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Participants' Experiences of Being Debriefed to Placebo Allocation in a Clinical Trial

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Abstract

Participants in placebo-controlled clinical trials give informed consent to be randomized to verum or placebo. However, researchers rarely tell participants which treatment they actually received. We interviewed four participants in a trial of acupuncture for irritable bowel syndrome, before, during, and after they received a course of placebo treatments over six weeks. During the final interview, we informed participants that they had received a course of placebo treatments. We used an idiographic phenomenological approach based on the Sheffield School to describe each participant's experiences of being blinded to and then debriefed to placebo allocation. Our participants' experiences of blinding and debriefing were embodied, related to their goals in undertaking the study, and social (e.g., embedded in trusting and valued relationships with acupuncturists). We suggest ways in which debriefing to placebo allocation can be managed sensitively to facilitate positive outcomes for participants.

Keywords

ethics/moral perspectives; Giorgi; health care, alternative and complementary; interviews, semistructured; phenomenology; research participation; research, quantitative

Concealment is inherent in placebo-controlled clinical trials. Well-designed placebos resemble the real (*verum*) treatment in every possible way barring the active pharmaceutical ingredient. Design features such as visual appearance, taste, and smell, make the placebo indistinguishable from verum treatment. If trial participants can reliably distinguish between placebo and verum treatments and thus identify their treatment, then blinding is considered to have failed and the trial's validity is questionable (Fergusson, Glass, Waring, & Shapiro, 2004). Although participants give informed consent to be randomized to verum or placebo, they are typically never told which treatment they actually received: they are not debriefed to treatment allocation (Di Blasi, Kaptchuk, Weinman, & Kleijnen, 2002). Investigators give various reasons for not debriefing trial participants including: never having considered it, being concerned not to bias follow-up assessments (Di Blasi et al., 2002), having concerns about the resources required and wanting to avoid possible negative effects on participants (Shalowitz & Miller, 2008). However, there is consistent evidence that research participants do want to be debriefed (Shalowitz & Miller, 2008). For example, 93% of 1492 participants in the PROSPER study wanted to learn their treatment allocation (Dinnett et al., 2005). Participants in the placebo-controlled ORACLE study were disappointed that a summary of the results did not reveal their own treatment allocation (Dixon-Woods, Jackson, Windridge, & Kenyon, 2006). This issue is potentially relevant to a large number of trials. Despite debates regarding the acceptability of placebo-controlled trials (Stang, Hense, Jöckel, Turner, & Tramèr, 2005) it remains common practice in many settings to use placebo controls (Evans, Clark, Moore, & Whorwell, 2007; Hochman & McCormick, 2010; Naldi et al., 2010).

Shalowitz and Miller (2005) argued that an obligation to debrief participants (if they desire it and it will not threaten personal safety), flows directly from the ethical principle of

respect for autonomy. Official guidelines do not yet incorporate this argument. According to the United Kingdom's research governance framework, researchers should provide prompt feedback to participants concerning the results of a study (Department of Health, 2005). However, it is unclear whether this feedback should include information about treatment allocation. In the United States, guidelines emphasize the potential for feedback to have negative psychological effects and suggest that research findings should be proven clinically useful before being shared with participants (Shalowitz & Miller, 2005). In genetics research, there are specific arguments for not disclosing individualized findings to participants, and these have been incorporated into guidelines (Beskow et al., 2001; Richards, Ponder, Pharoah, Everest, & Mackay, 2003).

Debriefing to placebo allocation appears to raise more issues than debriefing to verum allocation. Three concerns can be identified. One, that people who have benefited from placebo treatment might relapse on debriefing. This is not entirely supported by the literature (Chung, Price, Verne, & Robinson, 2007; Sandler, Glesne, & Geller, 2008), but more research is needed particularly in clinical populations. Two, that debriefing to placebo might engender mistrust of physicians and harm future doctor-patient relationships. The converse is also conceivable: not being told what treatment one has received (i.e., continued deception) might engender more mistrust than would open and supportive debriefing. Three, that debriefing to placebo might have negative psychological consequences for participants. Negative psychological consequences have been documented, but there is also evidence of positive psychological consequences.

Participants with Parkinson's disease who had all been debriefed to placebo allocation (in 14 different trials) were surveyed about their experiences approximately twelve months later. Most (54%) remembered being surprised or shocked but 36% had thought they were on placebo; the majority (60%) reported feeling neutral, a minority (28%) felt "disappointed", and a few

(12%) felt “pleased”. Respondents were generally positive about their experiences and were willing to consider taking part in future trials (Goetz, Janko, Blasucci, & Jaglin, 2003). Most participants (83%) in a trial of corticosteroids for heel pain wanted to be debriefed, and the reactions of participants who were debriefed to placebo ranged from “slight embarrassment” to “amazement and excitement” (Di Blasi, Crawford, Bradley, & Kleijnen, 2005). Other investigators have reported that debriefing to placebo has few detrimental effects (Avins et al., 2008; Buchwald et al., 1993; Dinnett et al., 2005). Shalowitz and Miller (2008) argued that even if debriefing to placebo might cause psychological distress, this is insufficient to justify not communicating results to participants. Surely any potential distress could be minimized through the sensitive use of well-considered procedures to debrief those participants who want to be debriefed, and to provide them with a rationale for their experiences (Di Blasi et al., 2005).

