

POGP CONFERENCE 2016

Korean hand acupuncture for pregnancy-related pelvic girdle pain: a feasibility study

C. Clarkson

Department of Sport, Exercise and Rehabilitation, Northumbria University, Newcastle upon Tyne, UK

Abstract

Despite approximately 20% of all pregnant women developing pregnancy-related pelvic girdle pain (PPGP), very little literature has been published on interventional strategies, and there is a dearth of UK-based studies. Of the interventions that have been investigated to date, acupuncture has yielded some promising findings, although the effects of Korean hand acupuncture on PPGP remain unclear. In line with the UK Medical Research Council framework for complex interventions, any potential treatment should be subjected to feasibility testing prior to a definitive randomized controlled trial (RCT). This three-phase feasibility study followed a mixed-methods paradigm, which was underpinned by pragmatism, and found that a definitive RCT would be feasible.

Keywords: feasibility study, Korean hand acupuncture, pregnancy-related pelvic girdle pain.

Introduction

Pregnancy-related pelvic girdle pain (PPGP) is a condition that affects between 10% (Brown & Johnston 2013) and 84% (Bastiaanssen *et al.* 2005) of expectant women, although a recent Cochrane Review by Pennick & Liddle (2013) suggested that its prevalence is likely to be around 20%. The following definition of PPGP (Vleeming *et al.* 2008, p. 797) is consistently put forward:

“Pelvic girdle pain generally arises in relation to pregnancy, trauma, arthritis and osteoarthritis. Pain is experienced between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the SIJ [sacroiliac joint]. The pain may radiate in the posterior thigh and can also occur in conjunction with/ or separately in the symphysis.”

However, this description is devoid of any psychosocial context; it actually refers to PGP in any population and is not specific to pregnancy. Östgaard *et al.* (1994) argued that PPGP should be considered to be a separate entity from low back pain in pregnancy after they found that

clinical tests could be performed to differentiate the two conditions. In a systematic review, Wu *et al.* (2004) stated that there is enough evidence to support the separation of low back pain in pregnancy and PPGP in research terms, although they acknowledged that both can, and often do, appear to be synonymous.

According to the literature, PPGP produces pain (Wu *et al.* 2004) and restricts activities of daily living (Röst *et al.* 2004). In addition, researchers have discussed the impact of this condition on quality of life (Elden *et al.* 2013), fear (Fredriksen *et al.* 2008) and social interactions (Elden *et al.* 2013). It would also seem that PPGP can continue after pregnancy, and therefore, have a further impact upon women and behave like a chronic condition (Stuge *et al.* 2004). This provides a strong rationale for not only investigating PPGP in terms of how it affects women in the UK, but also exploring avenues for potential treatment. Pham (2014) put forward the notion of overcaution in pregnancy by researchers, clinicians and patients, which stemmed from serious adverse events that occurred because of drug trials in the 1950s and 1960s. This has culminated in a general reluctance to research interventions for pregnancy-related conditions in general, and more specifically, PPGP.

A recent systematic review by Clarkson *et al.* (2015) indicated that it is safe to administer

Correspondence: Dr Carl Clarkson, Senior Lecturer in Physiotherapy, Department of Sport, Exercise and Rehabilitation, Northumbria University, Coach Lane Campus, Coach Lane, Benton, Newcastle upon Tyne NE7 7XA, UK (e-mail: carl.clarkson@northumbria.ac.uk).

acupuncture during pregnancy. Overall, it was found that the reporting of adverse events was poor on several counts. Of the 25 studies identified as being eligible for inclusion, only 17 remained in the final analysis because the other eight did not mention adverse events at all. Bearing in mind the poor quality of reporting, the trend for adverse event occurrence was very similar in the penetrating acupuncture and non-penetrating intervention groups, and the adverse events that did occur were largely minor and transient (Clarkson *et al.* 2015). This lends credibility to investigating the use of acupuncture in pregnancy, but decisions on treatment should not be made outside of the context of its potential benefits. Several studies have investigated the effectiveness acupuncture for PPGP.

