspects of life such as problems with sitting, tight clothing, gastrointestinal function and intimacy (30).

Date of last menopausal period will also be collected at the time of completing these questionnaires, as there is evidence to support the influence of the menstrual cycle on pain sensitivity for women presenting with PPP (31).

In addition to these clinical outcomes, the Australian Pelvic Floor Questionnaire (APFQ) will also be completed. This validated self-reported questionnaire (32) assess all pelvic floor symptoms including bladder, bowel and sexual function and prolapse symptoms, and condition-specific quality of life. Completion of this questionnaire is standard practice for women referred to the RBWH Physiotherapy Department with PPP (see attached 'APFQ' document).

Patient Satisfaction: A study specific survey has been developed for each cohort to evaluate patients' experience and satisfaction towards the intervention that they received. A subset of questions will be identical between the two cohorts, while addition questions directly related to the hydrotherapy intervention have been included in the survey to be completed by those women assigned to the intervention group. Patients will be invited to complete this survey following completion of the intervention period. This survey should take less than 5 minutes to complete. Patients will be able to complete the survey via an electronic or paper format.

Service Utilisation and Cost Analysis: The number of appointments scheduled during the 8-week intervention period (both individual land-based and group-based hydrotherapy) will be recorded for participants in both cohorts.

Costs to deliver physiotherapy services for both cohorts will also be calculated based upon service utilisation data. Direct labour costs (+25% on-costs) will be calculated based upon time spent by clinical (i.e. physiotherapists, and Allied Health Assistants) and administrative staff and multiplied by their appointed wage rates. All other additional non-labour costs associated with service delivery will also be collected. Service revenue will be calculated by using

the weighted activity unit prices associated with the Independent Hospital Pricing Authority Tier 2 Physiotherapy (40.09) and Hydrotherapy (40.05) codes for FY19-20.

3.7 SAMPLE SIZE AND STATISTICAL ANALYSIS:

Sample Size:

As this clinical trial is a pilot study, a power analysis has not been completed. Instead recruitment into the study will stop once a minimum of ten participants have been assigned to each cohort. Results from this study will then be used in variance estimates for estimation of a sample size in a definitive study.

Data Analysis:

Analysis would initially consist of a baseline comparison for demographic and clinical variables. Due to the small sample size, group-by-time interactions for the primary outcomes of interest (i.e. Pain VAS, PPIQ and EQ-5D-5L) will be analysed using non-parametric statistics (e.g. Friedman test), while within-group differences over time will be analysed using Wilcoxon signed-rank tests.

Patient-related experience and satisfaction surveys will be presented descriptively where identical items between the two cohorts will be compared using Mann-Whitney U tests.

Service utilisation between the intervention groups will be compared descriptively. The net financial position of each intervention group will be calculated based upon the total estimated revenue (attracted through attended appointments) less total estimated costs (through direct labour and non-labour expenses) incurred during the intervention period.

4. CONSIDERATIONS:

4.1 PREVENTION OF BIAS:

Bias in the randomisation process has been minimised by using concealed allocation in opaque envelopes and selection by an independent researcher who is separated at a distance from the clinicians providing the physiotherapy programs in each group. This randomisation will occur after written consent has been obtained. Due to the nature of the study, blinding of the participants or clinicians providing the intervention cannot be achieved. However, all participant outcome measures will be collected by a blinded assessor. Baseline characteristics that may confound the outcome will be measured and any differences adjusted for statistically in testing the primary outcome.

4.2 RESOURCE CONSIDERATIONS:

It is anticipated that the RBWH Physiotherapy Department will be able to accommodate the usual care provided to both cohorts as these patients would currently be seen as part of standard clinical practice.

Weekly hydrotherapy classes will be in addition to standard care as this is not a current service provided by the department (for this specific patient population). In-kind support has been sought to cover the costs of additional labour resources required to provide the hydrotherapy classes. Completion of outcome measures will be undertaken by a member of the research team as part of their role within the Physiotherapy Department.

4.3 CONCOMITANT TREATMENT DURING TRIAL PERIOD:

Participants from either group will be free to undertake concomitant treatment (from other healthcare professions) throughout the intervention time period. If a participant shows signs or symptoms of deterioration in their condition that does not improve with standard physiotherapy management techniques explained within this

study, they will be appropriately referred to suitable healthcare professions (e.g. General Practitioner, Gynaecologist, etc.) as part standard clinical practice. This will be documented in the patients' medical record and a note will be completed in the participant's case report file at that time point.