We have argued above that debriefing participants to placebo allocation is an important and worthwhile activity. However, our current understanding rests on a small number of predominantly quantitative studies. Very little has been written about participants themselves, about how they experience being debriefed to placebo allocation. We decided to explore participants’ perspectives using an existing set of rich qualitative interviews with trial participants who were debriefed to placebo allocation. We drew these interviews from a qualitative study which was itself nested within a major clinical trial (described below). Investigators in the original qualitative study explored prospectively the experiences of trial participants who received placebo treatment; the primary report did not describe participants’ experiences of being debriefed to placebo. We decided to conduct an idiographic phenomenological analysis to focus in depth on participants’ experiences of being blinded to and then debriefed to placebo allocation in this clinical trial. We chose a phenomenological approach

to facilitate the rich description of participants' unique lived experiences. We chose an idiographic approach to explore these experiences in depth (Yin, 2009). In this article, we describe in detail how participants responded to being debriefed to placebo allocation, with a view to (a) foregrounding an experience that has rarely been written about; (b) developing a preliminary understanding of the nature of participants' experiences; and (c) suggesting future directions and implications for research practice.

Methods

Setting

The primary goal of the parent study and the nested qualitative study from which the current interviews were drawn was to examine placebo effects. The detailed protocols and main results of the parent trial have been published elsewhere (Kaptchuk et al., 2008) as has the nested qualitative study (Kaptchuk et al., 2009). The research team told participants that the study was a placebo controlled trial of acupuncture and participants gave consent on that basis. At the end of the study, researchers told participants that the primary aim was to explore the patient-practitioner relationship and placebo effects and gave them the opportunity to withdraw their data. The institutional review board (IRB) of the host institution approved the entire research project.

The parent trial. In brief, participants with irritable bowel syndrome (IBS) were randomly allocated at baseline to one of three arms: a waiting list control, placebo acupuncture with limited interaction consultation, or placebo acupuncture with augmented interaction consultation. In the limited interaction consultations, practitioners introduced themselves in the initial consultation and explained that they had been "instructed not to converse with patients." This introduction lasted at most five minutes. In the augmented interaction consultations, practitioners spent 45

minutes developing rapport with patients at the initial visit. They followed guidelines concerning content (e.g., ask questions about symptoms, relationships and lifestyle) and style (e.g., active listening). Practitioners performed placebo acupuncture with a validated placebo needle that touched but did not penetrate the skin and instead retracted into the handle of the needle (Streitberger & Kleinhenz, 1998). Participants received treatments twice a week for six weeks and were re-randomized after the first three weeks to continue on placebo acupuncture or switch to real acupuncture. As a retention device, the research team offered participants who only received placebo acupuncture a free course of treatments at the end of the trial. Overall, 262 patients took part. As hypothesized, augmented consultations resulted in clinically and statistically significant improvements beyond those resulting from limited consultations (Kaptchuk et al., 2008).

The nested qualitative study. The research team randomly selected 27 trial participants (nine per treatment arm) to take part in the nested qualitative study. Semistructured interviews were scheduled for before, half-way through, and at the end of each participant's treatments. The team analyzed 12 participants' experiences of receiving placebo treatment (six had received placebo throughout and six had received placebo for the first half of the trial only). Participants "hoped" for but did not "expect" improvements in their health and wellbeing, reported various kinds of improvements with differing levels of confidence, and were concerned with the veracity of their treatments and the cause of any perceived improvements (Kaptchuk et al., 2009). The primary report did not describe participants' experiences of debriefing to placebo. Therefore, we undertook the present analysis to address this topic.

Participants

This article is based on interviews with three men and one woman. Ideally, we would have selected a sample of participants for this study from all those who had received placebo acupuncture and completed the main qualitative study. Unfortunately, this was not possible because some staff at the research facility found the debriefing process disruptive and, after four participants had been debriefed in person, they contacted the IRB who then asked the study team to debrief subsequent participants by mail. Participants who were debriefed in person were debriefed as part of their final end-of-study interview. Participants who were debriefed by mail were sent letters after their final interview and were not interviewed again about this experience. Thus, four participants' reactions to being debriefed to placebo were audio-recorded and available for inclusion in this study.

