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IVF, acupuncture and mental health: a qualitative study of perceptions and experiences of women participating in a randomized controlled trial of acupuncture during IVF treatment

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Abstract Infertility treatments such as in-vitro fertilization (IVF) are stressful and challenging to mental health and well-being. The use of alternative therapies adjunct to IVF treatment, such as acupuncture, is common and women hope to improve their chance of pregnancy and live birth. While many women engage in acupuncture adjunct to IVF in Australia, few qualitative studies of women's motivations and experiences have been conducted in this field. A qualitative study was nested within a randomized controlled trial of acupuncture during IVF treatment in order to explore women's perceptions of acupuncture, its effects in the context of IVF treatment, and how acupuncture is perceived in relation to the outcome of IVF. Fifty women randomized into both acupuncture and sham acupuncture groups were interviewed using a semi-structured format. In-depth interviews were transcribed, coded and categorized in a theoretical thematic analysis. Two primary themes emerged: 'psychological benefit' and 'perceived influence of acupuncture on fertility/medical outcome'. Regardless of randomization, women in both groups described similar psychological effects suggesting that a placebo effect was present. They were not convinced that acupuncture could enhance their treatment outcome through biomedical pathways. Rather, they perceived that acupuncture or sham acupuncture gave them a psychological advantage through increased relaxation, reduced psychological stress, and enhanced well-being and self-efficacy. In conclusion, there are significant features associated with a placebo effect in acupuncture that might be exploited to provide psychological benefit for women undertaking IVF.

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Introduction

Infertility is physically and psychologically stressful regardless of the social context or cultural mores in which it is experienced (Greil et al., 2010), and can be associated with serious sequelae such as depression (Peterson et al., 2014). Patients report infertility treatment to be one of the most stressful experiences in their lives (Rockliff et al., 2011), and repeated experiences of uncertainty, lack of personal control and reduced self-esteem contribute to reduced well-being during IVF treatment (Benyamini et al., 2005).

Many women discontinue infertility treatment due to the emotional distress they experience, coupled with the physical burden of repetitive IVF experiences and a growing sense of defeat (Boivin et al., 2011; Brandes et al., 2010; Galhardo et al., 2016; Gameiro et al., 2012; Lopes et al., 2014; Olivius et al., 2004). Significant attrition rates of 25–35% have been suggested (Gameiro et al., 2012).

In Australia, 74% of women in the general population are reported to use some form of complementary alternative medicine (CAM) (Meurk et al., 2012), and women's use of CAM whilst having IVF treatment is common (Boivin and Schmidt, 2009; Stankiewicz et al., 2007). Smith et al. showed that after 18 months of infertility treatment, 29% of their cohort of couples ($n=428$) had used CAM, and 23% of those using CAM had used acupuncture (Smith et al., 2010). Domar et al. reported that approximately one-third (30%) of a cohort of women ($n=106$) had undergone acupuncture prior to IVF treatment, and almost half (47%) had acupuncture during IVF treatment (Domar et al., 2012). Qualitative studies have found that the primary motivation for women using acupuncture is to improve their chance of pregnancy (Barr et al., 2016; de Lacey et al., 2009; Rayner et al., 2009); however, we recently reported the findings of a randomized controlled trial (RCT) of acupuncture compared with a sham control in women having IVF in which no difference was found between the live birth and pregnancy outcomes between groups (Smith et al., 2018, 2019).

This paper reports the outcomes of a qualitative study that was nested within this same RCT and which aimed to explore women's perceptions of acupuncture, its effects in the context of IVF treatment, and how acupuncture was perceived in relation to the outcome of IVF.

Materials and methods

This study was approved by the Southern Adelaide Flinders Clinical Human Research Ethics Committee (Ref. 330.11), and the human research ethics committees of the University of Western Sydney (Ref. H8936), IVF Australia (Ref. 058), Western Sydney Local Health District [Ref. HREC2012/7/4.2(3553) AU RED HREC/12/WMead/238], Albury Reproductive Medicine (no reference number provided), Melbourne IVF (Ref. 08/12), the Royal Women's Hospital Melbourne (Ref. 13/01) and Greenslopes Private Hospital (Ref. 11/10). The multi-centre trial also recruited women from three IVF units in New Zealand; however, women for this qualitative study were not sought from the overseas recruiting centres.

