

Opinions of research participants about study paperwork

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Background

This paper is based on the findings of focus groups with women who took part in a pilot study of traditional acupuncture for the menopausal side effects of tamoxifen taken as an adjuvant treatment for breast cancer.^{1,2}

Demand for evidence has meant that researchers have to design case report forms to capture quantitative data on patients' responses to complementary and alternative medicine (CAM). For many CAM studies this has proved difficult, as traditional medical endpoints are not relevant. In this study there were easily documented endpoints, but measurement had to be undertaken by the patient rather than by diagnostic tests or imaging.

When the study was submitted to the Local Research Ethics Committee, committee members expressed misgivings about the quantity of paperwork which the participants would be required to complete. At the beginning of the study patients would monitor their hot flushes for two weeks using a Hot Flush Diary, and complete two other questionnaires (see Table 1). They would then be given eight weekly acupuncture sessions, and would be followed up for 29 weeks. On four further occasions they would be asked to complete the same three sets of paperwork.

Table 1 shows the paperwork the women were asked to complete on these five occasions.

Table 1

Paperwork	Description
Hot flush diary	Each hot flush recorded, with details of intensity every 2 hours for 2 weeks.
Women's Health Questionnaire	Validated questionnaire; 37 questions about symptoms, emotions, sleep and other aspects of quality of life, each rated on a 4-point scale.
Hot Flush Frequency & Problem Rating Scale	7 questions including 3 using a 10-point scale to rate the extent to which the flushes were a problem and interfered with daily life.

The research team included completing the paperwork among the topics to be covered by a series of focus groups aimed at exploring the experience of taking part in acupuncture research. The opinions of the participants about the experience of having the treatment within a study are described elsewhere.³

Methods

The team contacted all 50 women who had completed the course of eight acupuncture treatments and invited them to take part in one of a series of groups; a total of 16 women agreed to take part. Three groups took place, with seven, five and four participants. The group facilitator agreed the questions with the research acupuncturist, and they included a question about completing the paperwork.

The discussions were tape recorded and transcribed verbatim. The transcripts were analysed using qualitative analysis techniques based on Grounded Theory.⁴ This involves coding each statement (i.e. reducing it to a few words) and then grouping these codes into categories. These can then be organised either to develop theory or to elucidate opinions and experience. This study did not aim to develop theory, and no attempt was made either to achieve a purposive sample or to reach saturation, which would be essential in a study using Grounded Theory in its pure form.

Following the analysis, the draft report was sent to all the participants, together with a feedback form. One minor amendment was made to the final report as a result of this exercise.

Findings

In contrast to a scientific paper, there is no standard structure for presenting qualitative findings. In this paper we have chosen to present the participants' opinions in the following order:

- Completion rates for the Hot Flush Diaries
- Overview of the paperwork
- Design of the paperwork

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- Difficulties experienced with completing it, and strategies for overcoming them
- What it showed them
- Motivation for filling it in

Completion rates for the Hot Flush Diaries

The most onerous of the questionnaires was undoubtedly the Hot Flush Diary, as it required the number and intensity of flushes in each 2-hour period of every day and night for 2 weeks at a time. Over the course of the study this meant that there were potentially 840 entries for each participant, or a total of 45,360 for the study as a whole.

During statistical analysis data were imputed if at least 7/12 of the 2-hour time periods had been completed. Otherwise the data were considered missing and a mean number of hot flushes per day could not be calculated.

It was possible to calculate the mean number of hot flushes for every patient at baseline. Of the 54 initial recruits, four dropped out of the study, and of these, two completed only their baseline data. Of the remaining 52, six failed to complete all the questionnaires on every occasion.

However, 19 of the 54 recruits completed data for every 2 hour period of every questionnaire, and a further 20 completed 95% of entries. The overall rate of missing data was only 8.4%.

Overview of the paperwork

It was generally agreed that there was a lot of paperwork, which could be a burden and took hard work to complete.

I had to make myself work. 'You haven't filled that in, you know, as soon as you get home you need to remember, or tomorrow you'll forget.' (Participant 2)

On the other hand, some found it interesting, and felt that the burden of completion was balanced by the ability to see trends and patterns. One woman commented that the repetitive nature of the questionnaires was inevitable if such trends were to be demonstrated.

