Factors affecting recruitment and attrition in randomised controlled trials of Complementary and Alternative Medicine (CAM) for pregnancy related issues

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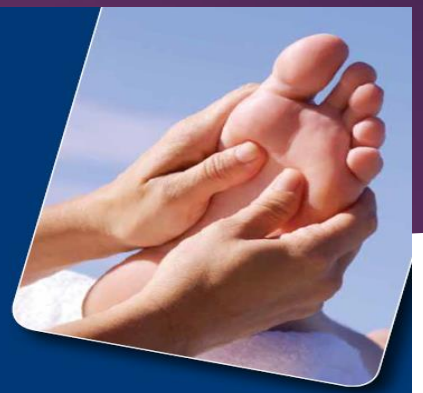
Background

- CAM frequently used for pregnancy related issues
- Poor evidence base of effectiveness for CAM use in pregnancy
- Recruitment issues CAM in pregnancy eg: Mollart (2003) Kimber et al. (2008)
- Recruitment issues in general pregnant women
- Short term attrition rates frequently above the acceptable 20% eg: Kvorning et al. (2004) Lund et al. (2006)
- High attrition rates in control groups eg: Wedenberg et al. 2000

The CAM in Pregnancy Trial

University of ULSTER

Faculty of Life and Health Sciences



CAM in Pregnancy Study

(Complementary and Alternative Medicine in Pregnancy)

- Are you having your first baby?
- Do you have pain in your lower back or pelvis?
- Are you 18 - 27 weeks pregnant?
- Would you like to take part in a study about complementary therapy?

Please ask your **midwife** for an information pack or contact:

Ciara O'Prey

Julie McCullough

Methods

- CAM in Pregnancy Trial (ISRCT26607527)
- Midwives briefing-one off face to face meeting, posters, information sheets
- Data from trial collected on recruitment (e.g.. those eligible and not eligible) & attrition
- Focus group post trial

Inclusion and exclusion criteria

Inclusion	Exclusion
Primigravid	Multiple pregnancy
18 years old and above	Previous low back/ pelvic surgery
Able to read and write	Placenta previa grade 3 or 4
Good English	Neurological condition
Lower back pain and/ pelvic pain	Unresolved low back or pelvic pain from a RTA
	Serious spinal pathology
	Fungal foot infections or verrucae
	DVT
	Current CAM use

Results: Recruitment

428 primigravids invited to participate

-52 not eligible

-37 were participating in another trial

376 remained eligible

70% (n=262) expressed interest- written info given

30% (n=114) declined participation- 37 provided a reason

105 made contact to participate

90 actually participated

Results: Reasons for declining participation

Results: Drop outs (n=26)

Reflexology n=6	Footbath n=15	Usual care n=4
1-preclampsia	1-preclampsia	1-preclampsia
1-travel issues	3-work commitments	1-unhappy with treatment allocation
1- no longer had pain	3-unhappy with treatment allocation wanted reflexology	3-unknown
1-verruca	1-travel issues	
1-unknown	1-personal issues	
	5-unknown	

Focus group findings

- 14 participants (8 reflexology, 4 footbath, 2 usual care)
- Mean age 33
- 13/14 previous CAM use

Focus group: Themes and Subthemes

Main theme	Subtheme
Factors negatively affecting recruitment	(i) Lack of awareness and support for the trial from maternity staff (ii) Poor visual and verbal promotion of the trial
Factors positively affecting recruitment	(i) Interested or experienced research (ii) Desire for pain relief
Factors negatively affecting attrition	(i) Maternity staff unblinding the trial (ii) Footbath not helping with pain

Factors negatively affecting recruitment: Lack of awareness and support from maternity HP's

"My own community midwife was like…ah…I wish they had of told me about that (the trial)… she was raging," Reflexology participant

"I think if they (midwifery staff) were a bit more versed about it (trial) they may have been a bit more proactive," Reflexology participant

"No offence to some of the midwives but they were a bit blassah about it," Reflexology participant

"When I was with my midwife they asked what the sticker was on the front of my notes …they had never heard about it," Footbath participant

Factors negatively affecting recruitment: Poor verbal and visual promotion

" I believe the posters were up at that stage …bit I missed them..I must of missed them they didn't catch me eye," Reflexology participant

"If there was more detail in the poster," Reflexology participant

"It wasn't mentioned to me at the 20 week scan, and I mentioned to them about pelvic pain," Reflexology participant

Factors positively affecting recruitment: Interested in research

"I just thought research is really important if loads of people in the future that it helps..you have to start with things like this," Standard care participant

"Well I just think research is really important… I would be interested in research," Footbath participant

"I am a research scientist…so I just wanted to take part …to give back in some way I appreciate how hard it is to the number," Reflexology participant

Factors positively affecting recruitment: Desire for pain relief

" So as to determine if reflexology would help … was going to be helpful for the pelvic pain, there was nothing else on offer," Standard care participant

"It was probably a bit more selfish if I am honest…I would have taken anything on offer…I wasn't really thinking beyond that ," Reflexology participant

"I am a great believer in holistic therapies and not a big fan of pain killers…I mean I will be honest I had a miscarriage before I had XXXX and didn't want to take any additional medication encase it had an effect," Reflexology participant

Factors negatively affecting attrition: Maternity staff un-blinding trial

"I mean I was told it was free reflexology…that's how it was sold to me ," Reflexology participant

"I was told it was reflexology and it would help your back pain …I wasn't told there was three groups, " Usual care participant

"It was probably a bit more selfish if I am honest…I would have taken anything on offer…I wasn't really thinking beyond that," Reflexology participant

Factors negatively affecting attrition: Footbath not help pain

"I mean I found it reflexing but not for the pain," Footbath participant

"I mean although it was great to get that time to myself…it just wasn't helping my pain," Footbath participant

So what could we do differently in future CAM trials for pregnancy issues?

- Recruitment timing- later in pregnancy; co-ordinate with antenatal appointments
- Better planning of recruitment- Multi-centre approaches
- Ongoing briefing sessions to maternity staff-Challenge midwives/ doctors personal views on CAM in pregnancy
- Better promotion-Social media, improve posters, testimonials
- Educate pregnant women on CAM-Balance risk and benefit; effectiveness & safety
- Better sham treatments

References

L. Mollart, "Single-blind trial addressing the differential effects of two reflexology techniques versus rest, on ankle and foot oedema in late pregnancy," *Complementary Therapies in Nursing and Midwifery*, vol. 9, no. 4, pp. 203–208, 2003.

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