Study design

Semi-structured interviews were conducted with a sample of 50 women drawn from the cohort who had consented to take part in the RCT. In the RCT, women aged 18–42 years having a fresh IVF or intracytoplasmic sperm injection cycle and not using acupuncture were recruited and randomized to a control sham acupuncture or treatment group. Women received acupuncture or sham acupuncture during their treatment cycle with a study acupuncturist onsite or near the IVF clinic who was specifically trained in the study protocol. Acupuncture in any setting typically takes a holistic approach, and involves the provision of a warm, comfortable setting and a sympathetic and nurturing approach by the practitioner. The sham control group received non-insertive acupuncture using the Park sham needle, a device housing a retractable needle shaft and a blunt tip. In contrast to acupuncture treatment where a needle was inserted into the skin at specific points based on traditional Chinese medicine and manipulated, the sham needle was placed lightly against the skin surface at locations away from known acupuncture points and the needle was not manipulated thereafter. For further information regarding the design and conduct of the RCT, see Smith et al. (2018, 2019).

Recruitment

As women consented to participate in the RCT, they were invited to also participate in the qualitative study. They were given information about the study by clinic nurses in recruitment centres; if they verbally agreed to participate, their contact details and demographic information were sent to the qualitative researchers (SdeL, ES). When contact details were received by ES, each woman was contacted with the goal of scheduling an interview either face to face or by telephone shortly after she underwent an embryo transfer procedure. We remained blinded to the randomized allocation of participants to study groups until the qualitative study was completed.

Figure 1 describes the process of recruitment in this study. A preliminary sample of 50 women was sought with the notion of continuing recruitment to achieve maximum 'information power' (Malterud et al., 2016). After 35 interviews, recruitment and data were reviewed. The data were saturated at this point and the sample met the standards of specificity and quality of dialogue; however, the sample was homogenous, consisting mainly of Caucasian, middle-to-upper-class Australians educated largely at university level and living in urban areas. Thereafter, purposive sampling was applied for recruitment of the remaining 15 participants. On notification of a participant's willingness to participate in the qualitative study, the potential participant's demographics were reviewed against inclusion criteria which included ethnicity other than Australian, education below university education, and household income of less than \$80,000 per annum. Women who met these criteria were contacted to arrange an interview; 24 women who did not meet these criteria were excluded and not contacted. Interviews were conducted by both researchers (SdeL, ES) but primarily by ES, and were recorded digitally. Prior to each interview, informed consent was obtained from each participant.

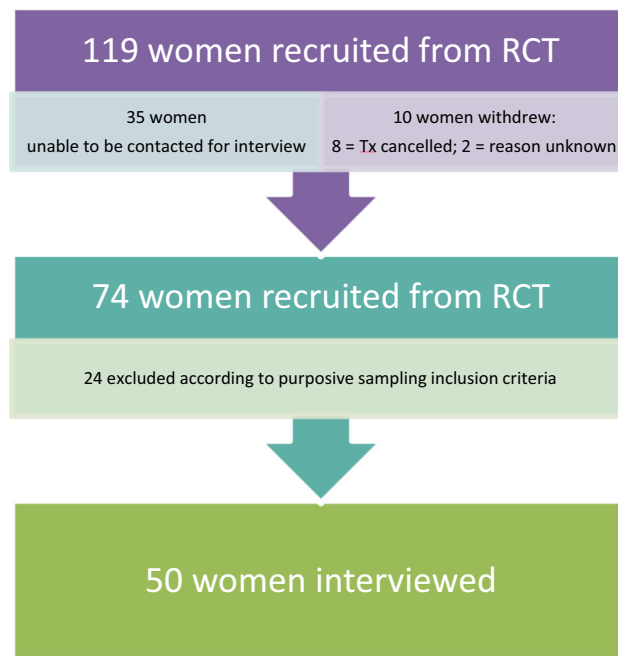


Figure 1 Recruitment of women from randomized controlled trial (RCT) to nested qualitative study. Figure 1

Interviews

The interviews were semi-structured and followed a general interview schedule which aimed to gather data about the context of infertility preceding IVF treatment; the woman's experience of treatment; her beliefs about acupuncture and understanding of how it might affect IVF outcomes; and her experience of having acupuncture (see [Figure 2](#)).

As the conversation unfolded, probing questions were used to clarify and expand the responses of participants ([Minichiello et al., 2004](#)). The interviews were transcribed by a professional transcription service who signed a

confidentiality agreement with the researchers. Each transcript was checked for accuracy, and the names of participants were removed and replaced with pseudonyms to protect privacy and confidentiality. The transcribed interview of each participant was later coded as belonging to the treatment or sham acupuncture group.

