Complementary Therapies in Clinical Practice 20 (2014) 291–296

Contents lists available at ScienceDirect

Complementary Therapies in Clinical Practice

journal homepage: www.elsevier.com/locate/ctcp

Receiving or not receiving acupuncture in a trial: The experience of participants recovering from breast cancer treatment

Mackereth Peter [b, *], Bardy Joy [a, b], Filshie Jacqueline [c], Finnegan-John Jennifer [d], Molassiotis Alexander [a]

[a] School of Nursing, Social Work & Midwifery, University of Manchester, United Kingdom
[b] The Christie NHS Foundation Trust, United Kingdom
[c] The Royal Marsden NHS Foundation Trust, United Kingdom
[d] Florence Nightingale School of Nursing and Midwifery, Kings College London, United Kingdom

Keywords:
Fatigue
Acupuncture
Control group
Cancer
Clinical trial

A B S T R A C T

Objective: To explore the experience of breast cancer patients who either received acupuncture or were allocated to the control group.
Methods: Focus group/interviews nested within our multi-site randomised controlled trial. Participants were recruited from the standard care and experimental arm. The interviews/focus groups were transcribed and analysed thematically.
Results: Of the 302 eligible participants 13% ($n = 40$) contributed to the focus groups/interviews, across three study sites in the UK. Five common themes were identified, including: drivers to take part, the experience of receiving acupuncture, being allocated standard care (control) and reflections on taking part in the trial. The subgroup of control group participants ($n = 9$) reported disappointment on hearing their allocation, but recognised the value of their role to the study.
Conclusions: Recipients of acupuncture reported beneficial effects in managing fatigue and related symptoms. The finding that control participants were disappointed warrants further investigation and consideration when designing interventional studies.

1. Background

Cancer-related fatigue (CRF) can be viewed as a debilitating form of chronic fatigue, that incorporates various other symptoms including headaches, insomnia, difficulty in concentrating and joint pain [1]. It is reported to affect up to 90% of patients undergoing cancer treatment [2,3] The treatment for women with breast cancer can be lengthy and physical symptoms and psychological concerns including fatigue, hot flushes and fear of recurrence can persist for many years after treatment is completed [4,5]. Fatigue management entails programmes of exercise, diet or taking antidepressants. Interest in the use of complementary therapies by patients living with CRF, led us to explore whether acupuncture could be of benefit [2].

The majority of acupuncture studies are observational in nature and have focussed on the practitioner delivered acupuncture. Several RCTs have found acupuncture beneficial in reducing chronic fatigue, but a paucity of literature prevails with regards to cancer related fatigue. There is a growing interest in complementary therapies, but evidence to suggest its efficacy has been unreliable [6]. However, a synthesis of evidence has shown acupuncture to have benefit to patients with CRF [6]. An uncontrolled trial in patients with cancer ($n = 37$) found a clinically important improvement of 31.1% in fatigue levels with acupuncture delivered once or twice a week [7]. A later study investigated the effects of acupuncture in fatigued patients ($n = 47$) with a range of cancers to ascertain if an RCT was feasible [2]. The results suggested improvements in fatigue levels, but that the interventions may be needed for a longer period to maintain improvements.

The experience of acupuncture has received scant attention from qualitative researchers. Griffiths and Taylor (2005) explored 'being needled' with participants ($n = 12$) who reported it as 'not painful', 'bearable', 'sharp pinch' and like a 'tiny bite' [8]. Post treatment participants reported feelings of being 'energised', 'spaced out' and even 'giddy'. A recent survey ($n = 107$) by Salmon

* Corresponding author. Complementary Health & Wellbeing Services, c/o The Rehabilitation Unit, The Christie NHS Foundation Trust, Wilmslow Rd, Manchester M20 4BX, United Kingdom. Tel.: +44 0161 446 8236.
E-mail address: Peter.Mackereth@christie.nhs.uk (M. Peter).

http://dx.doi.org/10.1016/j.ctcp.2014.10.002
1744-3881/

[9], in an oncology setting, reported that 23.8% of patients accessing acupuncture expressed prior 'nervousness' about attending. Needling was experienced by 9.5% of the sample as 'painful'. Over 95% of participants were satisfied with the acupuncture service and would definitely continue treatment. A variety of cancer related symptoms were treated with 80% of the sample reporting improvements. For those with fatigue, 22 out of 24 patients reported improvement.

