**Abstract**

Despite Pregnancy related Pelvic Girdle Pain (PPGP) developing in approximately 20% of all pregnant women, there are currently very few studies that have investigated interventional strategies, with a dearth of UK based studies. Of extant interventions investigated to date, acupuncture studies have shown some promising findings, although the effects of Korean Hand Acupuncture (and Hand KHA) on PPGP remain unclear. In line with the Medical Research Council (MRC) framework for complex interventions, any potential treatment should be subjected to feasibility testing prior to a definitive RCT. This three phase feasibility study followed a mixed methods paradigm underpinned by pragmatism, and found a definitive RCT to be feasible.

**Introduction**

Pregnancy related pelvic girdle pain (PPGP) is a condition which affects between 10% (Brown and Johnston, 2013) and 84% (Bastiaanssen *et al.* 2005) of pregnant women, although a recent Cochrane review by Pennick and Liddle (2013) suggested its prevalence is likely to be around 20%. The Vleeming *et al.* (2008, p.797) definition of PPGP is consistently put forward, and reads: ‘…(it) generally arises in relation to pregnancy, trauma and/or osteoarthritis. The pain can be located anywhere around the pelvic girdle, more specifically around the posterior iliac crest and gluteal folds, and/or radiating to the posterior thigh and to include pain around the symphysis’. However, this is devoid of any psychosocial context, and actually refers to pelvic girdle pain (PGP) in any population, not specific to pregnancy. Osgaard *et al.* (1994) put forward an argument for PPGP to be considered as a separate entity to low back pain in pregnancy (LBPp), after they found clinical tests could be performed to differentiate between the two. Wu *et al.* (2004), in their systematic review, considered that there is enough evidence to support the separation of LBPp and PPGP in research terms, although they acknowledge that both can, and often do, appear synonymously.

It would appear from existing literature that PPGP produces pain (Wu *et al.* 2004) and restriction to activities of daily living (ADL) (Rost *et al.* 2004). In addition, researchers have discussed the impact of PPGP on quality of life (Elden, Lundgren and Robertson, 2013), fear (Fredriksen, Moland and Sunby, 2008) and social interactions (Elden, Lundgren and Robertson, 2013). It would also seem that PPGP can remain post pregnancy, impacting upon the woman and behaving as a chronic condition (Stuge *et al.* 2004). This provides a strong rationale to investigate PPGP, not only in terms of how it affects the PPGP sufferer in the UK, but to also explore avenues for potential treatment. Pham (2014) put forward the notion of over caution in pregnancy by researchers, clinicians and patients, stemming from serious adverse events that occurred from drug trials in the 1950’s and 1960’s. This has culminated in a general reluctance, and therefore paucity, of research for interventions treating pregnancy related conditions, and more specifically, PPGP.

A recent systematic review by Clarkson, O’Mahony and Jones(2015) indicated that acupuncture is safe to administer during pregnancy. Overall, it was found adverse event reporting to be poor on several counts. Out of the 25 studies identified as being eligible, 17 remained in the final analysis due to eight not mentioning adverse events at all. Taking into account the poor quality of reporting, the trend for adverse event occurrence was very similar in penetrating acupuncture and non-penetrating intervention groups, and the adverse events that did occur were largely minor and transient (Clarkson, O’Mahony and Jones, 2015). This lends credibility to investigating acupuncture in pregnancy, but decisions on treatment should not be made outside of the context of potential benefits, with several studies investigating acupuncture effectiveness for PPGP.

**Acupuncture for PPGP**

For over 2000 years, acupuncture has been administered as a treatment for a host of conditions, with its origins likely from ancient China (Hopwood, 2004). Although acupuncture can adopt many forms, it is defined as “piercing of the skin with a fine needle” (Roschke *et al.* 2000, p.73). The Traditional Chinese Medicine (TCM) approach is the most commonly used, with clinicians needling acupoints which are found throughout the body. These acupoints are thought, in TCM practice, to be located on meridians, and are needled when a person has pain or ill health. Pennick and Liddle (2013) and Gutke *et al.* (2015) recognised acupuncture as an approach with a promising evidence base for PPGP. Although researchers such as Wedenberg, Moen and Norling (2000) and Da Silva *et al.* (2004) have found acupuncture to be effective when compared to a control group, they lacked sufficient methodological quality upon which to base clinical practice. Higher quality studies by Elden *et al.* (2005), Elden *et al.* (2008) and Wang *et al.* (2009) have also yielded promising results.