Qualitative analysis

The data were subjected to theoretical thematic analysis to provide a detailed account of the data pertaining to the attitudes and beliefs of the participants on acupuncture,

- 1) Could you tell me some background about your fertility issue? When did it start and what actions have you taken so far?
- 2) What is it like for you to have IVF treatment? How does it affect you personally? How does it affect your partner and your relationship? How does it affect your family relationships and friendships? Your work and working relationships? What is it like for you after embryo transfer while waiting for the outcome? How does IVF affect your budget?
- 3) What are your views about acupuncture? What understanding do you have of it?
- 4) Please describe the sorts of things you do to cope with IVF treatment? What have you tried? What works for you and what doesn't? Do you seek help to cope and if yes, who from? Do you have professional help? Was your experience of coping any different this time?
- 5) What was it like to have acupuncture during IVF? What happened in the acupuncture session? How did it feel to you? Was there an aspect of acupuncture that had an impact on you? How did it affect your mood, your coping, your relationships? How do you make sense of any differences? Do you think it influenced the outcome of your treatment? If yes, in what ways?
- 6) What motivated you to take part in the RCT?

Figure 2 Questions and issues explored during interviews. IVF, in-vitro fertilization; RCT, randomized controlled trial. Figure 2

what it does, how it ‘works’ and what it feels like (Braun and Clarke, 2006). This semantic approach was chosen as it allowed a more detailed analysis of aspects of the data that were related to women’s lived experience and socially embedded perspectives. After preliminary analysis, we were given access to the RCT allocation for each participant to enable comparison between and within RCT groups. Computerized qualitative data analysis software (Nvivo 8.0, QSR International, Melbourne, Australia) was used to store and organize the data and to perform initial coding of the data. Coded data were read within the whole transcript to ensure that the context and meaning of the views of individual participants were preserved. Once we had been made aware of each participant’s RCT group, the coded data were re-read to compare similarities and differences between the two groups. The coded data were then grouped into subthemes. Two primary themes emerged in relation to women’s experiences pertaining to the psychosocial impact of participating in the trial and perceptions of the biomedical impact of acupuncture during IVF. In the interests of credibility and rigor, verbatim quotes are used below to illustrate and support interpretations of the qualitative analysis. For transparency, each quote is followed by the participant’s pseudonym and the RCT group.

Results

Table 1 presents the demographic characteristics of the study participants. The participants ranged in age from 25 to 42 years, and were recruited from four different Australian states.

Despite efforts to acquire a socially diverse sample, the study participants were largely well-educated, Caucasian women in their 30s whose household income was in the moderate-to-high income level in Australia. This is consistent with the social demographic of women undertaking IVF treatment in Australia. The length of time that participants had been experiencing infertility ranged from less than 2 years to more than 5 years. Eight women were having their first IVF treatment, but the majority were repeating IVF, most for the third or fourth time. Twenty-eight of the women had experienced acupuncture before, either during IVF, for infertility, or in relation to other ailments or injuries. By pure co-incidence, when we were given access to the RCT groups, it became apparent that half of the participants of the qualitative study had been allocated to the sham group ($n=25$) and half had been allocated to the acupuncture treatment group ($n=25$).

Table 2 summarises the codes drawn from the data as matched with verbatim quotes from participants. Two main themes were extracted from this process: ‘psychological benefit’ and ‘perceived influence of acupuncture on fertility/ medical outcome’.

Psychological benefit

Most of the women who participated in this qualitative study described a psychological benefit from having acupuncture (unaware of whether it was real or sham) during their treatment. They described feeling more ‘relaxed’ which they attributed to acupuncture, and some further described their relaxation as feeling ‘calmer’, more ‘peaceful’ and

Table 1 Social and medical demographics of participants.