Acupuncture for pregnancy-related pelvic girdle pain

With its probable origins being in ancient China, acupuncture has been administered as a treatment for a host of conditions for over 2000 years (Hopwood 2004). Although the technique can utilize many forms, it is defined as “piercing of the skin with a fine needle” (Röschke *et al.* 2000, p. 73). The traditional Chinese medicine (TCM) approach is the one that is most commonly used, and this involves clinicians needling acupoints, which are found throughout the body. In TCM practice, these acupoints are thought to be located on meridians, and are needled when a person suffers from pain or ill health. Pennick & Liddle (2013) and Gutke *et al.* (2015) recognized acupuncture as an approach with a promising evidence base for PPGP. Although researchers such as Wedenberg *et al.* (2000) and Guerreiro da Silva (2004) have found acupuncture to be effective when compared to a control, their work lacked sufficient methodological quality to form a basis clinical practice. Higher-quality studies by Elden *et al.* (2005, 2008) and Wang *et al.* (2009) have also yielded promising results.

Additionally, the type of acupuncture that is best suited to the management of PPGP has yet to be established. Authors such as Elden *et al.* (2008) opted for a body acupuncture approach, while Wang *et al.* (2009) used auricular acupuncture. Since PPGP would seem to be aggravated by moving from static positions (Stuge *et al.* 2011), further investigation into non-body acupuncture methods are warranted. Korean hand acupuncture (KHA) is one such approach that has found

favour with many acupuncturists world-wide (Kim *et al.* 2005). It is based on the theory that each hand represents 14 “micro-meridians”, and therefore, each body acupuncture point used in TCM can be found and represented as an acupoint on the hand (Yoo 2001). Korean hand acupuncture is an intervention that has not yet been investigated in a population of pregnant women, and therefore, the present author advocated researching its potential as a treatment for women with PPGP.

Rationale for a feasibility study

To date, there have been no published UK studies specifically investigating the impact of KHA on PPGP, and thus, the need for further high-quality research that can be applied to this population is required. The Medical Research Council (MRC) framework (Craig *et al.* 2008) highlights that evaluations of complex health interventions are often undermined by poor compliance, delivery of the intervention, recruitment and retention, and smaller-than-expected sample sizes, all of which can be measured by first performing a feasibility study. The MRC put forward a “development–evaluation–implementation process” (Craig *et al.* 2008, p. 4), which suggested that a complex intervention should be subjected to numerous tests on its journey from development to implementation. These are:

- (1) development;
- (2) feasibility/piloting;
- (3) evaluation; and
- (4) implementation.

Study design

The present study adopted a three-phase, mixed-methods research (MMR) design, in which the author was the chief investigator (CI) and data collector, and conducted the analysis. Although advocated by authors as early as the 1970s, MMR is a relatively new practice that has only become an established approach to scientific investigation in the past 10 years (Creswell & Plano Clark 2011). Creswell & Plano Clark (2011, p. 21) argued that MMR “provides the most complete analysis of problems” because of the limitations brought about by analysing numbers or words independently of each other. Verhoef *et al.* (2005) discussed treatments, such as acupuncture, that deal with “whole systems”, a concept that considers the whole effect that a treatment may have, as opposed to very specific effects on one area of the body. They advocated the MMR approach because

of the inadequacies of pure quantitative approaches, which are reductionist in nature, and therefore, unable to assess treatment effects in total (Verhoef *et al.* 2005). Bishop & Holmes (2013) stated that MMR approaches complement the strengths of both the qualitative and quantitative aspects of research. Despite the call for further MMR work, Bishop & Holmes (2013) recognized that research in complementary and alternative medicine is still overwhelming dominated by quantitative approaches. These account for 84% of articles published in the top 10 journals in the field, as opposed to MMR, which is only represented by 4% of publications.