Our study was nested within an RCT with the participants allocated to receive acupuncture for 6 weeks or to the standard care/control group [10,11]. The intervention group received acupuncture with insertion of six needles for 20 min on a weekly basis, four of which were SP6 and ST36 (bilaterally).

2. Aim

The aim of this study was to explore the experience of breast cancer patients who either received acupuncture or were allocated to the control group.

3. Methods

A qualitative study using focus group interviews, nested within our main acupuncture trial for breast cancer and fatigue [10]. Focus groups were chosen for their potential to extract information by developing a group dynamic; a 'synergistic factor' [12,13]. Trigger questions were formulated from the literature and reviewed with colleagues and patients (see Box 1) to initiate and guide the discussion [14] The inclusion criteria for the larger RCT focussed on those who had received chemotherapy, some had also received radiotherapy, but those with a life expectancy less than 6 months were excluded. Eligible patients needed to have completed chemotherapy for than 1 month and up to 5 years previously. Patients were asked not to receive concurrent complementary therapies during the RCT.

3.1. Procedures

Participants in each of the trial arms were sent an invitation letter, a patient information sheet, trigger questions and consent forms and a booking slip to confirm attendance. Two facilitators convened each group, with one taking a lead. All focus groups lasted for approximately 60 min and were audio recorded. Consent forms were either returned by post in advance or signed on the day of the focus group. Patients were assured that they could withdraw at any point during the session. Ethical approval was obtained from Nottingham Research Ethics Committee (07/Q2404/68).

Box 1
Trigger questions for the patient groups.

1. Tell us about what lead you to apply to be part of this study?
2. Did you have any reservations or concerns before you started? If so what were these?
3. When you received your allocation (acupuncture or control) what were your initial reactions?
4. It would be very helpful to hear about your overall experience/views on the value or otherwise of the project and treatment?
5. Were there any particular challenges/difficulties related to taking part, completing the questionnaires and/or attending the focus group?
6. Any further comments or suggestions you would like to make about the study and possible future studies?

3.2. Analysis

A thematic approach to analysing the transcribed data from the focus groups was taken [15]. Thematic analysis can provide "rich and detailed, yet complex account of data" [16]. Two researchers independently read and reread the transcripts to identify the emergent themes. The final themes and sub themes were agreed by negotiation.

4. Findings

Of the 302 eligible participants in the main trial, 13% ($N = 40$) were recruited and contributed data to this part of the nested study. A total of 36 women from the study sites participated in focus groups, while four participants provided personal communications with answers given to trigger questions supplied with the focus group invitations. Seven focus groups were planned in the North West of England and three in Central London. The 7 groups had between 3 and 7 members, while other planned groups became one-to-one interviews. Of the 40 participants, 9 did not receive acupuncture (standard care). For demographic details of participants see Table 1. In accordance with ethical requirements, reasons for not attending the focus groups were not sought. In the audio-recorded dialogue each participant was given a personal code that identified the centre, (e.g. P1 for participant one and N for North West; CG for control group). Themes and sub themes are summarised in Fig. 1 with examples of responses and dialogue reported here.

Table 1
Demographic characteristic of the participants.

Indicator	Description	Frequency
Age (years)	30–39	1
	40–49	7
	50–59	21
	60–69	9
	>70	2
Marital status	Single	6
	Married	24
	Divorced/separated	9
	Widowed	1
Ethnic group	Caucasian	39
	Asian/Chinese	1
Time since diagnosis	<19 months	20
	20–39	14
	40–60	6
Educational Attainment	Secondary school	10
	College/diploma	13
	University degree	8
	Postgraduate	9
Living arrangement	Alone	10
	Husband/partner	26
	Other	4
Occupational status	Employed full-time	12
	Employed part-time	11
	Retired	7
	Not working due to ill heath	7
Occupational group	Professional	20
	Managerial/technical	2
	Skilled non-manual	10
	Unskilled	6
	Not applicable	2
Duration of fatigue	<12 months	6
	12–23	11
	24–49	10
	50–59	3