| Demographic | $n=50$ |
|--------------------------------------|--------|
| Age (years) | |
| 20–29 | 3 |
| 30–40 | 32 |
| >40 | 15 |
| Education | |
| University | 32 |
| High school | 5 |
| Trade or similar | 12 |
| Not stated | 1 |
| Household income per annum (AU\$) | |
| <40,000 | 1 |
| 40,000–60,000 | 3 |
| 60,000–80,000 | 13 |
| >80,000 | 29 |
| Not stated | 4 |
| Ethnicity | |
| Caucasian | 35 |
| Asian | 8 |
| Hispanic | 1 |
| Lebanese | 3 |
| Not stated | 3 |
| Duration of infertility (years) | |
| <2 | 16 |
| 2–5 | 20 |
| >5 | 12 |
| Not stated | 2 |
| Number of previous IVF treatments | |
| None | 9 |
| 1 | 8 |
| 2 | 12 |
| 3 | 11 |
| 4 | 3 |
| ≥5 | 6 |
| Not stated | 1 |
| Previous experience with acupuncture | |
| Yes | 28 |
| No | 21 |
| Not stated | 1 |
| RCT randomized group | |
| Sham | 25 |
| Treatment | 25 |

IVF, in-vitro fertilization; RCT, randomized controlled trial.

more ‘positive’ about the treatment. When asked whether they perceived any effects from having acupuncture, participants explained:

Relaxation definitely. I think it must stimulate some sort of blood flow. I'd be really, really relaxed, so much so that I'd have to sit in the car for 15 minutes to wake up before I drove home (Emily, acupuncture group)...it's about relaxation, peace more so than the increase in blood flow for whatever the other scientific reasons are (Melissa, sham group).

When participants spoke of feeling relaxed, it was evident that they referred to a different state than that achieved through other adjunct therapies, such as massage:

Table 2 Coding of the data prior to extraction of the themes.

| Perceptions of acupuncture | Verbatim quotes from participants |
|----------------------------|--|
| Relaxation | <p>Emily: 'Relaxation definitely....I'd be really, really relaxed, so much so that I'd have to sit in the car for 15 minutes to wake up before I drove home'</p> <p>Samantha: 'It does feel good, very relaxing. You know, you tend to just go in your little fairy world and think and dream'</p> <p>June: 'It's more relaxing than anything else. I don't know how it works [and] I don't know if I was even on the proper acupuncture or the sham, but I certainly felt relaxed and I think that was a positive'</p> |
| Feeling good | <p>Shelby: 'I did actually find it quite calming and relaxing. I felt good when I got there, good during the process and good when I left and I just felt calm. I felt more positive too, yeah, optimistic'</p> <p>Wendy: 'I feel like I'm doing something, I'm taking control of a situation I have no control over... trying to do everything in my power to give the best shot possible...I come out feeling empowered, more calm and in control'</p> |
| Time out/resting | <p>Jasmine: 'I'm a fairly firm believer that if I did the placebo that would have helped. The mere fact that they got me to stop and lie down for half an hour in a quiet room helped'</p> <p>Fiona: '... I think it [the relaxation] was just being able to be in the quiet and away from everybody and just having that half an hour just to let the mind drift and not really think about anything'</p> <p>Tilly: 'If nothing else, it will let me relax somewhere and I can't do schoolwork and I can't do housework, I just have to lie there and do what I'm told'</p> |
| Time to soak it in | <p>Jessica: 'It [embryo transfer] does feel like this is a momentous occasion... that was quite nice, going back for a second lie down [acupuncture], just to take things on board a little bit'</p> <p>June: 'Just lying there for that half an hour and having it done, you kind of have time to just relax and just soak it all [the embryo transfer] in and I felt positive when I left'</p> |
| Reducing stress | <p>Wendy: 'I just I felt it reduced my stress levels and probably gave me a bit more energy than I might have had'</p> <p>Ethel: 'Probably more than anything, the stress relief'</p> |
| Doing something new/more | <p>Martha: 'It's very difficult to stay positive but doing something on top of this IVF treatment, like acupuncture was something on the top so I tried to convince myself that I'm doing something new, something different this time. But at least for acupuncture when I was in the trial I knew I was doing something extra'</p> <p>Ruby: 'I've done something more...I've done IVF and also acupuncture. I've done something a little bit more [towards treatment]. So even when you don't believe in something but you do it, [it] can have positive effect'</p> |
| Improving body function | <p>Bianca: '[Acupuncture] affects the body in a way that changes something that then makes it a bit more conducive to getting pregnant'</p> <p>Callista: 'It's [acupuncture] stimulating blood flow and your chi and that's making the ovaries more receptive to implantation'</p> <p>Sarah: 'I think it changed the fluctuations in my body [energy] that I'm not aware of, that, I suppose, the people that I'm working with [medical team] haven't assessed'</p> <p>Teagan: 'It's all about getting the nerves to stimulate blood flow down in that area somewhere [reproductive organs]'</p> <p>Hannah: 'There may be medical benefits from having acupuncture in promoting better cells, better womb quality, uterus quality, your fallopian tubes suddenly flushed because of where the needle is'</p> |