Philosophical context

Pragmatism is most frequently adopted as a philosophical argument for MMR because it is inclusive of all types of knowledge generation. Pragmatism, as defined by Morgan (2014, p. 26), is “a philosophy in which the meaning of actions and beliefs are found in their consequences”. In essence, all actions and interactions that a human being has, and will ever have, impact upon every subsequent or future decision and experience. Creswell (2014) proposed that every experience, no matter how small, will influence a decision made in some way. The more times that an individual has very similar experiences that produce very similar outcomes, the more that person develops a sense of the predictability of any future outcome, which pragmatists call warranted beliefs (Morgan 2014). Put another way, constantly changing warranted beliefs are created as understanding changes, producing an overarching warranted belief about the research process and/or condition being researched. This can then be extended to the likely process that all researchers go through to ensure that they arrive at meaningful conclusions to their research, and is perhaps reflective of the MRC framework for complex interventions.

Ethics

Approval was sought and granted by the Faculty of Health and Life Sciences Research Ethics Review Panel of Northumbria University, Newcastle upon Tyne, UK, on 24 October 2013 (reference number: RE-HLS-12-130701-51d1815248c3f). It was then passed for ethical approval by the Newcastle and North Tyneside 1 National Research Ethics Service Committee, which was given on 7 April 2014 (reference number: 14/NE/0060).

Participants and methods

Phase 1

The aim of the first phase of the feasibility study was to gain an understanding of PPGP, as experienced by women in the UK.

Eight, one-to-one semi-structured interviews with eight women with PPGP explored stakeholder's views about the condition. This purely qualitative study was conducted in a women's health physiotherapy clinic in the North East of England, and the interviews lasted for approximately 1 h. An interview schedule was produced to help guide the interviewer, and in accordance with the suggestion of Rubin & Rubin (1995), there were both main and probing questions. The main questions were global and open-ended, and were designed to allow individuals to discuss their own views of their experience of PPGP (Liamputtong 2009). All questions had neutral wording, as suggested by Turner (2010), which was integrated to help avoid asking leading questions (Liamputtong 2009). The probing questions were included to help gain further insight or obtain an optimal response (Turner 2010). According to Rubin & Rubin (1995), these discussions would be considered as being conducted in a topical interview style because the questioner is looking for specific facts and descriptions of what it is like to have PPGP. Field notes were taken, but these were written after the interview in an attempt to make the interview more qualitative and less clinical. All interviews were audiotaped and then transcribed verbatim before the data were thematically analysed.

Phase 2

The aim of this phase was to develop a believable non-penetrating KHA (NPKHA) approach in a non-pregnant population of women.

A two-group, between- and within-subjects design to measure the believability of a novel NPKHA approach was adopted. Twenty non-pregnant, healthy women were randomized to either penetrating KHA (PKHA) or NPKHA. Participants were blinded to PKHA and NPKHA via blindfolds.

Based on Sherman *et al.* (2004), the outcome measure within this study included a Likert-type item that ranged from “definitely received PKHA” to “definitely did not receive PKHA”. This was followed by an open-ended question (“Why do you think you have/have not received Korean hand acupuncture?”) in order to identify if there were any factors that could blind/unblind

the participant to the group to which they had been allocated. This was completed immediately after the 30-min KHA session, and again 1 week later. This 1-week remeasurement was completed via e-mail. Demographic and adverse event data were also collected.

For the present study, both procedures, i.e. toothpick and needling, replicated common practice for how KHA is delivered, and the protocol used followed that of Sherman *et al.* (2004). The CI gave the same explanation of what to expect to both groups in order to try to control for his input being an influencing factor. The NPKHA procedure involved participants in long sitting on a treatment plinth, with blindfolds placed on them by the CI and confirmation given that the woman was unable to see.

As per standard practice, the CI held the skin taut around each KHA point, and placed a standard KHA needle guide tube containing a toothpick against the skin. Next, he tapped the toothpick, and then quickly withdrew both the toothpick and guide tube. The participant remained on the plinth for 30 min to simulate the period that KHA needles are typically left *in situ*. Finally, to simulate withdrawal of a needle, the CI tightly stretched the skin around each KHA point, pressed a cotton ball firmly on the stretched skin, then momentarily touched the skin with a toothpick (without a guide tube), and finally, pulled the toothpick away quickly using the same hand movements employed in regular needle withdrawal. A sticking plaster was placed over the area of pricking, which the participant was asked to keep *in situ* for 24 h. She completed the believability outcome measure immediately after the 30-min session, and repeated the outcome measure via e-mail 1 week later.

