



Research paper

Participation in a randomised controlled trial of acupuncture as an adjunct to in vitro fertilisation: the views of study patients and acupuncturists[☆]



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ABSTRACT

Introduction: Acupuncture is now emerging as a complementary medicine used in conjunction with in vitro fertilisation (IVF). The aim of this study was to examine participation in a randomised controlled trial of acupuncture as an adjunct to IVF from the perspective of women and study acupuncturists.

Methods: Descriptive qualitative study using a survey and semi-structured in-depth interviews with study the women receiving acupuncture as part of the trial and acupuncturists.

Results: Data was obtained from a convenience sample of 146 women and 17 acupuncturists. A number of themes emerged in relation to important features of the trial consultation and treatment sessions and why features were important to both women and acupuncturists. Features most valued by women were the physical and psychological benefits of acupuncture experienced during treatment encounters, information sharing and health advice, pain free treatment and the opportunity to participate in research. Acupuncturists assigned importance to providing a high standard of care through professional treatment and diagnosis, supporting and empowering women, developing positive therapeutic relationships and considering women's perceptions of acupuncture, IVF and research.

Conclusions: Trial participants' and acupuncturists perceptions of trial participation were mostly positive, with the identified needs of women being complementarily matched by practitioners. Therapeutic relationships formed during trial participation seemed to transcend the artificial research setting and were reciprocal and receptive.

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1. Introduction

Acupuncture has become an emerging therapy used as an adjunct to in vitro fertilization (IVF) [1]. A survey of acupuncturists from the United Kingdom consisting of 861 respondents indicated that 80% of practitioners reported most fertility work was related to assisted conception.[2]. These findings are also supported by an Australian survey which found 90% of acupuncturists reported providing fertility treatments and support to women during this time [3]. Women are often drawn to complementary medicine, making a choice to use therapies like acupuncture in conjunction with assisted reproductive technology (ART) to enhance health outcomes, treatment efficacy and experience the benefits of positive therapeutic relationships formed with practitioners [4,5].

There is a small but growing body of literature describing patients' views on receiving acupuncture in a clinical setting and their experiences of receiving acupuncture in a research context. Several studies have examined the experiences of women using complementary medicine including acupuncture to enhance their fertility and as an adjunct to IVF [4–9]. Themes shared among these studies were: reasons for seeking acupuncture treatment including dissatisfaction with conventional biomedical care; treatment experiences (e.g. needling sensation) and the therapeutic model of patient care.

A number of studies have reported acupuncturists' views about research participation [10–15]. Common themes in these studies expressed by practitioners included: the importance of individualised treatment; valued features of the therapeutic relationship as the basis for establishing trust and rapport; empowering and educating patients and reflections on conflicts and benefits of research participation including constraints imposed by treatment protocols.

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There is no literature reporting directly on the views of both research acupuncturists and women treated in a fertility acupuncture research setting. This study aimed to increase our understanding of trial participation relating to the acupuncture consultation and treatment from the perspective of women and acupuncturists participating in an ongoing randomised controlled trial (RCT).

2. Methods

This research is a nested study of the parallel RCT of acupuncture compared with a sham control using a non-invasive placebo needle, evaluating the effect of acupuncture as an adjunct to IVF [1]. Participants received an initial study treatment between days 6 and 8 of their stimulated IVF cycle. Two treatments were then administered immediately before and after embryo transfer. The placebo needle has a retractable needle shaft, a blunt tip, and skin penetration does not occur, and the needles have a supporting device. The location of sham non-acupuncture points are away from real points and are described in relation to anatomical landmarks and relationship to acupuncture channels. The study is

co-ordinated centrally from Western Sydney University Australia, and to date 18 IVF units have joined the multi-centre trial.

2.1. Participants

Participation consisted of women in the ongoing RCT, and the study acupuncturists delivering acupuncture to women in the trial. Trial participants were located in Australia and New Zealand. An application to amend an existing Western Sydney University ethics registration (H8936) was approved and permitted additional data collection from acupuncturists.

A convenience sample of 158 women was drawn from the RCT population of all women randomized to acupuncture or sham acupuncture who had completed trial participation as of March 2014. Women who consented to participate in a non randomized usual care group were excluded from participation in this side study. The trial is currently recruiting women aged <43 years undergoing a fresh IVF or intracytoplasmic sperm injection cycle and not currently receiving acupuncture [1]. Women were excluded if they were undergoing a frozen embryo transfer (ET), or had been previously randomised to the study, were planning pre

Table 1
Characteristics of women in the sample.

| Characteristic | | N | % |
|------------------------------------|---|------------|------|
| Age at trial entry | 20–29 | 10 | 6.3 |
| | 30–34 | 38 | 24.1 |
| | 35–39 | 79 | 50.0 |
| | 40–44 | 31 | 19.6 |
| | Mean (Standard Deviation) | 36.1 (3.8) | – |
| Relationship status | Single | 2 | 1.3 |
| | Married/defacto | 155 | 98.1 |
| | Separated/divorced | 0 | 0.0 |
| | Other | 1 | 0.6 |
| Ethnicity | Caucasian | 128 | 81.0 |
| | Asian | 21 | 13.3 |
| | Other | 9 | 5.7 |
| Education | Completed high school | | |
| | Yes | 150 | 94.9 |
| | No | 8 | 5.1 |
| | Completed tertiary education | | |
| | Yes | 134 | 84.8 |
| | No | 24 | 15.2 |
| | Type of Tertiary Education Completed | | |
| Qualification from TAFE or similar | 36 | 22.8 | |
| University degree | 98 | 62.0 | |
| None | 24 | 15.2 | |
| Employment status | Working full time (permanent, contract or casual) | 96 | 60.7 |
| | Working part time (permanent, contract or casual) | 40 | 25.3 |
| | Unemployed | 3 | 1.9 |
| | Home duties | 12 | 7.6 |
| | Student | 2 | 1.3 |
| | Other | 5 | 3.2 |
| Household income | Up to \$40,000 | 3 | 1.9 |
| | \$40,001–\$60,000 | 15 | 9.5 |
| | \$60,001–\$80,000 | 11 | 7.0 |
| | Greater than \$80,001 | 62 | 39.2 |
| | Not stated | 67 | 42.4 |
| Location | NSW – IVF Australia – Sydney Eastern Suburbs | 40 | 25.3 |
| | NSW – IVF Australia – Westmead Fertility | 9 | 5.7 |
| | QLD – Brisbane – Assisted Conception | 24 | 15.2 |
| | NZ – Auckland – Fertility Plus | 33 | 20.9 |
| | SA – Flinders Reproductive | 19 | 12.0 |
| | NZ – Wellington – Fertility Associates | 7 | 4.4 |
| | VIC – Melbourne – IVF | 26 | 16.5 |

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