5. WITHDRAWAL OF STUDY TREATMENT

In accordance with the Declaration of Helsinki, each subject has the right to withdraw from the study at any time. An investigator also has the right to withdraw subjects from the study in the event of intercurrent illness, adverse events or other reasons concerning the health or well-being of the subject. The investigator also has the right to withdraw subjects in the case of lack of compliance.

Following patient consent, all efforts will be made to keep the participant in the trial. The participant may withdraw from the study if they decide to do so, at any time, irrespective of the reason, or this may be the investigator's decision. Should a subject decide to withdraw all efforts will be made to complete and report the observations up to the time of withdrawal as thoroughly as possible. The reason for withdrawal will be recorded in the participant's case report file (CRF). All treatment discontinuation should also be recorded by the investigator in the patient's medical notes.

The reason, date, and time for withdrawal must be noted on the CRF.

5.1 MANAGEMENT OF PATIENTS FOR WHOM STUDY TREATMENT HAS BEEN WITHDRAWN

Patients withdrawn from either intervention group for any reason will be offered follow up individually by a treating physiotherapist as part of routine clinical practice.
A withdrawal of participation form (see attached documentation) will be completed if a patient withdraws from the study, including whether consent for data collection is withdrawn.

If withdrawn from the study the patient will continue to be offered standard management and care, i.e. referral to the Physiotherapy Department as clinically indicated. At no time will participating in, or withdrawing from, this study impact on any relationship the patient has within Queensland Health.

6. MONITORING

Regular team meetings will be held with the research team. Investigators will review study progress at these meetings, address pertinent issues and identify further actions to be taken. The principal investigator will ensure via this regular review process that data is managed appropriately (i.e. stored in a de-identified fashion) and that appropriate steps are taken for data cleansing and dissemination of results.

7. STUDY TERMINATION

The study may be terminated at any time at the request of the study investigator, or a regulatory authority. Reasons for termination or suspension should be given. Otherwise, the study will continue until completion of all patient treatments and evaluations, data analysis, dissemination of results, and a Final Report is submitted to the Human Research Ethics Committee (HREC).

8. ETHICAL CONSIDERATIONS

8.1 HUMAN RESEARCH ETHICS COMMITTEES

This study will be submitted using a Human Research Ethics Application (HREA) via the Ethics Review Manager to:

1. Royal Brisbane and Women's Hospital

8.2 ETHICAL CONSIDERATIONS

Patients with persistent pelvic pain conditions are routinely referred to the RBWH Physiotherapy Department for assessment and management of symptoms. Standard care will not be altered but it patients consent to participant they may be randomly allocated to receive weekly, group-based hydrotherapy in addition to their standard care (which involves individual land-based outpatient appointments).

All efforts will be made to ensure confidentiality for patients in either group. All outcome assessments will be conducted in a closed office environment with the blinded assessor. Standard physiotherapy outpatient appointments ('usual care') will take place in a closed consult room to maintain privacy due to the sensitive nature of the interventions that are undertaken.

If participants show signs or symptoms of deterioration in their condition that do not improve with standard physiotherapy management techniques explained within this study, they will be appropriately referred to suitable healthcare professions (e.g. General Practitioner, Gynaecologist, etc.) as part standard clinical practice. This will be documented in the patients' medical record and a note will be completed in the participant's case report file at that time point.

8.3 INFORMED CONSENT

Participants will initially be referred to the RBWH Physiotherapy Department for assessment and treatment of their persistent pelvic pain condition and should be capable of understanding the information provided.

Eligibility criteria will be applied to all patients at the time of their initial assessment with the RBWH Physiotherapy Department, and if the patient meets the eligibility criteria, the investigator will discuss the project with the patient. The patient will be invited to participate in the study and will have the opportunity to ask questions about the study. Upon verbal consent, the patient will be provided with the Participant Information Sheet and Consent Form.

The Consent form will be completed, signed and personally dated by the patient. A copy of this document will be provided to the patient for their own records.

9. DATA MANAGEMENT

Upon entering the research project, each participant will be assigned a unique de-identified participant code (blinded to the intervention group the participant has been assigned to). An electronic, password-locked Master File will be created that matches participants' names to their unique code to ensure accuracy of data collection is maintained throughout the project. All hard-copy information and data collection pertaining to each individual (specifically in relation to this research project) will be stored in individually marked (with unique code) manila folders that will be kept within a locked filing cabinet of a security-access office (Physiotherapy Department, RBWH). All electronic files containing participant data will be kept on a secure network within the PI's research team (Physiotherapy Department, RBWH, where only members of the research team will be able to access its contents.