I think with a massage you just relax, and you can actually fall asleep and my mind's not racing a million times, whereas with the acupuncture I felt like my mind was racing but I was also very relaxed and calm (Carter, acupuncture group). I think acupuncture for me was good for my head space but a massage for me is 'oh I've got tight muscles and oh, they feel really good now': it's more of a physical kind of feeling good. But I've found with the acupuncture I feel relaxed and I feel good and happy in my head (Fiona, sham group).

Acupuncture was also described as reducing feelings of stress:

I just felt it reduced my stress levels and probably gave me a bit more energy than I might have had. It's always hard to tell because you

know I'm quite resilient and I can cope with a lot of stuff anyway, but I had a lot of stuff going on at work and [after acupuncture] I felt I was much better able to cope with things (Wendy, acupuncture group). The fact that I was relaxed [after acupuncture] definitely helped. You can get a bit snappy when you're a bit stressed or something like that but just being relaxed I think made me feel just better and a bit happier (Belinda, sham group).

Unexpectedly, several participants indicated that they expected to experience relaxation by participating in the trial, and considered that this would occur even if they received the sham treatment. They perceived relaxation as arising from the belief that they were receiving a real

treatment, or from the processes and environment that accompanied acupuncture, and this was considered to provide a 'psychological advantage' equal to that expected of a 'real' acupuncture treatment:

Yes [even the placebo would help] because you're in a situation where you're vulnerable and anything would help that calmed you down and reassured you – even if it's a psychosomatic thing. Look it would enable you to take your mind off things (Deborah, sham group). It's good [the trial] because even if it's the placebo I'm still on a psychological advantage...and I'm still lying down in a relaxing environment and taking some time out and all of those things are helpful (Jasmine, acupuncture group).

Other women described a sense of well-being as arising from the practice and environment that accompanied acupuncture.

Several participants described the social context in which IVF took place as busy, sometimes frenetic, and their working lives as stressed. This context was exacerbated by the demands of their IVF treatment. Typically, following contact with the reproductive medicine clinic, they rushed back to work or returned to other activities straight away. Women in the trial were required to be recumbent and still for 30 min while the acupuncture or sham needles were *in situ*. In some settings, this took place at the acupuncturist's practice, while in other settings, the acupuncture was conducted within the reproductive medicine clinic. The treatment, therefore, whether acupuncture or sham, afforded women an opportunity to take time out and rest:

I was actually surprised because I'd never had it before and ..I don't know [which group I was in] but I found myself really relaxed because at the time we were doing it we were coming up to the end of financial year so it's quite a busy time at work and a bit high stressed. I was having my appointments in my lunch break and I just found it was actually really, really good because it was quite relaxing, and I'd go back to work in a good frame of mind. It was good... I think a lot of it was just being able to be in the quiet and away from everybody and just having that half an hour or however long it was just to let the mind drift and not really think about anything (Fiona, sham group). I'm a firm believer that even if I did [get] the placebo that would have helped. The mere fact that they got me to stop and lie down for half an hour in a quiet room helped (Jasmine, acupuncture group).

This enforced period of rest brought other positive psychological effects, particularly following embryo transfer.

Having an embryo transfer procedure was described by several women as a special moment truncated by having to drive 'like a mad thing' across the city and back to the demands of work or the demands of everyday living. Some women described how the period of stillness required by acupuncture provided them with a rare opportunity for reflection and allowed them 'soak it [the meaning of embryo transfer] in':

You kind of like think 'whoa', and it [the embryo transfer] does feel like a momentous occasion. [I think] in the eyes of the

people that are doing the transfer, it's [a clinical procedure]. So, after embryo transfer I made my way back to the acupuncturist and it was quite nice [having] a second lie down, and [time] to just take things on board a little bit (Jessica, sham group). Just lying there for that half an hour and having [acupuncture] done, you have time to just relax and just soak it all in. I felt fairly positive when I left. I don't know if that's an acupuncture thing, or if it's a mind thing, but whatever it is, it was helpful (June, acupuncture group).