Three participants took part in all three interviews; one did not have a pretreatment interview. Three received augmented interaction consultations; one received limited interaction consultations and modified the frequency of treatments because of family commitments. All four received placebo acupuncture throughout the trial. Participants ranged in age from twenty-something to sixty-something; all had at least some college education. They constitute a homogeneous sample for this analysis in that they all took part in the same trial; such a sample can be helpful when initially exploring a phenomenon (Giorgi, 1985) and so we did not attempt to locate and interview people who had been debriefed to placebo after participating in other trials.

Interviews

We used semistructured open-ended interviews to explore participants' experiences of IBS and the trial. The interview guide was designed to elicit participants' narratives and models of illness

and of therapy, their somatosensory experience, their experiences of social support, and their expectations related to the trial. A medical anthropologist (Eric Jacobsen) performed all interviews in a large teaching hospital where participants also received their trial treatments. Participants gave informed consent to take part in the nested qualitative study and were reminded at the start of each interview that they could skip any questions that they did not want to answer. The interviewer debriefed participants during the final interview, by giving or reading a letter to them. The letter provided an explanation of placebo effects and information about how to access a course of real acupuncture (paid for by the study) if the participant so desired. Each interview lasted approximately forty five minutes and was audio-recorded and transcribed verbatim.

Traditionally, phenomenological studies collect reflective, narrative accounts of what it is like to experience a particular phenomenon. However, semistructured interviews have been used in phenomenological studies (e.g., Ashworth, Freewood, & Macdonald, 2003) and can provide valuable first-person accounts of participants' experiences depending on the interviewer's approach. In our study, we chose to undertake the phenomenological analysis reported here after the interviews had been completed. We believe that the interviews were nevertheless suitable material for this analysis because the interviewer used open-ended questions and allowed participants to give detailed personal accounts of their experiences in the trial before probing for additional details. Furthermore, the interviewer asked phenomenological questions about how participants felt about not knowing their treatment allocation. To avoid missing important aspects of participants' experiences of being blinded to treatment, we did not focus exclusively on this material. Instead, we considered these answers in the context of participants' experiences of the whole trial and also in the locally-situated context of the interview.

In the final end-of-study interviews we recorded the act of debriefing itself. Participants had had neither time nor opportunity to reflect on their allocation but rather offered their immediate responses and (sometimes) went on to develop more detailed interpretations. This offered a unique opportunity to focus on how participants made sense of their debriefing in real time, in the presence of and sometimes in collaboration with the interviewer-debriefer. We thus attended to both the interviewer and the interviewee in analyzing these experiences.

Analytic Strategy

As explained above, our approach was idiographic and phenomenological. We based our analytic methods on those developed by Peter Ashworth and the Sheffield School (Ashworth, 2003), which incorporates some steps described in Giorgi's descriptive phenomenological psychology (Giorgi, 1985). The Sheffield approach was developed in phenomenological psychology and has been used to examine diverse phenomena such as plagiarism (Ashworth et al., 2003) and Alzheimer's disease (Ashworth & Ashworth, 2003).

We chose to follow the Sheffield School's methods because they are particularly suited to social and cultural phenomena which are not foundational matters of human existence. Being debriefed to placebo is not a matter "without which lived experience would be unimaginable" (p.264, Ashworth et al., 2003) but is instead tied to a particular local context of medical research, practice, and governance. For such matters, the phenomenological aim becomes to elucidate the meaning of the phenomenon for a particular person in the context of their lived and felt experience (Ashworth, 2003; Ashworth et al., 2003). To achieve this elucidation, the researcher must put aside presuppositions and enter the lifeworld of the participant through a bracketing process. This involves setting aside personal and academic assumptions about the phenomenon (internal suppositions) as well as other wider assumptions connected to the external phenomenon

(external suppositions) for the duration of the analytic process (Gearing, 2004). According to the Sheffield approach, the assumption that any essential or general structures will emerge should also be bracketed and hence a small sample is appropriate and we retain an idiographic approach in the presentation of our results (Ashworth, 2003; Ashworth et al., 2003).

To guide the elucidation of meaning of contingent phenomena in the lifeworld, Ashworth has identified and described seven fragments of the lifeworld from key phenomenology texts (Ashworth, 2003). These fragments are seen as essential features of human lived experience, distinguishable yet intertwined, which can be used as heuristics to guide the phenomenological description of particular lifeworlds (see, for example, Ashworth & Ashworth, 2003; Ashworth et al., 2003). Although they are not seen as individual elements, not all fragments will be central to any one phenomenon. In Table 1 we describe each fragment and illustrate the types of questions raised in our analysis.

INSERT TABLE 1 ABOUT HERE

Analytic Procedures

As the principle researcher in this study, Felicity Bishop began by familiarizing herself with the data, approaching the interview transcripts with an open mind and viewing them as records of participants' experiences within the trial produced with the help of the interviewer. She examined each interview from a single participant in the context of their other interview(s), and proceeded idiographically by working through the following steps for each participant in turn. Felicity split interview transcripts into meaning units (sections of speech that convey a single meaning) which she then subjected to a series of translations. When performing translations, she wrote a detailed description of the meaning in each segment while staying close to the data and trying to reflect the world of the participant (Ashworth & Ashworth, 2003) rather than

employing any hermeneutic of suspicion (Ashworth, 2003). She used Microsoft Excel to facilitate this process, entering each meaning unit into a separate row (in order) and each translation into adjoining columns.

