UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES

School of Medicine

‘Forging a conviction’ – Participants’ experiences of a western acupuncture randomised controlled trial

by

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ABSTRACT

FACULTY OF MEDICINE, HEALTH AND LIFE SCIENCES
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'FORGING A CONVICTION' – PARTICIPANTS' EXPEREIENCES OF A WESTERN ACUPUNCTURE RANDOMIZED CONTROLLED TRIAL

By Clare Marie Hill

Research into acupuncture has shown that individuals continue to report favourable clinical effects despite the lack of systematic evidence supporting a point specific therapeutic effect for real acupuncture treatment. This thesis presents a qualitative study, nested within a large randomised controlled trial of acupuncture specifically designed to investigate both specific and non-specific effects of western acupuncture for osteoarthritis pain. The aim was to explore the non specific effects of acupuncture in a trial context from the participants' perspective, in particular the therapeutic relationship and any additional influences on the patient experience that might lead to non-specific effects on outcomes.

Participants were recruited from hip or knee joint replacement waiting lists and randomised to one of three treatments (real acupuncture or 2 placebo controls) and one of two consultation conditions (empathic or non- empathic). The qualitative methodology was grounded theory. Data collection combined 27 post trial audio taped, semi structured interviews with post treatment debriefing, participant and non participant observation and personal reflections.

The findings of this study identified a core category of 'forging a conviction' and a substantive theory of 'active trial participation' was developed. Participants gave reasons for entering the trial and for maintaining their commitment to it, despite numerous barriers. These experiences helped to forge convictions about the trial interventions and their effects. As a result a combination of specific and non specific influences appeared to impact on the participants' reporting of outcomes, leading to discrepancies between the quantitative and qualitative data.

This theory of 'active participation' in clinical trials challenges some of the basic assumptions of randomized controlled trials, most notably that participants are passive recipients of an intervention and report its effects factually.

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Last but not least I owe a great deal of gratitude to all the people who welcomed me into their homes to be interviewed. This thesis is dedicated to you all – Thank you.

Key to Transcripts

The following abbreviations have been used within all the transcripts (example in appendix 7), and in this thesis document where excerpts of participant interviews are documented.

Names:	All names of participants are pseudonyms.
(Data in brackets)	Treatment and consultation randomisations
Plain text:	These are the participants own words.
Italic text:	The researcher's own words.
Italic bold text:	This denotes a situation or incident that occurred that but was either not recorded at the time or transcribed after the interview due to editing
…	This represents a pause within the original interview data.

Chapter 1 Introduction

1.1 Introduction

This thesis presents a qualitative study, nested within a large randomised controlled trial of western acupuncture, referred to throughout this thesis as the 'hip/knee trial'. A primary aim of the hip/knee trial, funded by the Department of Health (DoH), was the investigation of the process of acupuncture treatment, and the relative contributions of specific and non-specific effects. This included the effects of empathy within the consultation. The purpose of the qualitative study was to explore the participants' perceptions of the consultation and to highlight any additional influences on the participant experience that might lead to non specific effects on outcomes.

I was appointed to work on the hip/knee trial as a practitioner researcher, responsible for the day to day running of the trial which involved recruiting individuals from two National Health Service (NHS) sites and participation in the trial as one of three acupuncturists. In addition to this I was also given the opportunity to register for a PhD and to further develop the nested qualitative aspect of the trial's protocol taking ownership of it. It was anticipated that the gathering of qualitative data about the experience of participation in the hip/knee trial would facilitate the interpretation of the quantitative results. The potential danger of bias associated with my background as an acupuncturist and my involvements in the study was recognised at an early stage but were felt to be offset by the opportunities for applying insider knowledge and direct observation.

Within this chapter I aim to orientate the reader as to the rationale for the study of acupuncture, highlighting the importance of non specific effects and their subsequent exploration. This will be followed by the aim of the thesis and an outline of the document. Firstly however I must return to the issue of bias. As a researcher I am inexplicably part of the qualitative study and therefore as a means of minimising bias and identifying pre existing personal beliefs I have detailed my own personal background in the next section.

1.2 Personal Background

My first experience of acupuncture was as a patient 20 years ago. Since then I have trained as both a Registered General Nurse, and 'professional acupuncturist' in the belief that both these skills enhance each other and my ability as a health care professional. In 2002 my career path led me into work as a research acupuncturist on a study evaluating the efficacy of standardized acupuncture treatment for chronic, disabling non-malignant breathlessness. Treatments were given during home visits and the role was to provide both acupuncture and a placebo treatment in the form of an inactive Trans-cutaneous Electrical Nerve Stimulation (TENS) machine on a crossover basis. From personal experience patients were seen to regularly improve during the trial, especially in relation to their enthusiasm, personal interaction, symptoms and on occasion self esteem. I was disappointed to learn of the statistically non significant result of the study, in terms of a specific therapeutic efficacy i.e. the reduction of breathlessness with acupuncture. However the overall findings were that those individuals entered into the study did experience clinically significant benefit from both treatments therefore a clinical effect was clearly demonstrated. It concluded however that this was probably due to the non-specific process of receiving domiciliary treatments (Lewith, Prescott & Davis 2004). This difference in efficacy and effectiveness initiated my interest into the possible non-specific effects of these encounters and caused me to question my beliefs about the specificity of my chosen therapy. I wanted to explore the notion that acupuncture offers many therapeutic options, which may produce clinical effectiveness through both specific and a variety of non-specific mechanisms. Undertaking this PhD has allowed me this opportunity,

1.3 The acupuncture anomaly

Acupuncture is one of the most widely used of the CAM therapies (Thomas, Nicholl & Coleman 2001). Its use in the treatment of chronic pain, specifically musculo-skeletal pain, is well documented (Eisenberg, Davis & Ettner 1998; MacPherson, Thomas, Walters & Fitter 2001;Orpen, Harvey & Millard 2004; Price & White 2004; Vickers & Zollman 1999; White 1998; White, Hayhoe, Hart

& Ernst, 2001), however the ever increasing number of systematic reviews and meta analyses evaluating the treatment of chronic pain with acupuncture over the last decade (Ernst & White 1999; Ezzo, Berman, Hadhazy, Jadad, Lao & Sing 2000; Patel, Gutzwiller, Paccaud, & Marazzi, A1989; Tier Reit, Kleijnen & Knipschild 1990; Van Tulder, Cherkin, Berman, Lao & Koes 1999; White & Ernst 1998) are often inconclusive as to its effect over 'placebo acupuncture'. Indeed even recent trials investigating the efficacy of real acupuncture in comparison to sham acupuncture[1] for the chronic pain conditions of fibromyalgia (Assefi, Sherman, Jacobson et al 2005) and migraine (Linde, Streng, Jurgens et al 2005) demonstrated either minimal or no efficacy when compared to placebo intervention. However what is clear from all the recent large German studies that compared real and sham acupuncture with conventional treatment is that while real and sham acupuncture may be equivalent, they are both consistently superior to current best conventional practice in the treatment of musculo-skeletal pain (Witt, Brinkhaus, Jena, Linde, Streng, Wagenpfeil, et al 2005; Brinkhaus, Witt, Jena, Linde, Streng, Wagenpfeil, et al 2006).

Initially exclusive to private practice, acupuncture is now increasingly available as a NHS provision in both primary and secondary care. Yet this popularity exists within a culture of evidence based medicine that recurrently presents inconsistent outcomes with regard to efficacy of real treatment when compared to sham placebo controls. Furthermore those individuals receiving acupuncture treatment continue to anecdotally report favourable clinical effects (Lewith et al 2004) despite evidence collected systematically that does not always support a specific effect. This raises the issue of effect versus efficacy in acupuncture from the patients' perspective; it seems to work for many people so 'how can it all be placebo?'

For the purposes of this thesis it is helpful to differentiate between efficacy and effectiveness. There are a number of ways in which these terms can be defined, for example Donabedian (1990) explains them in relation to quality of health

[1] The term sham acupuncture is used to describe a control procedure that, ideally, is identical in appearance and experience to acupuncture but lacks any of the presumed treatment- specific effects. (MacPherson et al 2008).

care. Efficacy and effectiveness are just two of seven attributes of health care that characterize its quality. Efficacy is defined as the ability of care, at its best to improve health, whereas effectiveness is the degree to which attainable health improvements are realized (Donabedian 1990).