A sense of euphoria was associated with acupuncture. 'Feeling good', as Shelby described it, arose from relaxation and a combination of having time out and being the recipient of holistic nurturing, and was related to internal feelings – feeling good 'in oneself':

I did find it quite calming and relaxing. I remember thinking that and I felt good when I left. I felt good when I got there, good during the process and good when I left, and I just felt calm. I guess I felt a bit more positive too, yeah, optimistic I should say. Just felt good... I think it was just that idea of having acupuncture and what it could do and just trying to be calm so that it can work even better. But also, having that half an hour to just relax and sit there and not be interrupted and that was what I think helped as well. It's just that whole effect of getting that extra attention and care and relaxing and all that kind of stuff that possibly helps as well (Shelby, acupuncture group).

Feeling good was also described as feeling good 'about oneself', arising from having taken steps to do something 'more' towards conceiving. This action also led to positive feelings or optimism about treatment:

I think it's [having acupuncture] a psychological effect. I'm thinking, now I've done something more. You know what I mean. I've done that too – like the IVF and acupuncture. I've done something a little bit more. So maybe even when you don't believe in something, but you do it, the psychological effect can have positive effect (Ruby, sham group).

Feeling good was also described as resulting from taking a novel or different approach to a repeated treatment. Martha described her belief that having acupuncture produced a psychological benefit rather than a physical benefit:

I really feel very nervous or tense during the process because after the negative result [in a previous cycle], it's very difficult to stay positive. But doing acupuncture was something on the top [of the IVF treatment] so I tried to convince myself that I'm doing something new, something different this time so it could still work. The difficulty of IVF is that there is not much I can do. I just have to hope and get the transfer and just wait. I really don't know what else I can do. But at least for acupuncture when I was in the trial I knew I was doing something extra (Martha, sham group).

As Martha explains, having IVF treatment can be a disempowering experience for women in which they perceive they are passive recipients of medical treatment. However, as

Wendy explains, adding acupuncture through participation in the trial, and previously, produced a sense of empowerment:

I don't necessarily [enjoy acupuncture]. I feel like I'm doing something, I'm taking control of a situation I have no control over... just trying to do everything in my power to give the best shot possible... So that's good. I guess I come out feeling empowered, and that's maybe why I feel a bit calmer and in control (Wendy, acupuncture group).

Perceived influence of acupuncture on fertility/medical outcome

When describing their understanding of a relationship between acupuncture, fertility and their treatment outcome, the women in the study described their beliefs regarding the relationship between acupuncture and IVF, and used language that suggested they were uncertain about whether or how acupuncture could influence embryo quality or implantation. Several prefaced or ended their descriptions of the effect they perceived acupuncture had (or was supposed to have) on the nervous and circulatory system with expressions such as 'I don't know', 'I have no idea', 'I think it is', 'I'm not really sure' and 'I would assume'. Their beliefs ranged from doubt that acupuncture could influence the scientific process of IVF and embryo transfer to expressions of hopefulness that it could make a positive difference:

Oh look, I'm a bit sceptical. I don't believe that it would make the difference to an outcome on a cycle. Just because I'm a strong believer in Western medicine and I think if they're putting an egg and a sperm together and an embryologist, scientist is doing this, how could putting needles in your body change that? To me it's too far out. But it could, I don't know, I don't know...Look I do believe acupuncture helps reduce stress, so maybe that can play some kind of a factor (Emma, sham group).

Many expressed a belief that it 'worked', even though they perceived it acted completely independently to treatment processes:

I believe the acupuncture worked but without it being successful [having a direct impact on treatment outcome]. Like I wouldn't say it was a waste of acupuncture [that] it didn't work. I would say that the acupuncture did work and did do what it had to do. But obviously there's an underlying problem or something that no one can sort of answer why, so even if it [the treatment] wasn't successful I would believe that acupuncture still did do what it was meant to do (Ruth, sham group). I think that acupuncture is helpful for your body, so I'm a bit mixed – yes and no. I just think that it might help your body to be more prepared, but it doesn't mean it is going to help that IVF if that makes sense...just better energy flow for your body but more in general health it helps better flow of your energy through your body and that might down the track help you. If IVF is supposed to work, it will work regardless of if you do acupuncture but then it might help some people who might of

needed a bit more energy to fall pregnant so I'm 50/50 (Belinda, sham group). If you speak to a certain camp of people, they will say that stress is an enormous contributor to it [IVF] not working and then there are others, both in the medical profession and otherwise, who say that's ridiculous, it [stress] has nothing to do with it...So it's very difficult to discern and I don't know whether or not I've formed an opinion but I just kind of figured look, we're intervening medically big style to get this to happen. Anything that can support it, well that's great but do I think that that's likely to be the distinguishing feature between success and failure? No. I think it helps but I don't think it's going to define if a cycle will work or not. [But] if it helps me mentally, at the very least that's a real positive because it's a very difficult process to go through (Lynne, sham group).