Felicity first produced a descriptive translation of each meaning unit, employing the phenomenological epoche i.e., putting aside, or bracketing: questions of the "truth" value of participants' accounts (she treated accounts as true for the participant at the time and place of speaking); preexisting knowledge and personal beliefs related to the subject (e.g., theories, notions, and "facts" about the nature of real and placebo acupuncture); and all study aims beyond description (e.g., implications for future research). She then produced a second translation of each meaning unit, attempting to open up its psychological features while still remaining true to the participant's world. For example, this could involve a description of the participant's beliefs, cognitions, or emotions, but did not involve reading the text through a lens of any grand psychological theories (Langdridge, 2007). Felicity then produced a third translation, in which she considered each meaning unit in terms of the fragments of the lifeworld.

Finally, Felicity reviewed the translations in relation to each other, the original meaning units, and the interviews in their entirety, to create a narrative rendering of the analysis. Un-bracketing occurred after the production of the narrative rendering, at which point she made links to existing literature and considered implications for research and research practice. Below, we describe each individual participant's experience of being blinded and then debriefed to placebo allocation. We use pseudonyms in place of real names; quotes and excerpts from the interviews illustrate our analysis and enhance its transparency.

Results

Frances's Experiences

At the start of the study, Frances's project was to see whether acupuncture could help her, if it could reduce her IBS symptoms (constipation, abdominal pain, bloating); she hoped this would have happened by the end of her treatments. Although Frances had never tried acupuncture her mother had and, based on this, Frances knew that acupuncture could be beneficial and believed in it as an alternative medicine. Being blinded to treatment allocation presented a possible obstacle to Frances's project. If she did not know whether she was getting real or placebo acupuncture, then she could not determine whether acupuncture could help her. However, she did have a secondary project that could be accomplished: to help "somebody else" by participating in research.

When the interviewer first asked how Frances felt about being blinded to treatment allocation, Frances asked the interviewer about the nature of the two treatments. How placebo acupuncture was performed was Frances's "biggest question", which she raised multiple times across her three interviews. Until she was debriefed in her final interview, Frances believed that the real and placebo treatments both involved penetration with acupuncture needles and were therefore both forms of acupuncture. According to Frances, in verum acupuncture the needles were inserted into the body at points that were specific for IBS and in placebo acupuncture needles were inserted at points indicated for relaxation. During her second interview, she described her embodied experience. She found acupuncture relaxing and as she went through the trial her symptoms improved and she experienced very little abdominal pain and reduced bloating. She felt the needles but they did not usually hurt, although some were more noticeable like the needles that "went into my stomach and it seemed like a different area or they just went

deeper a little bit, and I could feel those." The interviewer asked how Frances thought acupuncture works, but Frances focused on whether it works rather than how it works:

> I'm a firm believer in acupuncture, not that I've ever had it [before the trial]. My mom did and a few other people I know have had it and they've always had positive results from it. So you know, I figure, hey, any kind of acupuncture is bound to make a difference in something. I don't know exactly what. Maybe they're sticking needles where there is nothing. I don't know! But it's working, whatever it is.

By her third interview, Frances knew that her symptoms had improved and was reasonably confident that this could be attributed to the treatments she had received. At this point, Frances had achieved her goal to find out that acupuncture can help her IBS symptoms. She was surprised ("wow") when the interviewer told her that she was in the placebo group. Finally, Frances's big question was answered and she was told that placebo needles do not pierce the skin. This directly contradicted Frances's embodied experience that she had previously shared with the interviewer. The possibility that Frances was wrong was quickly dismissed - she was certain that she felt the needles penetrate her skin - and a collaborative effort was made to explore an alternative that was consistent with both Frances's experience and interviewer's information, that a mistake had been made and some of Frances's treatments had been placebo acupuncture and some had been real acupuncture. Subsequently, when the interviewer asked how Frances now felt about having been in the study she replied "Good if it helps, if it helps somebody." Here, Frances returned to her secondary project to help others; although she was less certain whether acupuncture had helped her, this second goal was more certain (as it did not depend on her receiving real acupuncture).

Interviewer (I): You were in the placebo group.

Frances (F): Wow. But when they put the needles in, was the placebo group one where they just did relaxation acupuncture?

I: No. The placebo, it's a placebo needle. It doesn't really go in.

F: Mine did.

I: It just touches.

F: Well, mine went in deep.

I: You're sure?

F: In my stomach, yeah.

I: I'll have to check that. The letter says.

F: Oh. Hmm.

I: I'll double-check.

F: Yeah, 'coz like, the first girl didn't, it didn't hurt. I could feel them going in. They put tape on and then they put the needle in.

