

KHA for PPGP: A Feasibility Study




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In the beginning




<http://imgur.com/gallery/wAvgM>



Pregnancy related Pelvic Girdle Pain (PPGP)

- ▶ On review of the Literature:
 - ▶ What is it?
 - ▶ Exact aetiology unknown
 - ▶ Presents as pain in the pelvic region
 - ▶ Distinct entity, though related to PLBP (Ostgaard *et al.*, 1994; Wu *et al.* 2004)
 - ▶ Definition largely in the **biomedical** context
 - ▶ Prevalence
 - ▶ Range from **10%** (Brown and Johnston, 2013) - **84%** (Bastiaanssen *et al.* 2005), though most rigorous work suggests **20%** (Albert, Godskesen and Westergaard, 2002).
 - ▶ Reporting more apparent in Scandinavian countries



Review of the Literature cont..

- How to deal with it?
 - Medication remains a taboo (Pham, 2014)
 - Weak to moderate evidence to support physiotherapeutic interventions (Gutke *et al.* 2015)
 - Moderate – strong evidence to support Pelvic belts, and acupuncture (Gutke *et al.* 2015)
 - Recent systematic review highlights safety of acupuncture (Clarkson, O'Mahony and Jones, 2015)
- And yet....
 - Very little UK based research into PPGP
 - Very little research into micro system acupuncture

Therefore....

- ▶ Korean Hand Acupuncture for PPGP: A Feasibility Study
 - ▶ Three phases, influenced by the MRC guidelines for complex interventions:
 - ▶ Aim 1: Exploration of PPGP sufferers views
 - ▶ Aim 2: Develop a non penetrating form of KHA
 - ▶ Aim 3: Develop and implement a feasibility study investigating KHA for PPGP
 - ▶ Mixed Methods Methodology with a Pragmatic Philosophical underpinning





Why Mixed Methods?

- ▶ Lack of patient voice in the UK
 - ▶ Pure Quant often fails to gather rich, clinically relevant info
- ▶ Qual alone will not provide adequate, timely assessment of KHA effectiveness
- ▶ MRC guidelines and expert opinion in acupuncture recommend Mixed Methods
- ▶ Provides a broader scholarship than one method alone



Aim 1: Exploration of views

- 8 semi structured, one to one interviews
- Thematic analysis with Pragmatic philosophical standpoint
- 4 researcher developed themes:
 - Reality of PPGP
 - Knowledge is Power
 - Vulnerability
 - Support mechanisms
- In summary, findings support current Scandinavian Qual lit whilst producing an original contribution to knowledge

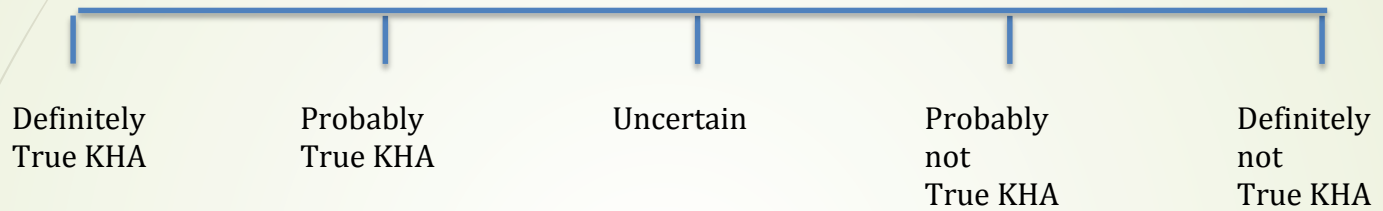


Aim 2: Development of non penetrating KHA

- ▶ Spanned across two phases;
 - ▶ First, 20 non pregnant female students randomised to penetrating KHA (pKHA) or non penetrating KHA (npKHA)
 - ▶ Second, Feasibility study of 40 PPGP sufferers, randomised to pKHA or npKHA
- ▶ Assessment of believability via a 5 point likert type item and qualitative comments, in both phases
 - ▶ Non pregnant at baseline and 1 week post KHA
 - ▶ PPGP at initial, 3rd and 6th (final) KHA session