From research perspective Sherman, Linde and White (2008) offer the idea that the terms efficacy and effectiveness may be described by the research question associated with it. For example an efficacy trial may ask the question 'does the treatment work under highly controlled settings with optimal administration of the treatment?' Whereas an effectiveness trial enquires as to whether there is a therapeutic benefit when the treatment is given under everyday conditions (Sherman et al 2008). The definition used within this thesis however is that of the quantitative, scientific view as asserted by White, Linde and Schnyer (2008). In these terms effect is defined as the overall improvement from a baseline value as a result of receiving a course of treatment. This is in comparison to efficacy which is an evaluation of whether acupuncture is better than a placebo i.e. efficacy informs us as to whether it is the intrinsic therapeutic action of needling itself that improves outcome or whether the change in clinical picture is due to some other element (White et al 2008). One possible explanation offered for this effect versus efficacy anomaly in acupuncture, is the impact non specific effects of the treatment may have on outcome.

1.4 Non- Specific effects of acupuncture

Within clinical trials, non specific effects are defined as the contributions to outcome from anything other than the specific component that is being tested (Macpherson, Hammerschlag, Lewith & Schnyer 2008). What constitutes non specific effects varies depending on the hypothesis. It has been asserted that when acupuncture is performed in a clinical setting, the result of the treatment is a combination of specific and non-specific effects. Birch, Hammerschlag, Trinh, & Zaslawski (2002) suggest that specific effect is thought to arise directly from the puncture and manipulation of a needle in a recognized acupuncture point, all other factors presenting concomitantly with the treatment and effecting outcome are deemed non-specific.

Acupuncture generally involves the insertion and manipulation of fine, sterile needles into specific or tender points on the body. Many of these specific 'acupuncture' points are found along theoretical channels or meridians that run over the surface of the body. As mentioned previously the specific effect of acupuncture is thought to arise directly from the puncture and manipulation of a needle in a recognized acupuncture point (Birch et al 2002). Any other factors presenting concomitantly with the treatment and effecting outcome are deemed non-specific. These can include issues pertaining to context, beliefs, rapport in other words they are varied and complex in nature. In comparison to Birch et al's components of a therapy, Filshie & White (1998) classify the specific effect as a treatment factor in addition to relaxation, duration and repetition of treatment. They offer their own interpretation of factors that may influence treatment outcome; these are attitudes and expectations, socio-cultural beliefs, personal preferences and previous experience of the patient, and time, empathy, communication skills and the ritual therapeutic performance of the practitioner (Filshie & White 1998). However this is primarily related to the interaction within the Therapeutic Relationship (TR) and does not encompass the issue of context. Birch et al (2002) consider the research implications and hypothesise six main non-specific effects of acupuncture which they believe need to be addressed where research is involved (see Table 1).

Table 1 Birch et al's six main non specific effects of acupuncture

Non Specific Effect	**Example**
Context effects	Treatment environment
Patient based effects	Expectations and previous own experiences, or those of friends and family
Practitioner based effects	Enthusiasm. Intention
Patient/practitioner interaction effects	Rapport, communication, partnership
Regression to the mean	Natural fluctuations in or course of the disease/condition
Generalised needling effects	Analgesia, endorphin release, relaxation

(Birch et al 2002)

Miller, Emanuel, Rosentein & Straus (2004) agree with the notion of non specific effects emanating from a variety of sources and discuss the fallacious belief among CAM practitioners and teachers of '*post hoc ergo propter hoc'* (after this, therefore because of this). They assert that an improvement post treatment may in fact be due to a self-limited course of disease, waxing and waning of symptoms, spontaneous remission and the placebo effect in addition to treatment efficacy (Miller et al 2004). It can be concluded from this that Miller et al consider those factors described by Birch et al as part of the placebo effect and not individually recognisable non- specific factors in their own right. This will be considered further in chapter 2, along with a review of the introductory literature. However the bulk of the literature review is integrated into the discussion of the findings.

1.5 Research aims

Based upon the existing literature on the outcome of acupuncture for chronic pain, and the effect versus effectiveness anomaly that prevailed within this field the qualitative study wished to explore the non specific effects of acupuncture within a clinical trial setting. The research questions it wished to consider were:

- "What is it about acupuncture that causes recipients of the treatment to report benefits even if no significant specific therapeutic effect is demonstrated over a control intervention?"
- "Is it the efficacy of the treatment itself that is offered, or is outcome inherently linked to the delivery system used and or its associated non specific effects, experienced by those individuals receiving the treatment?"
- "What are the implications of receiving acupuncture within a clinical trial setting from a participant's perspective?"

Initially focusing on the participant's experiences of taking part in the trial, with the hope that an insight would be gained into the trial participants' experiences of varying practitioner interaction and the effect it may have on their response to

treatment, its emphasis became broader over time. This was in response to the study's emergent findings highlighting that the issue of practitioner empathic intent was apparently incidental in comparison to a complexity of factors underpinning participation in the hip/knee trial as whole.

1.6 Structure of the thesis

This thesis is presented in ten chapters. Chapter one has discussed the context in which this study is set, and the general purpose and aim of this thesis. In chapter two I present a background to acupuncture and discuss the challenges of researching such a complex intervention. Following this in chapter three I discuss the methodological challenges faced when working within two research paradigms (quantitative and qualitative), explaining my chosen method of enquiry and outlining in more detail the design and aims of the hip knee trial in which my qualitative study is nested. The fourth chapter details the method I used for the qualitative study. Chapter five details a background to the findings, which are then presented in chapter's six to nine inclusive. Finally in chapter ten I present my discussion, conclusions and recommendations for future research.

Chapter 2 An overview of acupuncture

2.1 Introduction

This second chapter presents a discussion on acupuncture in general and the challenge of researching such a complex intervention. Rather than include a specific literature review, existing introductory research forming the background to this thesis has been imbedded within the text of this chapter. Within it I will provide a brief overview of the history of acupuncture in both the East and West, followed by consideration of research specific issues pertaining to the topic.

Derived from the Latin *acus* meaning needle and *punctura-pungere* to prick (Mann 1973; Marcus 1991), acupuncture is a term used to describe skin penetration with a specific acupuncture needle. However the methods of actual treatments carried out under the title of acupuncture are varied and numerous, and it is argued by some practitioners of laser acupuncture and Japanese acupuncture that no skin penetration is required. There is no doubt that debate over the nature of the practice of acupuncture is substantial as observed by Martindale (2001), who states that although the skin is punctured by a needle in most cases, what happens next is dependant on who is asked. A Western practitioner may rationalise treatment in relation to pain relief based on nerve pathways or dermatomes, a Traditional Chinese Medicine (TCM) provider in relation to rebalance of *yin yang*, or a Five Element acupuncturist in accordance to a patient's emotional response. As a result the challenge of researching such a therapy is considerable.

2.2 Acupuncture in China

Acupuncture is generally accepted as being founded in China and dating back approximately 3000 years (Cadwell 1998; Unschuld 1985; Zhang 2002). However many argue as to the exact date of its origin, and there are even those that question its Chinese beginnings, hypothesising connections with ancient Egypt (Mann 1973) and Europe- circa 3200 BC (Dorfer et al 1998). Saito (2002)

suggests that the reason for this contradiction, is that evidence before written history is excluded, therefore leaving the definitive date of origin a mystery (Saito 2002). Historically, acupuncture is a treatment modality based within the principles and philosophies of TCM, and is often used in conjunction with other therapies such as herbal medicine, exercise, massage and dietary modification. With this in mind it is therefore difficult to separate medicine in China from Chinese Medicine. The first documented evidence of therapeutic activities, were recorded on bone and tortoiseshell in the Shang dynasty (16^{th}-11^{th} Century BC). During this period, society was based around superstition with illness tending to be regarded as a curse from the 'Ancestors' and or 'wind spirits' – the form of this natural phenomena still being foremost in the theory of TCM today. Shamans were employed to drive out these evil influences with the use of herbs, talismans and 'needle treatment' for demon related illnesses.

By 221BC and the Unification of the Chinese Empire superstition was on the decline and although magical beliefs were still prevalent, they were primarily in relation to nature. The doctrines of *yin yang* and the time-space rubrics of the *wu xing* (the five elements) were a well developed part of traditional Chinese thought. Followers believed that in order to remain in good health a normal fluctuating balance of *yin yang* was required, and survival was possible with adaptation to the seasons and their accompanying diseases (Jizong & Feng 1985). It is thought at this time that needles were used for 'bloodletting' rather than insertion (Epler DC 1980; Saito 2002), or as a magical symbol in the treatment of illness. Alternatively, Woodham (1994) and Jamil (1997) suggest that the Chinese originated the idea of acupuncture when soldiers wounded by arrows found that they recovered from both acute and chronic complaints in parts of the body distant from the wound. TCM is centred on the belief that 12 channels or meridians run through the body. These pathways mark the passage of 'vital energy' or *qi* and each channel is linked to an organ, not in the anatomical sense of Western medicine but the theoretical sense of TCM. In short, stimulation of a specific acupuncture point is thought to treat disease by rebalancing the flow of *qi*, depending on its position on a channel and the organ it is linked to. Thus giving rise to the notion that it was position in the body rather than the puncture

size of the ‘needle’ that was important, and so began the relationship between needling and cure.