Some women had firmer beliefs that acupuncture could assist in the treatment outcome:

It affects the body in a way that changes something in the body [and] makes it more conducive to getting pregnant. It could be in a number of places – it could potentially be the uterus, it could be the quality of the egg and the embryo (Bianca, acupuncture group). [Acupuncture] Help only to relax. I think when you relax your body you feel like each cell is relaxed. If you are tense, will not help with the implant. If for example, you've got soil really hard [in the garden] you can't plant the seed in. If you have soft soil, so easy. Know what I mean? (Margaret, acupuncture group) I think something to do with blood flow to certain parts of your body and look I don't – I'm not saying I felt this, but that's what I would assume, and also, from what I've read and heard, that it can sort of balance your hormones. Yeah, so that's what I would sort of be predicting (Mandy, acupuncture group).

Notably, none of the women in this study perceived acupuncture as carrying a risk to themselves or their treatment outcome:

it's [the information about acupuncture on the internet] not that negative [and] actually there were lots of positives around it. People are commenting that they were having acupuncture and it will help them to have a positive pregnancy. I never found something saying, no, it [caused] stomach pains or anything. So I figured, well, it's not going to harm it [the IVF treatment], so I might as well try it and see what happens (Alex, acupuncture group).

Discussion

This nested qualitative study found that the opportunity to undertake a short course of acupuncture during IVF (albeit random) was perceived by participants to have the principal outcome of providing them with a psychological 'advantage' during treatment.

Participants described themselves as active agents and their motivations as searching for a better outcome for their infertility (de Lacey et al., 2017); however, they were largely uncertain as to whether acupuncture would impact the medical outcome of pregnancy and live birth for them. Indeed, we recently reported that the findings of the RCT showed no difference in the primary outcome of live birth

and pregnancy outcomes between groups (Smith et al., 2018, 2019). Although some participants believed that acupuncture could improve reproductive receptivity, most perceived it more likely that mental health improvements could influence an improved reproductive 'environment' for implantation and ongoing gestation. This suggests that the relationship between stress and conception is a primary concern for infertile women.

Mental health emerges from thoughts, actions and experiences, and good mental health is widely described as well-being (Sointu, 2006). Emotional well-being is generally understood to involve positive thoughts, emotional balance and mindfulness which, in turn, increase the ability to manage stress and recovery from disappointment or trauma.

In this study, many women believed that their well-being was enhanced by having acupuncture during treatment, describing this as reduction of stress typically characterized as relaxation. Furthermore, they described experiencing higher-order features of well-being such as increased optimism, calmness, peacefulness, mindfulness and feeling good within and about themselves. These findings support reports of psychological enhancements found in previous studies (Barr et al., 2016; de Lacey et al., 2009; Domar et al., 2009; Rayner et al., 2009; Smith et al., 2011).

Previous studies have reported significantly less anxiety in a group of women having acupuncture (Isoyama et al., 2012), as well as increased coping, resilience and self-efficacy in the situation of infertility and medical treatment (de Lacey et al., 2009; Domar et al., 2009; Kovarova et al., 2010; Rayner et al., 2009; Smith et al., 2006, 2011). We also reported similar secondary outcomes in the RCT participants (Smith et al., 2019). Whilst the impact of acupuncture on anxiety was not measured specifically in this qualitative study, the narratives of women in the study group suggest that their descriptions of relaxation and reduced stress reflect increased well-being and thus reduced anxiety.

Previously, we reported that female participants in the qualitative study were proactive in seeking a better treatment outcome through involvement in the RCT, and described a sense of regained control over their situation (de Lacey et al., 2018).

Some small studies in this field have reported increased well-being as being associated with a sense of regained self-control (de Lacey et al., 2009; Rayner et al., 2009; Sointu, 2006), and similar findings have been reported by participants having acupuncture in other medical fields (Ee et al., 2018; MacPherson et al., 2006; Paterson and Britten, 2004). Indeed, searching for improved well-being and empowerment are commonly held reasons for individuals to seek acupuncture, regardless of the presenting symptoms or complaint (Jakes et al., 2014; Sointu, 2006).