I: Yeah, they always use the tape, yeah.

F: Yeah, and then the girl, the last, the second girl that I had I could feel her twisting them, putting them in. One time I didn't feel it go in on my leg.

I: Maybe they screwed up.

F: Yeah! And gave me half and half.

Alan's Experiences

Alan's project was to control his symptoms and not to let IBS restrict his activities. He had been frustrated by his doctors' lack of support and on entering the study hoped that acupuncture might

either help his stress and/or give him some relief from his symptoms (gas, constipation, pain). For Alan, IBS had two central elements – the psychological (stress, anxiety, emotions) and the physical (diet, gas, constipation). In his pretreatment interview, Alan supposed that acupuncture might work through promoting relaxation which might then improve his IBS symptoms. He had not thought much about acupuncture and joined because this was an opportunity to get some help with his IBS.

In both the second and third interviews, Alan believed that he had real acupuncture. He based this on noticing his acupuncturist's actions and his associated sensations, and thought that he could feel the acupuncturist pushing some of the needles in deeper than others. During one treatment he fell asleep and was woken up by a needle poking his wrist, which again suggested to him that he was receiving real acupuncture. Alan also experienced effects on his IBS symptoms (mainly reduced gas) and an increased sense of calmness. He thought the latter might be from the relaxing nature of lying down for 20 minutes or from the "acupuncture itself." The acupuncturist was important to Alan; she engaged him in conversation and tried to find out about his life, his stresses and anxieties, and the causes of his IBS.

> I think with something as dynamic as IBS where it, it's, you know, if your emotions are so tied in or could possibly be so tied into the actual physical symptoms that you feel that someone needs to be personable and understand who you are and what's going on in your life to be able to treat you correctly.

Alan was surprised to find out he had placebo. He questioned this, he questioned the news that the placebo needle does not pierce the skin, and he questioned whether his acupuncturist was indeed an acupuncturist. He then worked up a positive interpretation of his

being on placebo, that it shows how important mental factors are in IBS, which was entirely consistent with his understanding of IBS as he had described it throughout all three interviews. In so doing, Alan maintained a positive social identity in the interview and took his experience in the trial as a positive affirmation of his understanding of IBS.

I: So, so what's it like for you to find out that it was placebo?

Alan (A): It's a little surprising. Only because I was convinced that it was real.

I: [Laughter].

A: But it also is a good indication of how much of this condition may be mental.

I: Uh-huh.

A: So, and that doesn't surprise me, really, the effects that your mind can actually have on your body.

I: Yeah.

A: That, that really doesn't surprise me, but more because I, I've struggled with it, you know.

I: Yeah.

A: And I feel as though a lot of it is related to stress or anxiety and my body is, reacts to that.

David's Experiences

David wanted a way to control his IBS symptoms and was advised by his doctor to undertake the acupuncture study (rather than a study on herbal pills, which nevertheless remained an appealing option). Once enrolled, David was eager to see if acupuncture would work for him and stopped his antispasmodics to better see acupuncture's effects. However, he knew he might receive

placebo and wanted to be told his allocation (expressed without prompting in his first interview). He was "anxious" to be debriefed and anticipated being disappointed with placebo but took comfort in knowing that he would still be able to try acupuncture (at the end of the trial) even if he was in the placebo group. Despite this knowledge, concern about treatment allocation permeated David's experience of the study: "The jury is still out; hopefully it will tell me after the program." He described how his acupuncturist changed the points that she used during treatment and he interpreted this as meaning that she cared for him and was giving him real acupuncture. His IBS symptoms and overall well-being improved which he partly attributed to "an emotional thing" (consistent with his identity as "an emotional person") and he thought that his feeling emotionally supported by the "wonderful" study personnel was enhancing the acupuncture's effects. By the end of the study he felt so connected to and cared for by his acupuncturist that he could not imagine her giving him placebo. At the start of his final interview David was "really looking forward to" being debriefed and was unsure about his treatment allocation.

> There were times that I thought I was in the real group, but then there were times when I went to try to go to the bathroom, I said "maybe I am in the placebo group" so. There's been improvement, definitely, but I still, I think have a way to go.

When the interviewer asked directly what it had been like not knowing his allocation, David said he did not care and was just glad to have been in the study. Receiving placebo would not challenge this, nor would it necessarily challenge his project to control his IBS symptoms because he believed that sometimes taking placebos can make symptoms improve. On being given his debriefing letter, David announced the results as if at an awards ceremony: "And the

winner is? I was on placebo [sigh]. It's okay." He countered the explanation that the placebo needles did not pierce the skin "one day she definitely did."