One area in which historians are in agreement is the development of acupuncture within TCM, in relation to its textual evidence. Written around 100 BC (Downey 1988; Kaptchuk 1983), the *Huang- di Nei-jing* known today as the *Nei Jing* or Inner Classic of the Yellow Emperor is the first published Chinese medical text. The book which is often described as a ‘bible’ to TCM practitioners, documents a discussion between the Emperor and his Chief Minister. The text is divided into two sections – the simple questions and the spiritual axis. The first details the theoretical concepts of TCM, while the latter is primarily concerned with acupuncture and moxibustion (Kaptchuk 1983). Although undeniably a classic in this era of evidential literature, there is the usual debate over Chinese documents and their ‘loss in translation’, thereby categorizing this book today as work of historical interest rather than a reference for study. However in the Tang dynasty (600-907 AD) the text’s subsequent effect was the production of examination papers for students at the Imperial Medical College. The continuing developments and expansion of its *yin yang* and *wu xing* theories also laid foundation for TCM and the recognition of its importance in preventative care (Yanchi 1988).

Between 960 and 1279 AD many TCM texts were printed, yet opinion altered over time and in 1822 acupuncture was banished from the Emperor’s palace and officially prohibited from use in mainstream Chinese medical care in 1929 (White 1998). White does not elaborate on a reason for this alteration in attitude, but one can safely surmise that the introduction of Western medicine into China in the late 1800’s (Lewith 2000) was a mitigating factor for its decline. Yet Communist China revelled in all forms of traditional medicine, never forgetting its roots and by the 1950’s Mao Tse- Tung had re-established the practice of acupuncture. Its reintroduction was as a means of providing cheap, basic medical care through the barefoot doctors to the millions of liberated Chinese peasants following the Cultural Revolution (Lewith 2000; White 1998). As a result a Bureau of Traditional Chinese Medicine was set up by the government’s Ministry of Health, along with TCM colleges. Lewith (2000) notes, that at this

time many hospitals in China opened up clinics to provide and teach these traditional practices. The development of this form of medicine progressed and variations on these teachings continue in both the East and West today. Current medical practice in China supports doctors in having dual qualifications in both Western and TCM practices, thereby offering patients a medical system of conjunctive theories that theoretically provides them the best of both worlds.

2.3 Acupuncture in the West

As China and the East began to embrace Western medicine, so the West benefited from reports of acupuncture. Needham and Lu (1980) assert that TCM is documented in western medical literature as far back as the seventeenth century. Lewith (2000) concurs with this finding, highlighting an article from The Lancet dated 1823. Written by John Churchill, the first British known acupuncturist it publishes a series of results on the treatment of rheumatism with acupuncture. This subsequently led to further published articles between 1820 and 1840, and conclusions that acupuncture was an effective therapeutic method for such conditions (Lewith 2000).

However most authors are in agreement that the biggest influence regarding the influx of acupuncture into the West came in the 1970's following President Nixon's visit to China in 1972 (Cadwell 1998; Jamil 1997; Vickers& Zollman 1999; White 1998). This, together with the understanding of the neurophysiology of pain and the realisation by Western doctors that pressing, stimulation or injecting of superficial body points (often specific acupuncture points) can relieve pain resulted in a growth of acupuncture provision and practitioners in the West over the last 50 years. Since the late 1970's and in response to the growing world wide interest in acupuncture the World Health Organization (WHO) has followed the progress of acupuncture practice and promoted its development. In 1989 it convened a Scientific Group to approve a Standard International Acupuncture Nomenclature, which is widely disseminated and applied. By 1991 it stated at its 44th World Health Assembly that Member States be urged to introduce measures for regulation and control of acupuncture, especially in countries where modern Western medicine is the foundation of health care. The

group proceeded to develop a series of statements and guidelines relating to basic training, safety in clinical practice, indications and contraindications (Zhang 1999).

To date, there are three regulatory bodies governing acupuncture practitioners in the UK – the British Medical Acupuncture Society (BMAS), the British Acupuncture Council (BAcC) and the Acupuncture Association of Chartered Physiotherapists (AACP). These bodies adhere to strict training requirements, codes of practice, and promotion of professional development in addition to providing indemnity insurance for its members. The rise in acupuncture's popularity as a therapy and the current emphasis on the need for evidence based practice is resulting in imminent changes to the regulation of both acupuncturists and Chinese Medicine herbalists. Despite this, dispute still arises with regard to acupuncture practice. The argument being that in today's society various forms of treatment are available. For example Western acupuncturists appear to have accepted that the therapy can be used for pain relief, justifying it through its scientific explanations alone and not the principles of TCM. Yet Vickers & Zollman (1999) and Van Tulder et al (1999) argue that no clear distinction between traditional and Western acupuncture exists, as practice has or was adapted as differing schools of training emerged over recent decades. Although similar in characteristics to TCM acupuncture each style is distinct and today a service user can have the choice of Japanese, Korean, French Energetic, and Five element acupuncture in addition to Western or TCM practices (Van Tulder et al 1999).

Even the House of Lords report on CAM in the year 2000 indicates the difficulties in defining acupuncture practice. Acupuncture treatment is classified as group 1 – a professionally organised alternative therapy, however TCM is allocated to group 3a – a long established and traditional system of health care. The apparent rationale for this polar categorization is the lack of established evidenced based research to support the efficacy of these systems (House of Lords 2000). Acupuncture practitioners are left in no doubt that research into this therapy, in whatever form it is practiced, is essential for future development and recognition of the treatment. However, what is apparent is that funding for such

work is not limited to efficacy of a treatment alone, rather the holism of the entire interaction within the practice of acupuncture.

Within this thesis the acupuncture process under investigation is that of western, scientific model such as that offered in NHS pain clinics. A recent definition of Western medical acupuncture (WMA) has been offered by White (2009), in conjunction with the Editorial Board of Acupuncture in Medicine. This describes WMA as a therapeutic modality involving the insertion of fine needles; it is an adaption of Chinese acupuncture using current knowledge of anatomy, physiology and pathology, and the principles of evidence based medicine (White 2009).

It is necessary to acknowledge how this approach differs to the traditional methods of acupuncture practice which often include additional therapeutic tools as an adjunct to needle therapy, for example cupping and the burning of a specific herb – moxibustion (Artemisia vulgaris). In terms of using acupuncture for the treatment of a painful condition, a fundamental difference between a Western acupuncture approach and that of TCM is the former's requirement of a Western medical diagnosis. Marcus (1991) argues that diagnosis is an essential prerequisite prior to treatment as further specialist investigations may be needed along with subsequent referral to other medical experts. He continues that 'lay' acupuncturists may not recognise serious or potentially so conditions, and that provision of acupuncture may actually mask symptoms, thereby delaying urgent referral (Marcus 1991). Since the time of this article however many methods of 'professional' acupuncturist training have altered; from my own experience of training in 1998 practitioners with no formal medical experience are taught and assessed on a full medical examination, indicators of 'red flags' with regard to disease and the correct way to make a referral.

There has been much scientific acupuncture research that has defined mechanisms through which the treatment affects neurological and neurohumeral pathways associated with pain of both an acute and chronic nature (Lewith 2000). This thesis is not that of a neuro-anatomist therefore it will only be noted that these mechanisms are based around acupuncture as a sensory stimulus. The

effect of this treatment on the nervous system is explained as an increased release in endorphins and other substances that inhibit pain impulses, stimulation of the pain gate control in segmental acupuncture, and descending inhibitory systems in hetero-segmental acupuncture (Lewith 2000). Bowsher links the location of acupuncture points to areas in which small nerve bundles penetrate the superficial tissue and muscle thereby being stimulated at needle insertion (Bowsher 1990). For the medical acupuncturist, once a diagnosis has been established a point prescription is formulated depending upon location, tender or trigger points and standard recommendations from Western medical acupuncture texts related to the diagnosed condition. Knowledge of TCM is not required for such a treatment and although many practitioners have a basic appreciation of TCM theory they do not incorporate it into practice (Vickers & Zollman 1999). A TCM assessment requires detailed information pertaining to all aspects of a patient's bodily functions, life style choice and family history. By comparison though, a TCM practitioner may well be aware of a patient's Western medical diagnosis, however it is not essential to assessment, diagnosis and treatment.