Additionally, the type of acupuncture best suited to PPGP management is yet to be established, with authors such as Elden *et al.* (2008) opting for a body acupuncture approach, whereas Wang *et al.* (2009) used an auricular acupuncture approach. As 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, and has found favour with many acupuncturists worldwide (Kim *et al.* 2005). It works 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 been investigated within a pregnant population, and thus advocated its investigation within a PPGP population.

**Rationale for a Feasibility Study**

To date, there have been no published studies specifically investigating the impact of KHA upon PPGP which have been conducted in the UK, and thus the need for further high quality research that can be applied to the UK population is required. The MRC framework (Craig *et al.* 2008) highlights that evaluation 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 adopting a feasibility study. The MRC put forward a ‘development-evaluation-implementation process’ (Craig *et al.*, 2008), suggesting that a complex intervention should be subjected to numerous testing on its journey from development to implementation. These are:

1. Development
2. Feasibility/piloting
3. Evaluation
4. Implementation

**Study Design**

This study adopted a three phase, mixed methods research (MMR) design, in which the lead author was the Chief Investigator (CI), the data collector and conducted the analysis. Mixed methods research, although advocated by authors as early as the 1970’s, is a relatively new method/methodology that has only in the last 10 years become an established approach to scientific investigation (Creswell and Plano Clark, 2011). Creswell and Plano Clark(2011) put forward that mixed methods “provides the most complete analysis of problems”, due to the limitations that analysing numbers or words independently of each other provides. Verhoef *et al.* (2005) discussed treatments, such as acupuncture, that deal with ‘whole systems’, a concept that considers the whole effect a treatment may have as opposed to very specific effects to one area of the body. They advocate the MMR approach due to the inadequacies of pure quantitative approaches being reductionist in nature, therefore not being able to assess treatment effects in total (Vernhoef *et al.* 2005). Bishop and Holmes (2013) state that mixed method approaches complement the strengths of both the qualitative and quantitative aspects of research. Despite the call for further mixed methods work, Bishop and Holmes (2013) identify that research in complementary and alternative medicine is still overwhelming dominated by quantitative approaches, accounting for 84% of published articles in the top ten CAM journal as opposed to 4% MMR.

**Philosophical context**

Pragmatism is most frequently adopted as a philosophical standpoint for MMR, due to it being 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 has, and will ever have, impact upon every subsequent or future decision and experience. Cresswell(2014) puts forward that every experience, no matter how small, will influence a decision made in some way. The more times the individual has a very similar experience producing a very similar outcome, the person develops a sense of 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 on the research process and/or condition being researched. This can then be extended to the likely process that all researchers go through to ensure they arrive at meaningful conclusions to their research, and is perhaps reflective of the MRC framework for complex interventions.

**Ethics**

Approval was been sought and granted by the Faculty of Health and Life Sciences Research Ethics Review Panel 24th October, 2013, ref. number: RE-HLS-12-130701-51d1815248c3f. It was then passed for ethical approval via Newcastle and North Tyneside 1 NRES Committee 2.4.2014, reference number 14/NE/0060, 7th April 2014.

**Methods**

**Phase 1**

**Aim**

To gain an understanding of PPGP as experienced by women in the UK

Eight one-to-one semi-structured interviews with eight PPGP sufferers, explored stakeholder’s views on PPGP and was a purely qualitative study. This was conducted in a women’s health physiotherapy clinic in the north East of England, with interviews lasting approximately one hour. An interview schedule was produced to help guide the interviewer, and in accordance with the suggestion of Rubin and Rubin (1995), there were main and probing questions. The main questions were global and open ended, 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 there to help gain further insight, or to help obtain an optimal response (Turner, 2010). According to Rubin and Rubin (1995), these interviews would be considered a topical interview style, as the interviewer is looking for specific facts and descriptions of what it is like to have PPGP. Field notes were taken, however written after the interview to attempt to make the interview more qualitative and less clinical. All interviews were audio recorded the transcribed verbatim, before applying thematic analysis to the data.