Aim 2 findings

Non pregnant population



- **npKHA** no difference between baseline and 1 week (median remained at 2.5; IQR 1-5)
- **pKHA** no difference between baseline and 1 week (median remained at 2; IQR 1-4)
- **Qual data** provided insight into factors that influenced believability, and informed PPGP study:

Local needle sensation

Non needle sensations

Lasting symptoms

Needle marks

Sounds associated with treatment



Aim 3: Feasibility for KHA within PPGP population

- ▶ Conducted over 16 months in a women's health NHS clinic
- ▶ Two armed randomised, usual care controlled study
- ▶ 40 participants completed study
 - ▶ 20 in pKHA, 20 in npKHA
- ▶ Measured
 - ▶ Acceptability
 - ▶ Recruitment

Aim 3 findings: Recruitment

► Recruitment

- 16 month period on a part time basis
- 59 recruited, 40 completed
 - Numbers completed comparable / better than existing studies when adjusted for time dedicated to study
 - Drop outs high (32%), though comparable to population DNA frequency (34%)
 - Reasons for drop out were practicalities of getting to venue / getting childcare, gave birth, or felt unwell after session (n=1)

Aim 3 findings: Acceptability

- Clinicians

- Post study discussion highlighted value added to service

- Participants

- Zero serious adverse events reported

amount of women included in sample	total amount of sessions of penetrating KHA	amount of women effected by at least one adverse event	total amount of transient adverse events that occurred (% of sessions an event occurred in)	total amount of serious adverse events
24 (4 being drop outs)	136	23	76 (56%)	0 (zero)
35 (15 being drop outs)	145	1	2 (1.3%)	0 (zero)

- End of study questionnaire revealed 90% of pKHA would seek it again

Aim 3 findings: Trends in outcomes, NRS

➤ NRS at present


Time point	Median		IQR	
	pKHA	npKHA	pKHA	npKHA
Baseline	5	5	3-6	4-7
Mid point	4	6	2-6	5-7
Final point	3.5	6	2-6	4-7

Time point	Median		IQR	
	pKHA	npKHA	pKHA	npKHA
Baseline	6	7	5-7	6-8
Mid point	4.5	8	3-7	5-8
Final point	4.5	7	3-7	4-8

➤ NRS over previous week

Aim 3 findings: Trends in outcomes, PGQ

Time point	Median		IQR	
	pKHA	npKHA	pKHA	npKHA
Baseline	41	42	29-52	33-54
Mid point	37	42	21-48	31-56
Final point	39	47	26-52	33-57



Aim 3 findings: Qualitative comments

- ▶ Qual data also indicated that benefits were over and above that collected via outcome measures
- ▶ Symptom relief was the reason most women continued with the study (pKHA 60%, 52% npKHA)
- ▶ Symptoms not worsening was considered a benefit
- ▶ Taking fewer painkillers, and that 'feels acupuncture has made a significant improvement to my life' demonstrate treatment outcomes that were not measured via either NRS or the PGQ
- ▶ Eleven women in the pKHA group, and one in the npKHA group, recorded positive changes to wellbeing



Thesis findings

- ▶ PPGP behaves very similar to that of our Scandinavian counterparts (usual caveats apply)
- ▶ An npKHA approach that is believable has been developed, though future studies should continue to measure it's credibility
- ▶ It is feasible to conduct an investigation in to KHA for PPGP in a fully powered RCT




Future research / practice

- More appropriate definition and recognition of PPGP in the UK
- Implementation of Qual findings, such as information provision
- Experiments on PPGP treatment should incorporate general wellbeing outcome measures
- Mixed methods integral to understanding and developing healthcare interventions



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