In TCM understanding the different causes of pain is the basis for choosing the correct treatment method, several patients may complain of the same pain symptom but that same symptom may be brought about by different causes (Riley 2001). Pain may arise due to an imbalance within the body's energy flow as a result of internal or external causes. A diagnosis is differentiated according to the pattern of disharmony determined from the in-depth assessment process. It is based on the principle that signs and symptoms reflect the condition of the body, and that a 'part reflects the whole' (Maciocia 1989). TCM diagnosis involves four methods of investigation:

- Looking – observation of the spirit, body, demeanour, tongue and channels.
- Hearing & Smelling – listening to the voice and other bodily sounds and noting of an odour.
- Asking – the talk between practitioner and patient about all aspects of life in addition to how the condition arose. The most common format for this

process is the 10 questions which ask about the following areas: Chills & fever, sweating, head & body, thorax & abdomen, food & taste, stools & urine, sleep, deafness & tinnitus, thirst & drink and pain. For women there is an additional question pertaining to gynaecological history.

- Feeling – palpation of the pulse, skin, limbs, hands, chest, abdomen and acupuncture points. (Maciocia 1989).

In order to find the appropriate treatment, particular consideration will be given to the characteristics, location and timing of pain in addition to its response to pressure and temperature (Maciocia 2004). This enables the practitioner to derive which type of imbalance the pain is due to, chronicity and prognosis.

Acupuncture can be used to treat a plethora of conditions from maintaining good health to fertility problems however it is most commonly known in the UK as a method of pain control, and is regularly available in GP surgeries, physiotherapy departments and pain clinics. The main conditions being treated by both medical and professional acupuncturists surveyed in 2001 were musculoskeletal in nature (MacPherson et al 2001; White et al 2001). In recent decades acupuncture research in the West, prompted by increasing patient demand and popularity has attempted to define the treatment's efficacy for such conditions.

2.4 The challenges of researching acupuncture

Over 1000 English language randomized controlled trials have evaluated the therapy's efficacy since the 1970's with more than fifty percent of these involving the use of a placebo as a means of identifying specific effects of the treatment. Chapter one has already discussed the anomaly of outcomes from acupuncture in relation to the treatment of chronic pain, and there appears to be a need for researchers to ask themselves if the lack of conclusive results is inherently bound up with the way acupuncture, has been, and or is currently being researched.

The most prominent criticism is that the quality of the trials included within some systematic reviews is poor (White, Lewith, Berman and Birch 2002). The

argument is that there is considerable heterogeneity, small poorly designed studies and inadequate reporting of many specific and important details such as randomisation. As a means of addressing these issues, Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) recommendations were published to help encourage more precise descriptions of the interventions used in controlled trials of acupuncture and to improve the quality of these interventions (MacPherson, White, Cummings, Jobst, Rose and Niemtzow 2002). It is unknown as yet as to what extent these recommendations will have on the quality of trials until another meta analysis or systematic review is performed. Therefore there is still little definitive information regarding the clinical effect of acupuncture.

Manheimer & Berman (2003) still believe however that if one's aim is to learn which health care therapies work best through medical research, systematic reviews are the finest measure available to summarise data about, and support the effectiveness of CAM therapies. There will always be debate over whether an RCT is actually an appropriate means of evaluation of acupuncture or indeed any other CAM efficacy. Evans (2003) offers a unique perspective on the situation. His response to the assertion that the difficulty arising in clinical trials trying to prove that acupuncture is better than placebo, is due to a problem with the methodology of the trials, is one of dismissal. His argument is that an RCT methodology is no more than glorified counting, and to accuse it of inherent bias is to reveal one's own (Evans 2003). Rawlins (2008) challenges the 'pedestal' position of the RCT in the investigation of therapeutic interventions, and suggests that existing hierarchies of evidence in which the RCT is at the pinnacle, should be replaced by the embracing of a diversity of research approaches. Indeed others have suggested that as RCTs were developed to test new drugs and not complex interventions such as acupuncture, the use of placebo or sham controlled trial designs may lead to false negative results due to the intertwining of characteristic and incidental factors in acupuncture and other non pharmaceutical therapies (Paterson & Dieppe 2005). A further argument was not the issue of whether an RCT should be used, but rather the need for the integration of both qualitative and quantitative aspects of measurements within CAM research (Verhoef, Lewith, Ritenbaugh & Thomas 2004). This notion is

supported by Arnstein (2003) who also endorses the benefits of looking beyond disease specific outcomes to include patient orientated evidence as a means of enhancing understanding.

2.4.1 Placebos in acupuncture research

One significant consideration when carrying out research into acupuncture is the issue of placebo. This is because the term 'placebo' relates to different aspects of the research. The etymology of the word placebo is the Latin 'I will/shall please…'and was first documented in the Middle Ages (Arnstein 2003; Evans 2003; Walach & Jonas 2004). However by the eighteenth century it had entered medical dictionaries as a term for fake remedies (Evans 2003). In acupuncture research the word placebo can be used to describe the method of placebo control used in a trial e.g. 'Sham acupuncture'- needling of theoretically irrelevant sites away from the classical point locations (Lewith & Vincent 1998). By comparison it may also be associated with the 'placebo response' or effect that encompasses the nuances associated with the process of treatment for example – in a trial setting it may be a phenomena that occurs irrespective of treatment arm, real or placebo. It is this phenomenon that is often termed as non specific effects as asserted by Birch et al (2002).

2.4.2 Acupuncture placebo controls

Placebos have traditionally been supported for use within clinical trials since the work of Beecher in 1955, which convinced researchers that only by comparing a therapy with a placebo could they discover its specific effect (Beecher 1955). To clarify, a placebo is an inert substance or sham physical/electrical intervention that is believed to have no chemical, electrical or physical effect on the patient (Arnstein 2003). With regard to a clinical trial, it is an intervention that is administered with the intention of mimicking some other intervention so that an unbiased comparison can be made (Vickers 2002). Within the field of acupuncture research many forms of placebo controls have been used, as outlined in Table 2.

Table 2 Examples of acupuncture placebo controls

Invasive	**Non Invasive**
1) Needling of 'true' points, deemed inappropriate for the treatment of the condition under investigation.	1) Non insertion of real needles – touched onto skin only & not visible to the patient.
2) Needling of non acupuncture points i.e. locations deemed to have no activity.	2) Sham acupressure – e.g. elastic 'sea bands' worn at the wrist but with the active pressure inducing plastic stud removed.
3) Minimal acupuncture in the form of superficial needling at locations away from true and trigger (tender to touch) points.	3) Sham electrical stimulation – electrodes placed at the site of true points but no current passes to them from the electrical unit, but noise and lights visible.
	4) Placebo needles, a blunt tipped needle with a needle shaft that moves up into the handle when pressed on the skin. This gives the result of a prick on the skin and the impression of insertion to the patient.

(Vickers 2002)

Previous research of placebo devices highlighted that some physiologically inert placebos such as sterile water injections, other non therapeutic procedures, and acupuncture may have enhanced placebo effects but poor methodology within the available research precludes definitive conclusions (Kaptchuk, Goldman, Stone and Stason 2000). Subsequent research reports that a validated sham acupuncture device was found to have a greater placebo effect on subjective outcomes than oral placebo pills, when self report measures of trial participants were studied over time (Kaptchuk, Stason, Davis, Legedza, Schnyer, Kerr, Stone, Nam, Kirsch and Goldman 2006), thereby, offering a view that placebo effects may be malleable, and dependent upon patient and practitioner behaviour embedded in medical rituals.

There are two other methods of control used in acupuncture research that are unrelated to placebos. These are the 'No Treatment' and 'Active Treatment' options. Patients who are randomised to a no treatment arm of a trial receive usual clinical care, as if they were not actually part of the trial, but no additional active treatments either. By comparison the active treatment arm relates to patients receiving another active treatment which the acupuncture can than be compared to e.g. physiotherapy or massage (Vickers 2002).As one can see in Table 2 overleaf, the options of control available to a researcher in this area are varied, and could explain some of the methodological challenges the field faces.

2.4.3 The Placebo Effect

The placebo effect is of great importance to this thesis as it incorporates many of the hypothesised non specific effects of acupuncture within its description (see section 1.4). The term has many definitions that vary according to the beliefs and research paradigm that a researcher pertains to, for example:

- A potential confounder in assessing the efficacy of any therapeutic intervention (Beecher 1955; Ernst & Resch 1995).
- The self healing capacities of the person (Walach & Jonas 2004).
- The reduction in a symptom as a result of factors related to a subject's/ patient's perception of the therapeutic intervention (Vase, Riley & Price 2002).