The PKHA group underwent the same procedure, but in this case, needles replaced the toothpicks and remained *in situ* for 30 min. The introduction of the sticking plaster over areas that had received NPKHA or PKHA was an attempt to maintain the blinding of the latter group. The CI considered that it would be possible for the PKHA group to realize that needles had been inserted if needle marks were observed.

Phase 3

The aim of the final phase was to develop and implement a study investigating the practicalities of delivering KHA for PPGP.

This was a three-armed randomized controlled feasibility study that involved: (1) a control group (standard physiotherapy, SP); (2) an

SP plus NPKHA group; and an SP plus PKHA group (comparable to Wang *et al.* 2009). For SP, all participants were given stability exercises and advice. At the physiotherapist's discretion, participants were offered hydrotherapy, a pelvic belt, walking aids and/or manual therapy. The KHA approaches adopted in this phase were the same as described in phase 2; however, these were administered in six sessions over an 8-week period. The study design was later modified to include only the SP plus NPKHA and SP plus PKHA groups because of recruitment and randomization issues.

Potential participants were eligible to enrol if they were: considered to have PRPGP fitting Vleeming *et al.*'s (2008) definition; positive for the posterior pelvic pain provocation, active straight leg raise, pelvis palpation and Patrick's Flexion, Abduction and External Rotation tests; not contraindicated for physiotherapy or acupuncture; and undergoing a singleton pregnancy and within the second-to-third trimester period. Information pertaining to the acceptability and feasibility of the study design, demographic data, pain intensity, and activities of daily living were all collected using the Pelvic Girdle Questionnaire (PGQ).

Results

In phase 1, several similarities were found with existing qualitative studies in terms of information provision, the importance of support networks and the symptoms experienced. However, the findings produced during this phase demonstrate originality because it: is the first UK-based exploration of the views of women with PPGP; provides information about their expectations of treatment; is the first study to adopt a pragmatic philosophy of views about PPGP, as expressed via the PGQ; and is the first exploration of views about PPGP by a male lead author. Although this can be considered as a standalone study, it also informed the study outlined in phase 3.

In phase 2, the results supported the PKHA/NPKHA procedure that had been developed, and indicated that the PKHA and NPKHA were as believable as each another. This study was the first to investigate the believability of an NPKHA approach, and contributed directly to the intervention adopted in phase 3.

Finally, the phase 3 findings indicated that a three-armed study that included an SP-only group was not feasible, but a two-armed study

comparing PKHA to NPKHA was. This study produced an original contribution to research through being the first KHA study written in English about a pregnancy-related condition, the first study in English to compare PKHA and NPKHA, and the first study in the UK to utilize the PGQ as an outcome measure for PPGP.

Discussion

Several studies exist that have investigated acupuncture for PPGP. However, most either score low on the Physiotherapy Evidence Database (PEDro) quality scale (Gutke *et al.* 2015), or examine effects over a short time frame (Wang *et al.* 2009). Elden *et al.*'s (2005, 2008) studies are considered more robust experiments, and thus, lead a Cochrane Review by Pennick & Liddle (2013) to stipulate that acupuncture could be a useful intervention for PPGP. In addition, best practice is yet to be established, with Elden *et al.* (2005, 2008) opting for body acupuncture styles, whereas Wang *et al.* (2009) utilized a micro-meridian approach. The use of a micro-meridian system, such as KHA, that does not require the participant to remain in a static position may prove to be beneficial to those suffering from PPGP. However, higher-quality work is needed (Pennick & Liddle 2013), and UK-based research investigating KHA for PPGP is currently absent.

The MMR approach adopted in the present study demonstrated how quantitative and qualitative research can work in tandem. Importantly, it was observed that the studies investigating the feasibility of KHA, which were primarily quantitative, also collected qualitative data that helped to provide a context for and a better understanding of the effects observed. This feasibility study has demonstrated that a future definitive RCT that aimed to investigate the effect of KHA on PPGP would be both acceptable and feasible.

References

Bastiaanssen J. M., de Bie R. A., Bastiaenen C. H. G., *et al.* (2005) Etiology and prognosis of pregnancy-related pelvic girdle pain; design of a longitudinal study. *BMC Public Health* **5**: 1. DOI: 10.1186/1471-2458-5-1.