On asking about and learning that treatments were allocated at random, David could retain his high opinion of his acupuncturist – if she had allocated him placebo, this might have threatened his perception of her concern for him (he had planned to continue seeing her if he had been receiving real acupuncture). David then focused on the future and decided to have the free real acupuncture treatments (provided elsewhere) and enroll on the other study (of herbal pills, at the same facility) if the trial personnel would allow it. At the end of the interview, David considered the implications of receiving placebo for his experiences in the study. He attributed the benefits he accrued to the emotional support he felt and talked in general terms about how "people" benefit from emotional support: he was not unusual or unique in benefiting in this way. Finally, David questioned the terminology – he knew he felt better because of the study and did not think that the term placebo reflected this.

> David (D): I really do feel that, uh, I got benefit out of it, and it just goes to show you that when people are thinking, thinking that they're being taken care of, that they respond positively to that and that's really important, and I think that's a major, major lesson in all the health factors, that if you know that people are behind you, rooting for you, uh, you know, and that in itself carries a lot of weight in how one feels about oneself. So, yeah, um, I'm, I'm anxious to move forward, I would like to have real acupuncture. Um, I'm interested [in how] the needles feel this time. Uh, I [had thought] that was so funny, I would, I would - I always thought I was so relaxed, I would fall asleep. It was just like wonderful. Uh, so, emotionally, part of the whole thing, the thing is that - even though you call me the placebo group, I don't consider it totally placebo group because there are

other benefits that came out of it that would not have happened if I'd not been in this study. So it may be placebo and I accept that, but there were other things that I know made me feel better because I was in this study.

I: Oh, was this - those are coming here and being with people, and -

D: Even right now. Even, right now.

Ben's Experiences

Ben wanted to treat his IBS. Acupuncture appealed to Ben because it was consistent with his belief in alternative medicines in general, but it was not essential to his future management of IBS. He could take celantathral, which he previously took in a pharmacological trial to good effect. For Ben, taking part in this study was not only a way to try acupuncture, but also a way to help "somebody" through contributing to knowledge about acupuncture that could be disseminated to others. Accordingly, Ben was concerned to provide useful information that would help the researchers.

Ben's thoughts about having placebo were complex and shifting. During the second interview, Ben knew that the treatments were working for him (he was calmer, had a whole new outlook, and his symptoms improved) and this was more important than whether he was getting the real or placebo treatment. He cultivated a positive attitude, thinking this would mean he would get some benefit:

> I come into this gung ho. I figure if I didn't come into it gung ho, then I wouldn't get anything out of it. You know? I mean, I come in saying that if you're going to stick needles in me, and even if they may be a placebo, I'm probably the guy they're going to work on, anyway, because I'm the guy who wants it.

This approach was consistent with Ben's sense of himself as someone who believes that attitudes are important in health. He told other people (in his building, at church) that he was having acupuncture and thought that these people were curious but did not believe him that acupuncture was working. In his final interview, Ben was confident that he was on real acupuncture and when the interviewer asked directly what it had been like not knowing his allocation Ben said he never thought about it. He then returned to his socially oriented project of helping the researchers and worried that he might throw the results of the trial if he had told the researchers he was getting better when he was actually getting the placebo.

Ben was unsure about whether he wanted to be debriefed, but decided to be told his treatment allocation so that he could have the free acupuncture treatments on offer to placebo recipients. His immediate reaction on being told he had received placebo was to question it ("I did?") and then display surprise ("wow"), before asking for information about how placebo acupuncture is done. He conceptualized IBS as having "a lot to do with the mind" and thought that he had improved because he had entered the trial thinking that it would take care of him and help him to relax. This is very reminiscent of his ideas about cultivating a "gung ho" attitude and his beliefs about the role of attitudes and general outlook in health.

Ben's ongoing sense-making related to a number of lifeworld fragments. In relation to temporality, Ben focused on his immediate future and how to access the free acupuncture treatments provided by the study ("what's done is done"). He still believed that acupuncture could work and so still wanted to try it. In relation to selfhood, Ben integrated with his self-identity the explanation of placebo responding offered by the interviewer (as indicating self-healing abilities). A sense of empowerment emerged. Three aspects related to sociality. First,

Ben offered to let the researchers know how his real acupuncture works. He remained concerned to help generate knowledge. Second, Ben decided not to tell other people (outside of the trial) that he received placebo. He did not want to discourage them from trying acupuncture. Third, Ben did not reverse his positive evaluation of his acupuncturist (despite understanding that she knew his allocation). He was impressed that she was able to convince him he was receiving acupuncture and to facilitate his positive response.