Richardson (1994) develops Vase et al's (2002) description further by defining it as those effects of a treatment that are not attributable to the mechanics of the treatment but rather the circumstances surrounding it. In response to this Walker (1995) looks at this phenomenon in the context of physiotherapy, another therapy with tactile emphasis, and acknowledges that environment, attitude and even appointment time can all influence treatment outcome. This is not to say though that the placebo effect only occurs in pragmatic clinical practice, placebo effects are present in all treatments – both placebo and active (Gracely 2000).
It is this aspect that causes confusion in acupuncture research in interpreting outcome when we don't really understand what is 'real acupuncture treatment'

and exactly what an acupuncture placebo comprises. Evans (2003) argues that to provide convincing evidence of a placebo effect, it is necessary to show that those receiving the placebo did significantly better than those who received no treatment at all. The rationale being that the improvement shown could in fact be due to the natural course of the disease (Evans 2003). Walach & Jonas (2004) and Price (2000) agree that trials should include an 'untreated' arm so that a better understanding of the placebo effect of individual therapies such as acupuncture is gained. Placebo effects may well differ with regard to therapy and individual response, but they are also shaped by context (Hyland 2003). Hyland argues that the effectiveness of an active treatment can be enhanced if contextual factors contribute to a strong placebo effect and describes four psychological mechanisms associated with this – expectancy, conditioning, the therapeutic relationship and empowerment (Hyland 2003).

Subsequent research by Hyland has developed his work further and now offers a theory of motivational concordance (Hyland, Whalley, & Geraghty 2007), in which if a patient's understanding and belief about the context of the intervention is similar to that of the therapist then this may enhance the non specific effects of the intervention. Expectancy and conditioning have long been explored in the process of researching the placebo effect (Arnstein 2003; Price 2000; Walach & Jonas 2004). Walker cites Richardson's (1994) work examining the role of the therapist's attitudes and behaviour in the placebo effect and concludes from it that it may well be enhanced by strong belief, empathy, time and individualised treatment (Walker 1995). What is obvious from the descriptions of these contexts is that they are very similar to the non specific effects of acupuncture - treatment environment, patient expectations, practitioner intention, patient-practitioner rapport, regression to the mean and generalized effects of needle puncture, as asserted by Birch et al (2002).

Evans (2003) believes that acupuncture is a pure placebo. He explains only seemingly better results than placebo control in conditions that are placebo effect responsive, and attributes this to blinding issues in which practitioners are giving out subtle clues as to degrees of confidence in the treatment thereby influencing expectancy (Evans 2003). Vickers concurs that in a trial clinician confidence

may well be reduced in single blinded studies and this will be conveyed to the patients resulting in lowering of expectation (Vickers 2002). Certainly if trials continue to be methodologically criticised and refuted there is rational for the argument that evidence of specific therapeutic effect is also questionable (Araujo 1998; Birch, Hammerschlag & Berman 1996; White, Lewith, Prescott & Conway 2004).

In White's trial of acupuncture for the treatment of mechanical neck pain, a year-long follow-up suggested that acupuncture is effective over a prolonged period, but this effect may be non-specific rather than due to particular acupuncture point prescription, methodology or even needle insertion (White 2002).White also agrees that contextual considerations namely empathy, empowerment and the consultation in addition to the nature of the treatment rather than its efficacy, have a profound influence on the outcome for pain (White 2002). Lewith & Vincent summarise this challenge of acupuncture research concisely, recognising that a spectrum of non specific factors may influence responses to treatment and recommending the selection and assessment of one or more aspects of the placebo effect (Lewith &Vincent 1998). This advice was followed in the development of the hip/knee trial which chose the effect of the patient/practitioner relationship, and the potential subsequent effect of limiting empathy.[2]In response to the anomaly that acupuncture provision and popularity exists in a context of evidence that does not support specific effect, and the criticism of previous quantitative trials there was a call for a change in trial design. In other words the use of qualitative methods was encouraged to explore quantitative findings by seeking the participant perspective.

2.5 Qualitative research of Acupuncture, CAM and RCT participation

In recent years the use of mixed method, research approaches have been encouraged in CAM, and in particular acupuncture with the aim of exploring the efficacy versus effect phenomenon further (Verhoef et al 2004). However it is argued by some that although qualitative research into this area may provide

[2] Issues pertaining to the patient practitioner relationship and its exploration in CAM will be discussed in further detail in Chapter 3.

useful data into patient satisfaction and expectation outcomes, they do not permit valid inferences regarding treatment effectiveness (Ernst 2003; Miller et al 2004).

Much of the existing qualitative research to date has been conducted under the umbrella of CAM as a whole, rather than specifically to acupuncture. These initial studies have focused on the motives of individuals seeking CAM treatments (Luff & Thomas 2000; Murray & Shepherd 1993; Paterson & Britten 1999; Pawluch et al 2000; Sharma 1992). Since then however the use of qualitative research into the field of acupuncture has slowly grown but continues to remain limited. Early studies primarily explored user's perspectives of traditional acupuncture practice in both the USA (Cassidy 1998) and the UK (Gould & MacPherson 2001). Both studies came to similar conclusions in that patients appeared to value the 'holistic' approach that this form of acupuncture practice offered. Paterson & Britten (2004) in their longitudinal study into user's perspectives of the dynamics of acupuncture also looked at a TCM approach, using the holistic model but in different settings. The context in which the users received their treatments varied between the NHS and private sector, and it was interesting to note that even within this holistic model framework there were still complaints of rushed experiences and no time to talk in the NHS setting (Paterson & Britten 2004). At the time of this thesis' inception there had been no qualitative studies exploring participants' experiences of a western acupuncture following a 'reductionism' model in an NHS environment. Neither had there been any qualitative research into this type of acupuncture within the context of a clinical trial. This meant that this qualitative study would add a new perspective to existing research. In recent years however there has been a continued exploration of patients' experiences of acupuncture in an ever growing body of qualitative work (Paterson 2006; Paterson 2007; Paterson, Zheng, Xue and Wang 2008; Paterson and Britten 2008) which incorporates findings on outcome measurement, western style acupuncture and acupuncture performed in a trial setting.

Previous qualitative research on trial participation in conventional medicine is also limited. In recent years problems with recruitment and retention in clinical

trials has seen much of the existing qualitative literature focusing on research participation in hypothetical trials (e.g. Strauss, Sengupta, Kegeles, McLellan, Metzger, Eyre, Khanani, Emrick and MacQueen 2001) or specific contexts. These include trial participation amongst under represented populations or ethnic groups (e.g. Hussain- Gambles 2004), individuals with rare or life threatening conditions and phase 1 pharmaceutical trials (e.g. Moore 2008).

A small body of work however has focused on the perspectives of actual trial participants, exploring their experiences and reflections on motivations for taking part using in depth, semi structured interviews. Incorporating a wide variety of settings and contexts such as the parents of acutely ill infants (Snowden, Garcia and Elbourne 1997) and trials of treatment for psychiatric illness (Applebaum, Roth, Lidz, Benson and Winslade 1987) these studies have suggested that many trial participants are challenged by the notion of treatment randomisation. Research amongst male participants on a comparative trial for the treatment of benign urology symptoms supported these findings and suggests that participants appear to struggle to make a sense of participation, forming alternative accounts to explain treatment allocation (Featherstone and Donovan 2002). Furthermore the way in which participants understand their involvement may affect trial outcomes. For example some of the interview participants of the urology research expressed distrust in their clinicians, doubting the veracity of the trial and considering the differing treatment randomisations to be a money saving endeavour. As a result such beliefs may affect internal and external validity of a trial (Featherstone and Donovan 2002).

Subsequent research in the fields of welfare rights (Moffat, Mackintosh, White, Howel and Sandell 2006) and decision aids amongst individuals with chronic conditions (Heaven, Murtagh, Rapley, May, Graham, Kaner and Thompson 2006) has also suggested that the RCT context can affect both participant experience and outcome. Moffat et al's (2006) qualitative research highlighted important participant-centred benefits of increased independence and improved quality of life, not captured by the quantitative analysis, which challenged the negative findings of the trial. Whereas Heaven et al (2006) noted that there appears to be a variety of ways in which participants understand their

involvement in research. Within this complexity is the notion of trial identities e.g. volunteer or patient which can move on a continuum over the duration of a trial, holding implications for the design and interpretation of outcomes. For example Heaven et al noted that differing identities appeared to shape the participants perceptions of appropriate behaviour during the trial and the interventional task (2006). They suggest that these findings of behaviour modification may indicate that RCT trial interventions and participant self report outcomes do not reflect normal practice and should be interpreted with caution.

The new and existing qualitative research in the field of acupuncture and beyond presented in this section offers the findings of this thesis a greater opportunity for triangulation and subsequent assessment of credibility and transferability (see chapter 3). However despite this and Verhoef et al's (2004) encouragement of mixed method approaches to acupuncture research the practicalities of such a method are not without potential bias and issue. The following chapter will consider the methodological challenges of working within two research paradigms, as required by a mixed methods approach.