It's essentially repetitive, because you were seeing whether you had the same pattern at the beginning, and then half way through, and at the end. And then, you know, when you were finishing treatment, whether the hot flushes came back or they went away again. So I understood that. (Participant 10)

Others said that the data from them enabled conclusions to be drawn about the effectiveness of the treatment.

I think that's probably why the diaries are good because all these clever computers – you can feed in all these different things and they can reach a conclusion. Whereas when you're all talking together it seems a muddle. But I suppose that can sort out trends and things, can't it? (Participant 11)

One participant commented that it had forced her to be disciplined, and her ability to achieve this had given her hope.

I think it taught me a bit of discipline, because I'm not very good at writing letters and filling forms in. I put things off, and that was something I knew I had to do. And I did apply myself to that. So it made me feel there was hope. (Participant 2)

Design of the paperwork

On the whole the group members thought that the paperwork had been well designed, and was easy to understand and well thought out. They did comment on the size of the Hot Flush Diary, which was an A5 booklet, and wondered whether the pages could be made smaller to enable it to be carried around more easily.

It probably would have been easier if it had been slightly smaller, a bit more portable. (Participant 2)

One person had in fact simply folded hers in two to make it more portable.

Difficulties experienced with completing it, and strategies for overcoming them

Some participants seemed not to have had any difficulty with completing the questionnaires, and did not regard them as a problem at all.

How did you find the diaries to fill in? (Facilitator) OK, not a problem (Participant 7)

No (Participant 8)

I didn't find it a problem at all (Participant 5)

However, a number of women mentioned difficulties they had experienced with completing the Hot Flush Diary, which was the most onerous of the demands made of them. One difficulty was finding words to describe the flushes.

Trying to write words to convey how you felt, that was a bit difficult. (Participant 4)

Rating the intensity of the flushes was also difficult. They felt that it was an embarrassing topic which could not be openly discussed and they could not know whether a flush they described as intense would be rated in the same way by someone else.

What I found difficult actually was, was my hot flush, you know, the same as everybody else's? (Participant 2)

It's not something, really, you can talk to somebody else about, is it, really? Unless you're in this sort of context and you can't walk into work and say, "Hey, is your hot flush like mine?". (Participant 3)

In addition, they found it difficult to remember to fill in every flush. Sometimes when filling in the diaries they had forgotten when they had had one, or they had no pen and paper to hand to use as a temporary record. It was particularly difficult to ensure that every flush was recorded if they were at work or out of the house for some other reason.

I found it difficult to remember what time you'd had one. (Participant 2)

I just found remembering to record every one a bit of a problem, if you were out or you were at work, you know. (Participant 6)

The main way of overcoming these difficulties was either to carry pen and paper everywhere, or to use items that are usually to hand such as personal diaries, bus tickets or till receipts to note down number and times, and then to transfer the data to the Hot Flush Diary later.

I used to fill it in my diary and, you know, a little ticket or something, bus ticket. And then I'd fill the thing in properly in the evening. (Participant 1)

I ended up taking notes in the middle of the night (Participant 3)

The high completion rate for this questionnaire indicates that somehow or another the women were able and willing to take time and trouble to supply the data.

What it showed them

The participants felt that, in addition to providing data for the researcher, the paperwork had showed them a number of interesting, and sometimes surprising, things.

First, it showed them just how frequently they were having the flushes, and some felt that this validated their sense of distress. Several of them were surprised at just how many flushes they were having, and one said that she felt that without the numerical data no-one would believe her.

Were you surprised by how many you were having? (Participant 6)

I couldn't count all mine because you weren't where the sheet was to put it down. And I was amazed. I was absolutely amazed. (Participant 7)

I don't think any of us were conscious of quite how badly we all individually suffer. (Participant 8)

When we got the data sheets and we filled them all in I thought, "She's going to think I'm making this up", you know 20, 30, 40. (Participant 7)

Secondly, it showed them that the flushes came according to some pattern, and enabled them to identify triggers, such as alcohol or chocolate, which they found both interesting and useful.