The opportunity to compare the perceptions of women who received acupuncture during IVF with women who received a sham regime is unique to this study. Unexpectedly, this study found that women who received the placebo (sham acupuncture) described psychological benefits, such as increased relaxation, that echoed those described by women who received acupuncture, and this raises further questions about the mechanism of action.

Previous research suggests that sham controls may not be inert (Zhang et al., 2015), and the primary outcomes in the

main trial (Smith et al., 2018, 2019) suggested that the findings may be explained by potential activity from the sham control. However, it is unlikely that this activity explains these findings, as benefits related to anxiety were also reported in the secondary outcomes (Smith et al., 2019).

It is also possible that the use of sham acupuncture was so convincing that participants believed that they had received 'real' acupuncture. However, it is more likely that what was observed was a 'placebo effect' that was responsible for muddying distinctions between the experiences of women in the acupuncture and sham groups in this study. The term 'placebo effect' refers to the narrow effect of a dummy intervention coupled with a broad array of non-specific effects arising from patient, practitioner, their interactions and the context. Alternative therapies such as acupuncture are composed of needling but also holistic practices such as time and attention from a therapist, as well as the perceived credibility of the intervention and the participant's expectations (Paterson and Dieppe, 2005). These factors have what Kaptchuk terms potent 'performative efficacy'; that is, the positive effect may be invoked by hope, belief, imagination and expectation and/or 'an openness to experiencing what situations offer' (Kaptchuk, 2002, p. 402).

In this study, the attributes of acupuncture in the context of the RCT included the holistic process of talking and listening, and feature elements in the acupuncturist-participant interaction such as empathy and care. Neither acupuncture nor placebo was clinically significant in trial outcomes (Smith et al., 2018, 2019); however, in this qualitative study, participants reported that compassionate care and an opportunity to rest during IVF, and especially following embryo transfer, had an emotionally important effect. All women in the trial underwent the same procedural practices which involved bed rest during needling, among other comforts. Some women described benefitting purely from this opportunity to rest quietly in a supportive environment amidst the maelstrom of IVF. There was also recognition that this 'oasis', albeit brief, was an important time for allowing the meaning of having an embryo transferred to 'soak in', and presented an opportunity to 'be in the moment'.

Patients in the randomized placebo arm of a trial may experience incidental effects that influence the outcome of an RCT. However, such incidental effects are typically not considered to be clinically salient, and are thus seen to be less valid than the primary outcome and frequently go unreported (Kaptchuk, 2002). Nonetheless, they reveal an important experience of being in a trial for participants (Jakes et al., 2014; Vuckovic, 2002). Incidental effects in acupuncture RCTs are especially recognized as influencing outcomes because of the performative efficacy of the intervention (Kaptchuk, 2002; Paterson and Dieppe, 2005). Thus, this nested qualitative study provided insight into the experiences of participants, and the ways in which deliberate actions to manage stress adjunct to IVF treatment, such as acupuncture, might be supported and/or exploited to maintain emotional well-being and build psychological endurance for further treatments if needed. For instance, offering a rest period following embryo transfer may offer compassionate care with or without the presence of

acupuncture. Further investigation of the association between enhanced psychological endurance and the attrition in women repeating treatment would be informative.

The strength of this qualitative study lies in the relatively large sample and comprehensive documentation of the experience and perceptions of participants. However, there are some limitations. Despite our best efforts to recruit a socially diverse group of women, there was a dominance of Caucasian, well-educated women in the sample. The women in this study were drawn from only five of the nine clinic settings associated with RCT recruitment in Australia. It is therefore possible that these women presented views that may differ in the diverse social, geographic and acupuncture settings where the trial recruited. A further limitation is that half of the participants had experienced acupuncture previously. This was not an exclusion criterion and was unavoidable for the qualitative study; however, previous experience may have influenced the perceptions of acupuncture in this study and blurred comparisons. As this study was nested in an RCT, recruitment to it was limited to women who agreed to enrol in the trial and be subject to randomization. The women who did not agree to participate in the trial yet accessed acupuncture of their own volition may hold different views. However, it was not possible to recruit these women in this study. Nevertheless, the findings confirm the results of previous studies, suggesting that their views may be equivalent.

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