Chapter 3 Methodological Considerations

3.1 Introduction

Throughout this third chapter it is my intention to highlight the methodological considerations that arose from my dichotomous research role as detailed in chapter one. As previously mentioned the duality of my role as practitioner /researcher was not initially seen as a problem; however it did have implications for the authenticity and trustworthiness of the qualitative research due to the potential inherent biases arising from this situation. Over time the challenge of working within two differing research paradigms also emerged and I was required to adapt my role to the needs of the qualitative study.

To begin I will present a section on the specifics of the hip/knee trial in order to orientate the reader to the context in which the qualitative study was nested. I will follow this with a discussion of the challenges underpinning nested qualitative research and the rationale behind my choice of qualitative method; concluding with a description of grounded theory and the ethical implications identified.

3.2 The hip/knee trial

The trial in which my qualitative study was nested was conceived and granted ethical approval in 2003 (ethics ref no 170/03/T). Its overall investigation was the process of acupuncture treatment and, in particular, the relative contributions of specific and certain non-specific effects namely the impact of empathic, therapeutic intent on outcome (see trial protocol in appendix 1). Within a factorial design, the participants were allocated to one of three acupuncturists, to receive one of three treatments (1 real acupuncture and 2 placebo controls), under empathic or non-empathic conditions.

Originally deemed as a three year investigation, data collection was completed in 2008 but its findings are not published at the time of writing. The hip/knee trial

was a single blind (practitioners aware of randomization), multi parallel arm, dual-centre study. It involved NHS patients with a diagnosis of osteoarthritis that were awaiting hip or knee joint replacements. Participants were recruited from the local orthopeadic waiting lists at two NHS sites, although under differing 'consultant gatekeeper' circumstances (at one site we could approach prospective participants directly while at the other, their Consultants would approach the issue of the trial on our behalf). Initial recruitment focused on one particular site and the resulting number of participants enrolled in a single drive was the largest of the trial. This may have been due to the fact that the average waiting list at the time (winter 2003) was approximately a year to eighteen months. In the years that followed, recruitment slowed considerably, possibly due to a number of factors such as a reduced waiting times for surgery and the presence of other local osteoarthritis trials. It was as a result of the slow recruitment that the second trial site was established.

The hip/knee trial wished to explore the nature of non specific effects further, not only as a means of understanding the clinical benefits of acupuncture but to potentially enhance the available treatments especially in pain management. On the basis of White's (2004) study the trial protocol acknowledged the premise that acupuncture could be effective over a year long period but that this positive effect may have been due to non specific effects rather than explicit point prescriptions, method of acupuncture practice or even needle insertion. The design also chose to focus upon the potential impact of the non specific effect of the patient/practitioner relationship and considerations such as empathy (defined as 'accurate understanding' by Rogers, 1957), empowerment and the nature on the consultation on pain outcomes and analgesia consumption. The extent of non specific effect was therefore to be investigated in terms of intervention type and consultation type. Specific outcome measures were chosen to capture such information. These aspects of the trial design will now be described and discussed in further detail.

Regardless of intervention arm, treatment sessions lasted approximately 30 minutes, with the intervention duration being 20 minutes in total. Sessions were twice weekly for four weeks, and the participants were required to have at least

one rest day (no treatment) between their sessions. The frequency and duration of the interventions was determined from prior research (Ezzo et al 2000; White et al 2004).

3.2.1 Real acupuncture

The real acupuncture arm of the trial was based on western acupuncture practice, a scientific approach that requires a western medical diagnosis (see chapter two). This was in order to establish a point prescription formulated according to pain location, tender or trigger points and standard recommendations from western medical acupuncture texts relating to the diagnosed condition. A range of acupuncture points (see appendix 3) were specified as part of the trial design, from which the practitioner could chose the most relevant points for each individual participant. Two types of stainless steel real needles were used – 1 *cun* needles and 1.5 *cun* needles. These longer needles were required for participants with hip pain who required needling in the buttock. The points were located as required for the individual i.e. location of pain and a small plastic ring placed over them covered by a plaster. The needle was then inserted through the plaster within the confines of the ring. The needles were passed through the plaster, centre of the ring and inserted in to the participant to varying depths according to point location and clinical guidelines. All of the needles were sterile; single use and disposed of correctly in sharp's containers. During the treatment session the needles were rotated manually at intervals to elicit *deqi* (needle sensation).

3.2.2 The placebo needle

The Streitberger placebo needle was created in an attempt to stimulate an acupuncture procedure without penetrating the skin (Streitberger & Kleinhenz 1998). Superficial in nature to avoid any invasive stimulation, the needle is blunted and telescopic, acting like a stage dagger. The needles were packaged in the same way as 1 *cun* real needles; appearing to look the same apart from a blunt tip. The trial was single blind as it was not possible to blind the acupuncturists when using this method. It was aimed that the participants were blinded to the process by placing the Streiberger needle in the same manner as a real needle and in recognised acupuncture points. The placebo needles were single use and disposed of in a sharps container, as is the case with real needles.

All of the placebo needles were inserted in the same manner described in the real needling process and the needle appeared to visibly get shorter as the shaft moves upward into the handle of the needle as it is placed against the participant's skin, mimicking penetration. In the early weeks of the trial it became apparent in practice that the plasters were difficult to puncture with the blunted shafts. Due to the potential un-blinding that this act may have caused we substituted the plasters for a clear, medical tape in both needle intervention arms which rectified the problem immediately. Once in situ the Streitberger needles were gently moved against the skin to replicate the obtaining of *deqi* (needle sensation) as in the real acupuncture arm of the trial.

3.2.3 The modified electrotherapy machine

Falling in to the category of sham electrical stimulation (see Table 2) this validated non invasive placebo control was essentially a decommissioned electrical acupuncture unit. The machine was altered to only produce a light and variable noise patterns, no active electrical current passed from the machine. The participants were allocated their own specific use set of electrode pads, as used with TENS machines. Recognisable acupuncture points were located according to the participant's location of pain, and the pads are placed over the points. These pads were then connected via electrode wires to the machine. Once switched on the machine emitted a continuous green light, and either a continuous or intermittent buzzing noise which was volume adjustable. The machine also has a number of dials corresponding to the numbering of the electrode wires. These were also adjustable although inactive, giving the visual impression of being able to increase or decrease the intensity of the machine (see Figure 1 overleaf).

Figure 1 Modified Electrotherapy Machine

3.2.4 The Consultations

The RCT methodology involved the manipulation of the patient/practitioner relationship in both active and placebo arms of the trial. This was enacted as consultation type – empathic and non empathic. Gould & MacPherson (2001) allege that TCM acupuncture patients place a high value on their relationship with their acupuncture practitioner. In comparison Luff and Thomas (2000) examined patients' perspectives on complementary therapies in the NHS. They too found that the development of a therapeutic relationship with the complementary practitioner is central to satisfaction with treatment, and that this relationship depends on practitioner time and attention as well as therapeutic skill (Luff & Thomas 2000). The study, however, looked at NHS provision within primary care and did not specify the acupuncture methodology used by the practitioners. Bowling (1997) asserts that patients' evaluations of the communication process between doctor and patient are now recognised as an important component of the evaluation process and outcome of health services,

concluding that communication is important if health care is to be effective. Gracely (2000) summarises the issue concisely by discussing whether the behaviour of the clinician alone can evoke specific or non specific responses sufficient enough to result in a therapeutic success. With all this is mind the hip/knee trial design incorporated two differing consultation types.

The empathic consultations on the trial were pragmatic in nature. By this I mean that they were led by the participant's needs and are therefore variable from individual to individual. Participant's who wished to talk about issues other than the trial and interventions were at liberty to do so. Conversely if the participant's choose to lie quietly for twenty minutes and take the time to rest and relax without talking then this was also respected. Information regarding acupuncture was freely given.

The non empathic consultations were designed to remove the pragmatic aspect of practice, and limit the provision of information and conversation to clinical trial related matters only. Therefore we did not discuss personal issues, nor share any information about ourselves. Guidelines were devised prior to the commencement of the trial so that the practitioners had a scripted format to refer to in the early days of the study e.g. standard replies we could use to participant enquiries (see appendix 4).We also discussed the issue of breaking randomization. This related to the potential situation where during a session it was no longer appropriate to continue a non empathic consultation. For example if a participant became distressed and needed reassurance. Any such incidents were reported, and to date I know of only one occasion where this occurred, and this was a participant of mine.