> Ben (B): Well, I got to look at it in a positive way and say that, "Hey," you know, like, I mean, you know. It, nah, it it doesn't change, I still believe that acupuncture could work. You know? But it gives me, it tells me something good about myself, that, you know, if I want to be healed, I could be healed because I just, you know. I mean, I know a lot of people still struggling with cigarettes. I just reached my 15th year away from cigarettes, alcohol.
>
> I: Wow!
>
> B: Cocaine, I mean.
>
> I: Wow. That's quite an achievement!
>
> B: You know. So it's you know. So this only adds to that. It's just, you know, so you could take care of other things. You know? If you really wanted and you put your mind to it or whatever, you could take care of other things

Discussion

All four participants thought they had received real acupuncture and were surprised to be told they had placebo. Being debriefed to placebo allocation directly contradicted participants' embodied and social experiences in the trial and thus meant that someone was mistaken: either

the interviewer was mistaken and the participant had indeed received real acupuncture or the participant had misinterpreted their own experiences in the trial and had actually received placebo acupuncture. Frances refused to believe that she had received placebo acupuncture because she was sure the needles had pierced her skin. Alan interpreted his placebo responding as indicating that psychological features such as stress and emotions are very important contributors to IBS. David linked his placebo responding to the emotional support he valued during treatment. Ben integrated his placebo responding into a positive self-identity capable of healing, but was concerned that he might have thrown the trial by benefiting from placebo. These four participants' experiences each have unique features and the particular setting (an acupuncture trial) must be remembered. However, our analysis has produced some insights which bring to mind existing literature and suggest avenues for future research and research practice.

We found little direct evidence in these interviews of unresolved psychological distress on debriefing to placebo. However, our participants had all thought they were receiving real acupuncture and so being debriefed to placebo had the potential to be distressing and participants did develop revised explanations that reconciled their lived experience (of real acupuncture) with the conflicting news (of placebo acupuncture) from the interviewer. This reconciliation was linked to participants' reasons for being in the trial (their projects). Alan, David, and Ben all focused on their IBS rather than on acupuncture. They also believed, to varying degrees, that they could benefit from a placebo treatment. Their primary goals could thus be achieved regardless of treatment allocation. Ben and David also looked to the future and decided to have the real acupuncture treatments provided by the study, thus maintaining their additional goal to try acupuncture. Frances resisted revising her embodied experiences in the trial and instead

denied the contradicting "fact" that she had consistently received placebo. In this way, her primary project was maintained; by taking part in the trial she had tried acupuncture. Future studies should explore the relationship between project and reaction to placebo debriefing. Perhaps the tensions inherent in placebo debriefing could be eased by encouraging trial participants to have goals that relate to their illness or to the production of knowledge instead of the specific treatment being tested.

The embodied experience of our participants was that they had received real acupuncture. They felt the needles pierce their skin and experienced benefit from their treatments. The act of treatment was particularly salient to our participants and their proprioception that the needles entered their bodies was absolutely contradicted by the abstract fact imparted by the interviewer that placebo needles do not pierce the skin. Some participants maintained that the needles had pierced their skin, and such claims were not directly challenged by the interviewer. This is consistent with the observation from discursive psychology that descriptions of invisible subjective phenomena are generally resistant to challenge (Potter, 1996). Similarly, at debriefing participants rarely reconsidered whether or not they had received benefits from the trial. Instead, they reattributed these benefits to aspects of treatment that were not seen as exclusive to real acupuncture (e.g., emotional support, relaxation). This reattribution appeared to be facilitated by participants' understandings of IBS: Alan, Ben, and David understood IBS as involving the mind and/or emotions in some way and were able to make sense of their placebo-responding by interpreting their symptomatic improvements as occurring through psychological means.

Patients commonly attribute IBS to psychological factors, such as anxiety and stress, but also attribute it to physical illness (Lacy et al., 2007; Riedl et al., 2009). Attributing IBS to psychological factors has been associated with diminished mental but enhanced physical quality

of life (Riedl et al., 2009) and with increased anxiety and depression (in cross-sectional but not longitudinal analyses, Rutter & Rutter, 2007; Rutter & Rutter, 2002). The common sense model of illness representations suggests that patients seek treatments that they believe to be consistent with their understandings of their illness (Leventhal, Brissette, & Leventhal, 2003). Our findings show that both attributing one's condition at least partly to psychological factors and also understanding placebo as a psychological treatment can allow trial participants to make sense of benefitting from placebos. Researchers could consider how to help participants to develop positive interpretations of placebo responding in other contexts. Our participants valued positive explanations of placebo-responding in terms of self-healing. Different explanations might better suit participants in studies of conventional interventions or those who attribute their symptoms to physical factors. One option would be to inform participants at the start of the trial about the possible effects and mechanisms of action of the placebo. However, the consequences of such a strategy should be investigated because increasing the credibility of the placebo condition might also increase its effects, thus making it harder for researchers to detect small treatment effects.

Our participants' experiences of blinding and debriefing were social, in that they were embedded in trusting and valued relationships with acupuncturists, told to others outside the study, and described to an interviewer. Participants worked to maintain positive evaluations of their acupuncturists despite having been given placebo by them. This seemed easier when participants understood that the acupuncturists themselves did not allocate treatments. Seeing the acupuncturists as caring therapists working within constraints imposed by the researchers might have allowed participants to maintain a relationship with an acupuncturist who delivered placebo treatments. This need to retain a view of acupuncturists as supportive health care practitioners might be particularly strong in people with IBS (Håkanson, Sahlberg-Blom, & Ternestedt, 2010),

but is unlikely to be unique to this population. Having a clear separation of duties within a trial team and communicating this to participants might enable participants to attribute therapeutic motivations to therapists and still understand the primary purpose of the study to be the production of generalizable knowledge (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987).