Upon completion of the project, all data (both hard and electronic) will be stored for a minimum of 15 years as per recommended NHMRC guidelines (33). After such time, all hard-copy documents will be professionally shredded, while electronic copies permanently deleted.

10. DISSEMINATION OF RESULTS

The results from this pilot trial will be presented at appropriate conferences and published in journals and/or newsletters. Additionally, results obtained from this study will be used to inform change of practice internally at the RBWH and plan a larger, definitive trial.

11. SIGNIFICANCE

This pilot trial will prove to be highly significant, pending its results, as it is the first study of this kind to investigate the effectiveness of hydrotherapy on both pain and quality of life for women presenting with PPP. Outcomes from this trial will be used to plan for a much larger clinic trial that will be adequately powered in order to determine the definitive impact of hydrotherapy as a treatment modality for this patient population. In addition, these results may support a more efficient way of managing this patient population which then has the potential to change national and international practice. This is especially significant considering the burden of disease as pelvic pain occurs in 24% of women of both pre and post-menopausal status (1).

12. REFERENCES

1. Daniels JP, Khan KS. Chronic pelvic pain in women. BMJ. 2010;341:c4834.
2. The $6Billion Woman and the $600 Million Girl: The Pelvic Pain Report 2011 [Available from: https://www.pelvicpain.org.au/wp-content/uploads/2018/11/Pelvic-Pain-Report-rfs.pdf.
3. Chen I, Thavorn K, Shen M, Goddard Y, Yong P, Macrae GS, et al. Hospital-associated Costs of Chronic Pelvic Pain in Canada: A Population-based Descriptive Study. Journal of Obstetrics and Gynaecology Canada. 2017;39(3):174-80.
4. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Chronic Pelvic Pain. Victoria: RANZCOG; 2017.
5. Gentilcore-Saulnier E, McLean L, Goldfinger C, Pukall CF, Chamberlain S. Pelvic Floor Muscle Assessment Outcomes in Women With and Without Provoked Vestibulodynia and the Impact of a Physical Therapy Program. The Journal of Sexual Medicine. 2010;7(2):1003-22.
6. Hartmann D, Sarton J. Chronic pelvic floor dysfunction. Best Practice & Research Clinical Obstetrics & Gynaecology. 2014;28(7):977-90.
7. Fitzgerald MP, Payne CK, Lukacz ES, Yang CC, Peters KM, Chai TC, et al. Randomized Multicenter Clinical Trial of Myofascial Physical Therapy in Women With Interstitial Cystitis/Painful Bladder Syndrome and Pelvic Floor Tenderness. The Journal of Urology. 2012;187(6):2113-8.
8. Awad E, Ahmed HAH, Yousef A, Abbas R. Efficacy of exercise on pelvic pain and posture associated with endometriosis: within subject design. J Phys Ther Sci. 2017;29(12):2112-5.
9. Loving S, Nordling J, Jaszczak P, Thomsen T. Does evidence support physiotherapy management of adult female chronic pelvic pain? A systematic review. Scandinavian Journal of Pain. 2012;3(2):70-81.
10. Fitzgerald MP, Anderson RU, Potts J, Payne CK, Peters KM, Clemens JQ, et al. Randomized Multicenter Feasibility Trial of Myofascial Physical Therapy for the Treatment of Urological Chronic Pelvic Pain Syndromes. The Journal of Urology. 2013;189(1):S75-S85.
11. Chiarioni G, Nardo A, Vantini I, Romito A, Whitehead WE. Biofeedback Is Superior to Electrogalvanic Stimulation and Massage for Treatment of Levator Ani Syndrome. Gastroenterology. 2010;138(4):1321-9.
12. Bergeron S, Brown C, Lord M-J, Oala M, Binik YM, Khalifé S. Physical Therapy for Vulvar Vestibulitis Syndrome: A Retrospective Study. Journal of Sex & Marital Therapy. 2002;28(3):183-92.
13. Berghmans B. Physiotherapy for pelvic pain and female sexual dysfunction: an untapped resource. International urogynecology journal. 2018;29(5):631-8.
14. Bond JP, H & Ayre, C. Efficacy of a therapeutic wand in addition to physiotherapy for treating bladder pain syndrome in women: a pilot randomized controlled trial. Journal of Obstetrics and Gynaecology. 2017(120):12-27.
15. Hartmann D, Nelson C. The perceived effectiveness of physical therapy treatment on women complaining of chronic vulvar pain and diagnosed with either vulvar vestibulitis syndrome or dysesthetic vulvodynia2001. 13-8 p.