3.2.5 The hip/knee outcome measures

The hip/knee trial employed a number of outcome measures, specifically used to capture data relating to the varying aims of the trial. These were a self completed patient diary measuring change in mean pain from baseline to the 1 week post treatment as measured on a 100mm Visual analogue score (VAS); analgesia consumption was also recorded in the diary and questionnaires to assess quality of life. These included the Nottingham Health Profile (NHP) and a condition

specific measure (WOMAC). All were administered pre and post the course of intervention.

In addition a credibility rating, Holistic Health questionnaire (HHQ) and validated Empathy and Empowerment questionnaires i.e. the Patient Enablement Index (PEI) were administered to take account of any possible confounding factors. All subjects were also asked to complete the needle sensation questionnaire although for those undergoing mock electrical stimulation treatment, references to 'needling' were omitted. In the following sections of this chapter I will discuss the methodological issues that arose from nesting a qualitative study in a quantitative trial.

3.3 The challenge of nesting qualitative research

The challenges of conducting a qualitative study within the context of the hip/knee trial and the circumstances of my dual role were quite profound, although I was not entirely aware of the full implications at the outset. Essentially I was to be involved in research that stemmed from both positivist and interpretive paradigms. The tensions resulting from these opposing stances on inquiry were due to the underlying epistemological and ontological assumptions of the competing paradigms, which inform methodology.

Paradigmatic views differ with regard the acquisition of knowledge of reality (epistemology) and the form of the reality under investigation (ontology).The positivist position underlying the RCT was that of a hypothesis testing, deductive inquiry, based on a view of single reality in which the researcher and participants are independent of each other. By contrast the interpretivist paradigm underpinning the qualitative study was hypothesis generating, inductive inquiry in which multiple realities are possible, and the researcher and participants become inseparable. This has a potential for conflict as the findings from differing data sets may challenge each other's results.

The notion of researcher bias and criteria for judging the quality of the work is also influenced by the underlying epistemic assumptions of the research

traditions. Positivist researchers aim for objectivity and the elimination of bias as part of the research design. For example an RCT will have a specific protocol to be adhered to. In contrast, qualitative research cannot rely on such controls and necessitates the researcher to be overtly reflexive of both their professional and personal perspectives and the influences these may have on data collection and analysis. Establishing the extent to which a researcher's findings are accurate (validity) and are able to achieve consistent results (reliability) is essential within any research paradigm, however within qualitative research paradigms the assessment criteria varies according to the researcher's worldviews (Patton 1990).

Within the post positivist, constructivist and critical realist views there are an array of assessment criteria proposed as alternatives for the paradigms on which they have been based (Le Compte & Goetz 1982; Lincoln & Guba 1985; Miles & Huberman 1994). For example Lincoln & Guba (1985), argue that rather than using conventional methods of evaluating research such as rigour, reliability and validity for qualitative research, alternative criteria of credibility, transferability, dependability and confirm-ability should be sought to assess the quality. The values they describe are inextricably linked with the notion of authenticity and trustworthiness. Credibility can be liked to the positivist view of internal validity. An assessment is made to evaluate the faithfulness of the work e.g. are the researcher's findings compatible with those of the participants, in other words would the participants agree with the findings. The fit and meaningfulness to other contexts of the work, is known as transferability. It could be argued that this is simply jargon, and is only a replacement term for positivist generalizability. Strauss & Corbin (1998) speak neither of generalizability or transferability, but the 'representativeness' of concepts, and the applicability of a theory to other situations. It is this latter definition that will be used for the purposes of this study, therefore the findings will be judged on their applicability to other contexts. The dependability and confirm-ability of a study in which the accuracy and consistency of the research findings are determined, in addition to whether the aim has been achieved, can be addressed in various ways. These include triangulation in which multiple perspectives are sought, such as the findings of similar studies.

Previous qualitative studies (see chapter two) have highlighted another important factor that was required i.e. clear documentation of the research process, describing and justifying what was done at each step in the study (Sandelowski 1986). This record, often called an audit or decision trail, emphasises the connections between all aspects of the research process, allowing the reader to see the wider context and establish the value of the research (Lincoln & Guba 1985: Koch 1994). Especially for a paradigm in which research explores the social world which is ever changing and is context bound rather than a singular reality. Therefore it was my aim in this thesis to present a transparent and open account of how this study was carried out in the hope of demonstrating its appropriateness for the phenomena under exploration.

My continual and ongoing challenge throughout this qualitative study has been the issue of subjectivity. Subjectivity leads to the development of a critical perspective via self reflection. How I have aimed to address the issues surrounding this during my study will be discussed as they arise, later in this, and the next chapter. Subjectivity meant it was essential that I acknowledged my own experiences, beliefs and skills in order that the data emerging from my interviews was not subject to influence. This requirement was due to the interpretive creation of knowledge that qualitative methodology facilitates, which is in part determined by the researcher's cultural, political and social values. In short it is argued that theories induced from the use of qualitative methods always include some aspect of the researcher due to the interpersonal interaction that it demands (Altheide & Johnson 1994; Hutchinson 1993).

Such theories may have been influenced by factors such as research training and experience. For example, researchers will have varying degrees of experience and knowledge pertaining to the subject or phenomena under investigation. On a positive note, one could argue that experience can provide the researcher with certain advantages such as sensitivity to the phenomena, and a background in which to use as a basis for making comparisons and sample selection on theoretical grounds. In comparison it could be argued that experience can be

detrimental, clouding a researcher's judgement and resulting in interpretations that only partially explain the data (Corbin 1986).

Reflecting on one's experiences highlights both the positive and negative aspects of them. Documenting these reflections also informs the reader of the researcher's potential biases, strengths and weaknesses influencing the research process presented. I was caused to spend time reflecting on my personal and professional experiences, which led me to identify a number of opportunities for bias of which I was previously unaware. I recognised the inherent opportunity for biases on my part not only due to my background, but role within the hip/knee trial and the somewhat 'fait accompli' starting point of the qualitative study. By this I mean the nesting of the qualitative research within an RCT designed to investigate non specific effects of acupuncture, in which I was both a practitioner and researcher, and the differing consultation types.

Hanson (1994) discusses the problems of undertaking research within familiar settings, and the notion that if a researcher is directly involved and trained in an area of expertise then it is increasingly difficult to suspend his or her perceptions, thereby lacking critical distance. Therefore it was possible that my 'independent' position from the participants, as a practitioner on the trial influenced the nature of my role as a qualitative researcher, and vice versa. My own biases were potentially overwhelming due to my emersion in the everyday running of the trial and participation in the qualitative work linked to it. However I realised that this challenging aspect could be viewed optimistically if I chose a methodological approach that could incorporate my previous experiences and those of working on the hip/knee trial as a source of data, one such method being Grounded Theory.

3.4 Grounded Theory

Grounded theory is a systematic approach within qualitative research, (Glaser & Strauss 1967). It was developed in the 1960's by two sociologists – Anselm Strauss and Barney Glaser, as a result of their desire to explore the underlying processes involved in the experiences of patients dying in hospital. Its theoretical underpinnings stem from symbolic interactionism, which focuses on the meanings of events to individuals and how they act in relation to their beliefs. Grounded theory however is not only confined to sociology, it has become a popular research method in other disciplines such as health care, education and psychology. It shares many similarities with other qualitative approaches, not least that it is initially inductive in nature. Inductive knowledge is arrived at via the accumulation of verified facts capable of leading to theories and hypotheses, although this is not always the endpoint. By comparison deductive research is concerned with the empirical testing of the hypotheses and potential rejection or revision of the theories depending upon the outcome (Bryman 1988).

One way in which grounded theory is differentiated from other qualitative approaches however is its aim of generating theory from data. Grounded theorists collect data from a variety of sources, for example interviews, observation, literature and the researcher's own experiences. For example whilst working as a practitioner on the trial I have unintentionally observed practice, and had discussions with the other practitioners that may be considered a form of data. Theories grounded in data focus on processes that occur in certain aspects of the social world. This is especially useful in helping to explain phenomena where there is little already known or where a new perspective is needed in a recognized situation or setting (Strauss & Corbin 1998). For this reason, grounded theory was chosen in this qualitative study to explore processes at work within the hip/knee trial in the hope of generating a theory to explain non specific effects within it.

Another distinct feature of grounded theory is the interaction between data collection, data analysis and sampling procedures. Data collection and analysis occur simultaneously. In the early stages data is often collected by the process of

purposive sampling, in which a case is chosen because it illustrates some feature or process in which the researcher is already interested (Silverman 2000). Following on from this sampling becomes theoretical, due to the evolving analysis driving the subsequent selection of data (Baker et al 1992). This means that it is on the basis of this early data collection and analysis that a researcher decides what sort of data to collect next. These choices, within the back and forth of the procedures are facilitated by a process known as constant comparison. A constant comparative method of analysis is continuous in grounded theory.