By the time they were debriefed to placebo, participants had described to the same interviewer at least once before their experiences of treatment and their beliefs about allocation. This appears to have been partly supportive, offering an opportunity to work through concerns and consider the meanings of debriefing with a trusted member of the research team. However, it also appears to have presented additional challenges around maintaining claim to a positive social image (face - Goffman, 1967) that might have been less problematic if the debriefing had been carried out by someone else. Directly contradicting an interviewee's account was potentially face-threatening for both parties, because it suggested that one account was in some way wrong and the other was correct. It suggested that the participants had been deceived by the investigators (as intended) into believing that they had received real acupuncture. Tactful, supportive, facework was undertaken by the interviewer and participants to avoid conflict by reinterpreting "facts" and renegotiating accounts. This was vividly apparent in Frances's debriefing interview when an alternative account was worked up which allowed both parties to be (partially) correct and thus maintain face. Facework has been examined in clinical interviews (e.g., Bylund et al., 2007; Pollock, 2007); future studies should identify strategies to manage the face-threatening aspects of debriefing interviews. It could be that debriefing participants by letter helps to attenuate the face-threatening nature of this process. However, such methods probably have their own drawbacks (e.g., no opportunity to discuss the implications of treatment allocation with a member of the research team) and so should be studied in their own right.

We would like to acknowledge some limitations of this study. We were unable to interview our participants again some time after their debriefing. Future studies should do this, to explore the nature and extent of any long term sense-making. It is unfortunate that we were unable to select our participants from a wider pool of people who had experienced debriefing to placebo. However, our aim was the description of the particular rather than the production of general "knowledge" and we have systematically engaged with our participants' accounts to produce detailed phenomenological descriptions. To our knowledge, no such descriptions have been reported previously. The parent trial was single blind and the reactions of participants to debriefing might have been partially dependent on active collusion by the researcher to conceal allocation (Miller & Kaptchuk, 2004). Patients made bonds with our practitioners and could have easily felt a sense of additional betrayal that might not happen in double blind research where treatment allocation is concealed from both researcher and participant. Given our participants' emphasis on the sensations felt during treatment, it would be interesting to explore how (or even if) participants derive guesses of treatment allocation in studies of other treatments, where the treatment itself is less salient (e.g., pharmaceutical pills).

We have presented a rich description of four participants' immediate experiences of being blinded and debriefed to placebo in an acupuncture clinical trial, which suggests some implications for the practice of research. When recruiting volunteers to a placebo-controlled trial, researchers could consider exploring participants' reasons for taking part given that they might be allocated to a placebo treatment. When informing participants about trial treatments, researchers could consider communicating the possible effects and mechanisms of action of the placebo in a way that makes sense to the individual participant and links with their illness beliefs. When telling a participant they have responded to a placebo, researchers should be

sensitive to the face-threatening nature of this conversation. Our work suggests that debriefing to placebo allocation can be managed sensitively to facilitate positive outcomes for participants and that this requires thought not only at the debriefing stage but also when recruiting participants and obtaining informed consent. We acknowledge that routinely debriefing participants to treatment allocation will inevitably place extra demands on the limited resources of those running clinical trials. Additional work is needed to explore the long term costs and benefits of different methods to debrief participants and to develop best practice in this area.

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Bios

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Table 1. The Seven Fragments of the Lifeworld Used as Heuristics

Fragment	Meaning [a]	How Used in Analysis of Debriefing
Project	How does this affect the activities to which a person is committed and which they value?	What impact does placebo debriefing have on participants' goals for living with their IBS (seeking to cure/manage/alleviate it)? What do participants value about the trial and how does this relate to placebo debriefing?
Embodiment	How does this relate to the person's feelings about their body?	How does placebo debriefing relate to participants' sensations during treatment?
Selfhood	What does this mean for the person's social identity? What sense of agency, presence, and voice do they have in this situation?	How does placebo debriefing relate to participant's sense of self, their sense of agency or patient-hood in the trial?
Sociality	What does this mean for the person's relations with other people?	What does placebo debriefing mean for the participant's interactions with trial personnel and members of their wider social networks?
Temporality	What is the person's sense of time, duration, biography related to this situation?	What does placebo debriefing mean for participants' future plans for managing their IBS?
Discourse	What terms are used to describe the situation, what discourses are invoked?	What discourses are invoked to describe placebo debriefing? How is placebo debriefing managed in conversation?
Spatiality	How is a person's sense of place affected by the situation?	Not prominent in this analysis

[a] Descriptions adapted from Ashworth (2003).