16. Morihisa R, Eskew J, McNamara A, Young J. DRY NEEDLING IN SUBJECTS WITH MUSCULAR TRIGGER POINTS IN THE LOWER QUARTER: A SYSTEMATIC REVIEW. International journal of sports physical therapy. 2016;11(1):1.
17. Rajkannan P, Vijayaraghavan R. Dry needling in chronic abdominal wall pain of uncertain origin. Journal of Bodywork & Movement Therapies. 2019;23(1):94-8.
18. Bartels EM, Juhl CB, Christensen R, Hagen KB, Danneskiold - Samsøe B, Dagfinrud H, et al. Aquatic exercise for the treatment of knee and hip osteoarthritis. 2016.
19. Bidonde J, Busch A, Webber S, Schachter C, Danyliw A, Overend T, et al. Aquatic Exercise Training For Fibromyalgia: A Systematic Review. Arthritis Rheum. 2013;65(s10):S896-S.
20. Shi Z, Zhou H, Lu L, Pan B, Wei Z, Yao X, et al. Aquatic Exercises in the Treatment of Low Back Pain: A Systematic Review of the Literature and Meta-Analysis of Eight Studies. American Journal of Physical Medicine & Rehabilitation. 2018;97(2):116-22.
21. Scott K, Hellawell M. Effects of water-and land-based exercise programmes on women experiencing pregnancy-related pelvic girdle pain: a randomized controlled feasibility study. Journal of Pelvic, Obstetric and Gynaecological Physiotherapy. 2018;122:21-9.
22. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
23. Santoro LN, Brockwell BS, Johnston DJ, Crawford AS, Gold AE, Harlow AS, et al. Helping midlife women predict the onset of the final menses: SWAN, the Study of Women's Health Across the Nation. Menopause. 2007;14(3):415-24.
24. Baillie L. A review of pain assessment tools. Nursing standard (Royal College of Nursing (Great Britain) : 1987). 1993;7(23):25-9.
25. Ho K, Spence J, Murphy MF. Review of Pain-Measurement Tools. Annals of Emergency Medicine. 1996;27(4):427-32.
26. Price DD, McGrath AP, Rafii AA, Buckingham AB. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain. 1983;17(1):45-56.
27. Janssen M, Pickard A, Golicki D, Gudex C, Niewada M, Scalone L, et al. Measurement properties of the EQ-5D-5L compared to the EQ-5D-3L across eight patient groups: a multi-country study. An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation - Official Journal of the International Society of Quality of Life Research. 2013;22(7):1717-27.
28. Conner-Spady B, Marshall D, Bohm E, Dunbar M, Loucks L, Khudairy A, et al. Reliability and validity of the EQ-5D-5L compared to the EQ-5D-3L in patients with osteoarthritis referred for hip and knee replacement. An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation - Official Journal of the International Society of Quality of Life Research. 2015;24(7):1775-84.
29. Golicki D, Niewada M, Buczek J, Karlińska A, Kobayashi A, Janssen M, et al. Validity of EQ-5D-5L in stroke. An International Journal of Quality of Life Aspects of Treatment, Care and Rehabilitation - Official Journal of the International Society of Quality of Life Research. 2015;24(4):845-50.
30. Chalmers JK, Catley JM, Evans FS, Moseley LG. Clinical assessment of the impact of pelvic pain on women. PAIN. 2017;158(3):498-504.
31. Hellström B, Anderberg UM. Pain Perception across the Menstrual Cycle Phases in Women with Chronic Pain. Perceptual and Motor Skills. 2003;96(1):201-11.
32. Baessler K, O'Neill SM, Maher C, Battistutta D. A validated self-administered female pelvic floor questionnaire. International Urogyneacology Journal. 2010;21(2):163-72.
33. National Health and Medical Research Council. Australian Code for the Responsible Conduct of Research Canberra: Australian Government; 2007 [Available from: https://www.nhmrc.gov.au/_files_nhmrc/file/publications/r39_australian_code_responsible_conduct_research_150811.pdf.