**Phase 2**

The aims of this phase were to develop a believable npKHA approach in a non-pregnant, female population

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

Based upon Sherman *et al*. (2002), the outcome measure within this study included a Likert type item that ranged from ‘definitely received penetrating KHA’ to ‘definitely did not receive penetrating KHA’. This was followed by an open ended question ‘Why do you think you have/have not received Korean Hand Acupuncture?’, to identify if there were any factors that could blind/unblind the participant to the group they had been allocated to. This was completed immediately after the KHA session of 30 minutes, and again one week post penetrating/non-penetrating KHA session. This one-week re-measurement was completed via email. Demographic and adverse event data was also collected.

Procedure

For this study, both procedures, toothpick and needling, replicated common practice of how KHA is delivered, with the protocol used following that of Sherman *et al.* (2002). The CI gave the same explanation to both groups of what to expect, to try and control for the investigator’s input being an influencing factor. The npKHA procedure involved participants in long sitting on a treatment plinth, with blindfolds placed upon them by the CI and confirmation given that the participant was unable to see.

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

The pKHA group had the same procedure, only the needles replaced the toothpick, with the needles staying in situ for 30 minutes. The introduction of the sticky plaster over areas that had received npKHA/pKHA was an attempt to prevent from un-blinding the penetrating group; it was considered possible by the CI that the pKHA group could realise that needles had been inserted if needle marks were observed.

**Phase 3**

To develop and implement a study investigating the practicalities of delivering KHA for PPGP.

This was a three armed randomised controlled feasibility study, including a control group (standard physiotherapy, SP), a SP plus npKHA group, and a SP plus pKHA group (comparable to Wang *et al.,* (2009)). For standard physiotherapy, all participants were given stability exercises and advice. At the physiotherapists 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 they were administered in six sessions over an eight-week period. The study design was later modified to include only the SP plus npKHA and SP plus pKHA due to recruitment and randomisation issues. A potential participant was eligible to enroll if they: were considered to have PPGP fitting Vleeming *et al.*’s (2008) definition; positive tests on P4, ASLR, pelvis palpation and FABERs; not contraindicated to physiotherapy or acupuncture; had a singleton pregnancy and were within the 2nd-3rd trimester. Information pertaining to the acceptability and feasibility of the study design, demographic data, pain intensity, ADL’s via the PGQ were all collected.

**Findings**

In phase 1, there were a number of similarities with existing qualitative studies, such as information provision, importance of support networks and symptoms experienced. However, the findings produced from this phase demonstrate originality through it being the first UK based exploration of PPGP sufferer’s views, providing discussion around interviewee’s expectations of treatment, being the first to adopt a pragmatic philosophy in PPGP views, expressing views of PPGP sufferers upon the Pelvic Girdle Questionnaire (PGQ), and being the first exploration of views on PPGP by a male lead author. Although it 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 one 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 which included a 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 in English for a pregnancy related condition, the first to compare pKHA and npKHA in any English written study, and the first study in the UK to utilise the PGQ as an outcome measure for PPGP.

**Discussion**

A number of studies exist that have investigated acupuncture for PPGP. However, most either record low on quality scores via PEDro (Gutke *et al*. 2015), or have looked at effects over a short time frame (Wang *et al.* 2009). Elden *et al.* (2005) and Elden *et al.* (2008) are considered more robust experiments, and thus lead a Cochrane review by Pennick and Liddle (2013) to stipulate that acupuncture could be a useful intervention for PPGP. In addition, the method of best practice is yet to be established, with Elden *et al.* (2005) and Elden *et al.* (2008) opting for body acupuncture styles, whereas Wang *et al.* (2009) opted for 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 PPGP sufferers. However, higher quality work is needed (Pennick and Liddle, 2013), and UK based research investigating KHA for PPGP is absent.

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

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