Bishop F. L. & Holmes M. M. (2013) Mixed methods in CAM research: a systematic review of studies published in 2012. *Evidence-Based Complementary and Alternative Medicine* **2013**: 187365. DOI: 10.1155/2013/187365.

Brown A. & Johnston R. (2013) Maternal experience of musculoskeletal pain during pregnancy and birth outcomes: significance of lower back and pelvic pain. *Midwifery* **29** (12), 1346–1351.

Clarkson C. E., O'Mahony D. & Jones D. E. (2015) Adverse event reporting in studies of penetrating acupuncture during pregnancy: a systematic review. *Acta Obstetrica et Gynecologica Scandinavica* **94** (5), 453–464.

Craig P., Dieppe P., Macintyre S., *et al.* (2008) *Developing and Evaluating Complex Interventions: New Guidance*. [WWW document.] URL <https://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/>

Creswell J. W. (2014) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*, 4th edn. SAGE Publications, Thousand Oaks, CA.

Creswell J. W. & Plano Clark V. L. (2011) *Designing and Conducting Mixed Methods Research*, 2nd edn. SAGE Publications, Thousand Oaks, CA.

Elden H., Ladfors L., Olsen M. F., Östgaard H.-C. & Hagberg H. (2005) Effects of acupuncture and stabilising exercises as adjunct to standard treatment in pregnant women with pelvic girdle pain: randomised single blind controlled trial. *BMJ* **330** (7494): 761. DOI: <http://dx.doi.org/10.1136/bmj.38397.507014.E0>.

Elden H., Fagevik-Olsen M., Östgaard H.-C., Stener-Victorin E. & Hagberg H. (2008) Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: randomised double-blinded controlled trial comparing acupuncture with non-penetrating sham acupuncture. *BJOG: An International Journal of Obstetrics and Gynaecology* **115** (13), 1655–1668.

Elden H., Lundgren I. & Robertson E. (2013) Life's pregnant pause of pain: pregnant women's experience of pelvic girdle pain related to daily life: a Swedish interview study. *Sexual and Reproductive Healthcare* **4** (1), 29–34.

Fredriksen E. H., Moland K. M. & Sundby J. (2008) "Listen to your body": a qualitative text analysis of internet discussions related to pregnancy health and pelvic girdle pain in pregnancy. *Patient Education and Counselling* **73** (2), 294–299.

Guerreiro da Silva J. B., Nakamura M. U., Cordeiro J. A. & Kulay L., Jr (2004) Acupuncture for low back pain in pregnancy – a prospective, quasi-randomised, controlled study. *Acupuncture in Medicine* **22** (2), 60–67.

Gutke A., Betten C., Degerskär K., Pousette S. & Olsén M. F. (2015) Treatments for pregnancy-related lumbopelvic pain: a systematic review of physiotherapy modalities. *Acta Obstetrica et Gynecologica Scandinavica* **94** (11), 1156–1167.

Hopwood V. (2004) *Acupuncture in Physiotherapy*. Butterworth–Heinemann, Oxford.

Kim Y.-S., Jun H., Chae Y., *et al.* (2005) The practice of Korean medicine: an overview of clinical trials in acupuncture. *Evidence-Based Complementary and Alternative Medicine* **2** (3), 325–352.

Liamputtong P. (2009) *Qualitative Research Methods*, 3rd edn. Oxford University Press, Oxford.

Morgan D. L. (2014) *Integrating Qualitative and Quantitative Methods: A Pragmatic Approach*. SAGE Publications, Thousand Oaks, CA.

Östgaard H.-C., Zetherström G., Roos-Hansson E. & Svanberg B. (1994) Reduction of back and posterior pelvic pain in pregnancy. *Spine* **19** (8), 894–900.

Pennick V. & Liddle S. D. (2013) Interventions for preventing and treating pelvic and back pain in pregnancy. *Cochrane Database of Systematic Reviews*, Issue 8. Art. No.: CD001139. DOI: 10.1002/14651858.CD001139.pub3.