The paperwork ... in itself was interesting. You know, weeks go by and you think, "Oh, I've had so many this week", and then when you actually have to record them they sort of set a pattern. You know, you always seem to have one in the morning, or having a hot cup of tea ... you had a glass of wine, that was always definitely hot... It can be quite droll, you're quite sad that you've got to do it, but in a way, it's quite good that you do have it, because you realise that these hot flushes are not coming intermittently, just casually, they are coming according to a pattern. (Participant 10)

Thirdly, as the study progressed, the diaries demonstrated any changes that were occurring, such as improvement in sleeping or reduction in hot flush frequency.

I was quite surprised actually when asked to keep a diary in fact how many I had in a day, it went from something like 15 or 16 right down to six. (Participant 2)

I had almost immediate benefit and I hadn't realised how many I was having until I started keeping a diary, and that was sort of 17, 18 a day and went down immediately. (Participant 11)

Motivation to fill it in

Motivation for completing the paperwork was mentioned by several participants. Some wanted to help as repayment for being offered the treatment.

You're having this one to one treatment and you've just got this feeling that someone's really going to try and sort you out. It's almost a luxury. They're putting input into you and you feel you want to put input back in. (Participant 5)

Well I would say that anybody that was as desperate, as we all obviously have been, you would be quite happy to write a book, wouldn't you? It was so easily worded, and easy to follow, you were thinking, "Well if this benefits, it's just so worthwhile, just worth doing". (Participant 5)

The fact that it was a bit of a pain for us doesn't really come into it if you're keen on helping, does it? You just do it. That's how I felt. (Participant 1)

For one woman there was simply no question about it.

You're obviously going to keep them anyway. (Participant 9)

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Discussion

Only one third of the women invited to the focus groups actually took part (two of the 50 original study participants had left the area). This may have been because the groups took place during the summer holiday period, and two of them were held during working hours, but the actual reasons remain unknown. It is not possible to generalise from the comments made by those who did attend, nor can any inferences be drawn about the possible attitudes to the paperwork of those who did not.

Nevertheless, the high response/completion rate, as well as the low drop-out rate from the original study (only 2 out of 52) does indicate that the paperwork was not a major deterrent either to recruitment or to compliance.

Patients take part in research for a number of reasons, which may be more or less altruistic. The women who participated in this acupuncture research were offered treatments at no cost to themselves, and this treatment was available only as part of the research project. In addition, the treatment was for a distressing problem for which they had found no acceptable alternative solution. It is not surprising, therefore, that they felt inclined to express their gratitude by giving something back. It was also made clear as part of the informed consent procedure that the paperwork was integral to the study, and therefore the women may have felt an obligation to complete it. However, such a high compliance rate may indicate that this acceptance was more than a grudging one.

The acupuncturist took trouble to make the diaries as easy and pleasant to handle as possible, for instance by using pastel coloured paper and making it into a stapled A5 booklet rather than a series of A4 sheets stapled at the corner. One effect of this is to make it clear that there is text on both sides of the paper, thus avoiding the problem of participants completing only one side of a questionnaire.

It would seem that, at least for some research participants, completion of questionnaires can be both interesting and informative. They can demonstrate trends in what at first sight may seem to be a random series of events, and can show gradual changes, which might otherwise be overlooked.

In addition, where symptoms are very frequent and distressing but may be perceived by some as trivial, the completion of such paperwork as the Hot Flush Diary can confer legitimacy on the patient's distress.

Conclusions

This study demonstrates the difficulty of predicting how patients will react to individual aspects of participating in a study. Although these women had found the paperwork trying, they also reported a range of positive opinions which had been unforeseen by the researcher. It also offered some of them an opportunity to feel that they were making a contribution, and to express their gratitude for being given the treatment. It would be unfortunate if those evaluating a proposal were unaware of the benefits to self-esteem that such an opportunity may offer.

Although involving patients in the design of studies is becoming more common, those who had not been participants themselves might have been no more likely to predict some of these responses than the members of the ethics committees. Perhaps the key conclusion is that we should beware of making assumptions about patients' responses.

References

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