- Pham D. (2014) Ethical, legal, and regulatory issues regarding the study and use of medications in pregnant women. *Journal of Commercial Biotechnology* **20** (3), 23–30.
- Röschke J., Wolf Ch., Müller M. J., *et al.* (2000) The benefit from whole body acupuncture in major depression. *Journal of Affective Disorders* **57** (1–3), 73–81.
- Röst C. C. M., Jacqueline J., Kaiser A., Verhagen A. P. & Koes B. W. (2004) Pelvic pain during pregnancy: a descriptive study of signs and symptoms of 870 patients in primary care. *Spine* **29** (22), 2567–2572.
- Rubin H. J. & Rubin I. S. (1995) *Qualitative Interviewing: The Art of Hearing Data*. SAGE Publications, Thousand Oaks, CA.
- Rubin H. J. & Rubin I. S. (2012) *Qualitative Interviewing: The Art of Hearing Data*, 3rd edn. SAGE Publications, Thousand Oaks, CA.
- Sherman K. J., Hogeboom C. J., Cherkin D. C. & Deyo R. A. (2004) Description and validation of a non-invasive placebo acupuncture procedure. *The Journal of Alternative and Complementary Medicine* **8** (1), 11–19.
- Stuge B., Lærum E., Kirkesola G. & Vøllestad N. (2004) The efficacy of a treatment program focusing on specific stabilizing exercises for pelvic girdle pain after pregnancy: a randomized controlled trial. *Spine* **29** (4), 351–359.
- Stuge B., Garratt A., Krogstad Jenssen H. & Grotle M. (2011) The Pelvic Girdle Questionnaire: a condition-specific instrument for assessing activity limitations and symptoms in people with pelvic girdle pain. *Physical Therapy* **91** (7), 1096–1108.
- Turner D. W., III (2010) Qualitative interview design: a practical guide for novice investigators. *The Qualitative Report* **15** (3), 754–760.
- Verhoef M. J., Lewith G., Ritenbaugh C., *et al.* (2005) Complementary and alternative medicine whole systems research: beyond identification of inadequacies of the RCT. *Complementary Therapies in Medicine* **13** (3), 206–212.
- Vleeming A., Albert H. B., Östgaard H.-C., Sturesson B. & Stuge B. (2008) European guidelines for the diagnosis and treatment of pelvic girdle pain. *European Spine Journal* **17** (6), 794–819.
- Wang S.-M., DeZinno P., Lin E. C., *et al.* (2009) Auricular acupuncture as a treatment for pregnant women who have low back and posterior pelvic pain: a pilot study. *American Journal of Obstetrics and Gynecology* **201** (3), 271.e1–271.e9.
- Wedenberg K., Moen B. & Norling Å. (2000) A prospective randomized study comparing acupuncture with physiotherapy for low-back and pelvic pain in pregnancy. *Acta Obstetrica et Gynecologica Scandinavica* **79** (5), 331–335.
- Wu W. H., Meijer O. G., Uegaki K., *et al.* (2004) Pregnancy-related pelvic girdle pain (PPP), I: terminology, clinical presentation, and prevalence. *European Spine Journal* **13** (7), 575–589.
- Yin C., Seo B., Park H.-J., *et al.* (2007) Acupuncture, a promising adjunctive therapy for essential hypertension: a double-blind, randomized, controlled trial. *Neurological Research* **29** (Suppl. 1), S98–S103.
- Yoo T.-W. (2001) *Koryo Sooji Chim: Koryo Hand Acupuncture*. Eum Yang Mek Jin Publishing, Seoul.

Carl Clarkson qualified as a physiotherapist in 2004, and has practised in both the National Health Service and private sectors. He completed a Master's degree in acupuncture and a Postgraduate Certificate in Education in 2010, and has since worked as a physiotherapy lecturer at Northumbria University and taught postgraduate acupuncture courses internationally. Carl co-authored a systematic review on the reporting of adverse events in studies of acupuncture during pregnancy (Clarkson et al. 2015). His doctoral research investigated PRPGP within an MMR framework, and he continues to work with women's health clinicians in practice-based research. This paper is based on his doctoral thesis.