Chenitz & Swanson (1986) use the example of interviews when describing the start of the research process. For example initial data, such as two or three interview transcripts are compared for similarities and differences, relating to the experiences of those individuals being interviewed. Other sources of data may also be included- in my study this may be the participant's quantitative results. Data is then provisionally coded to reflect the substance of what is being said about the phenomena. In my study it initially appeared that empathy was an important factor in determining a positive outcome of acupuncture, as predicted by the design of the hip/knee trial. However subsequent data from a participant who described a positive experience despite receiving non empathic encounters quickly challenged this assumption, and shifted the focus of sampling onto those participants who had received non empathic consultations to explore this aspect further (see chapter four). This led to the emergence of other tentative hypotheses requiring testing.

Constant comparison continues as subsequent data is collected ensuring the emergence of knowledge that can result in predictions, explanations and interpretations (Glaser & Strauss 1967). It is argued by Glaser (1978) that it is at this point of knowledge researchers can get distracted by what they interpret to be emerging. Rather than using constant comparison as a process to aid concept development it distracts the researcher to test theories that have barely started to generate, thereby potentially forcing concept development rather than letting it truly emerge (Glaser 1978). This issue may be particularly problematic in research situations where the researcher has considerable experience of the field

under investigation and access to additional contextual information, as was my position.

A researcher's interpretation can also be seen as a form of deduction (Strauss & Corbin 1998). I have already mentioned that the initial stage of grounded theory should be inductive, however as it progresses it incorporates deductive aspects in terms of the ideas researchers gain from the developing hypotheses emerging from the data. This has implications for sampling, as the sample can change over time in relation to analysis, and the need to follow up subsequent findings. Such sampling methods are described as theoretical, because data is specifically sampled due to its relevance to the development of the emerging theory. Once initial data has been collected, analysed and examined, new concepts arise and people are then chosen who can further illuminate the issue (Glaser & Strauss 1967). Similarly theoretical relevance is essential, thereby ensuring that the groups chosen will help generate to the fullest extent as many properties of the emerging categories as possible. Using theoretical sampling in this way facilitates both an inductive and deductive approach to data collection and analysis, can be argued to safeguard against the introduction of personal biases. Cutcliffe (2000) asserts that as a result of the process, prior hunches, or those views held only by the researcher, bearing no meaning for the individuals being interviewed for example, can be discarded in the course of the research.

Additional tools for the grounded theorist are the reading of relevant literature, keeping of reflexive diaries, memo writing and observations. These can all help analysis and encourage the researcher to become theoretically sensitive to the emerging ideas and concepts from the data (Glaser 1978). My role in the study enabled me to use my own observations from working on the trial as data to contextualise the interview accounts. Embracing these techniques of grounded theory certainly enabled me to challenge my own assumptions and to become more open to, and acknowledging of the subtle influences upon research and practice. Sampling continues until nothing new is being said about the concepts and their properties being explored. This is known as theoretical saturation. Theoretical saturation is of great importance in grounded theory. The term relates to a point in the data collection where no new or relevant data seems to emerge

regarding a category, the category itself is well developed dimensionally and relationships among the categories are established and validated (Strauss & Corbin 1998). Yet as Backman & Kyngas (1999) remind us, it is difficult to predict when this is likely to happen in a research project and is not able to be predicted beforehand. Researchers must be aware however of the risk of 'premature closure' as described by Glaser (1978), when there has been a lack of full analysis of the data due to insufficient time or funding.

Since the inception of grounded theory, there have been many adaptations of the approach most notably the differing versions of the original authors – Glaser and Strauss. The approaches to grounded theory advocated by Strauss and Corbin and Glaser both incorporate the analytical processes of constant comparison and theoretical sampling. Strauss and Corbin (1990; 1998) offer a prescriptive 'micro' approach in which detailed data analysis commences with the first interview transcript. This has the advantage of providing security to novice qualitative researchers and was the approach I initially chose to use. However, Glaser (1992) argued that this can force superficial categories at an early stage and determine a conceptual framework that inhibits alternative theoretical viewpoints. He advocates a more theoretically reflective approach that demands persistent interrogation of the data with a view to understanding underlying conceptual processes. As my study progressed, I shared my transcripts with other researchers, including supervisors, who were able to suggest alternative explanations for the data. I also followed Glaser's recommendation that 'all is data' by looking beyond the interview data to incorporate my own observational data and information from the existing literature. This enabled me to abandon initial categories that appeared, in retrospect, to have been heavily influenced by my own personal assumptions.

3.5 Ethical considerations

A chapter on methodological considerations would not be complete without a discussion on ethics. The complexity of ethical considerations within qualitative research was an important factor in the design of the qualitative study. Although the issue of ethics must be considered in all methods of research it was an especially important consideration for the nested qualitative study as the participants were all NHS patients, recruited from the RCT. This meant that both the studies were bound to DoH research governance frameworks, highlighting ethics as the maintaining of dignity, right, safety and wellbeing of participants (DoH 2001). Ethical approval is guided by Beauchamp & Childress (2001) principles of biomedical ethics, and had already been given for a qualitative investigation involving the interviewing of trial participants when I commenced work on the project. These four principles are outlined below:

- The necessity for obtaining informed consent and respect of an individual's autonomy.
- Provision and adherence to the principles of privacy and confidentiality.
- To do no harm and act in the best interest of the individual at all times.
- Consideration of the 'power' relationship within the research process, thereby ensuring fairness and justice.

(Beauchamp & Childress 2001)

With regard to my study, it was extremely important that the participants who had completed the RCT did not feel coerced into the qualitative study. The qualitative study was detailed in the patient information sheet of the RCT and the consent form accounted for it (see appendix 2). However, respect for the participant's autonomy meant that they had a right to refuse this aspect of the investigation should they have forgotten this aspect of the trial. Therefore obtaining informed consent was considered ongoing rather than assumed and this meant requiring reconfirmation of their willingness to be interviewed. In order to adhere to the principles of privacy and confidentiality, the participants were offered a choice of setting for the interview, reassurances regarding confidential

disclosures and protection of their anonymity in any materials, presentations and publications. Beauchamp & Childress (2001) assert that research should do no harm and that the researchers act in the best interest of the individual at all times. As a practitioner I was aware of the potential opportunity for sensitive, even ethical issues to arise during the treatment process e.g. declaration of other medical conditions or distressing personal experiences. I was concerned that this may also occur during the interviews, especially due to the inductive nature of qualitative research. Due to my role in the RCT I was also very much aware of the potential 'power' relationship underlying the interviews. In effect, I was party to the participant's quantitative responses, treatment and consultation type, and who their practitioner had been. This imbalance of information is not the usual starting point for an interview process and I was conscious of the potential biases that may arise because of it. How this and the other ethical issues were addressed will be discussed in the next chapter which describes the method used in this qualitative study.

Chapter 4 Method

4.1 Introduction

This chapter is a detailed presentation of the method employed in this qualitative study. It includes sections on the recruitment, sampling; the interview process and analysis technique. Throughout the chapter I have also included personal reflections on how the method evolved over time.

4.2 Recruitment

The process of recruiting participants into the qualitative study was very much in accordance with the ethical implications detailed in the previous chapter (see section 3.5). All of the participants interviewed in this qualitative study had completed their required quantitative involvement in the hip/knee trial. Most were still awaiting their surgery, while a few were interviewed following their operation. Although consent for an interview was obtained at the outset of the hip/knee trial, I requested additional verbal consent be noted within the participant's trial documentation. The individual's practitioner broached the subject of being interviewed and recorded their response. The practitioner made the participants fully aware that they were free to refuse the interview, withdraw at any time and request that the qualitative data not be used in the future. Throughout the qualitative study only one trial participant declined to be interviewed when asked, and a rationale was not given. In an attempt to minimise the bias of power in the relationship, I decided to only to interview participants of the trial whom I had not treated. I also attempted to limit any other personal contact with the interview participants, i.e. initial assessments and obtaining of consent.

Once a participant had verbally confirmed their willingness to be interviewed I contacted them to arrange a convenient time and place. It was at this point I would first discuss the issues of privacy and confidentiality. Reassurances were given regarding the removal of any identifying data, and pseudonyms were used to preserve confidentiality. The protected storage of the data within a locked

cabinet at the primary medical care department of the university, and compliance with data protection requirements was also referred to in the information sheet. In order to safeguard the wellbeing of the participants during the interview I made sure I was prepared for sensitive disclosures of information that may cause distress. The participants seeking acupuncture and choosing to take part in the hip/knee trial had chronic pain that for some had a great impact on their lives, both physically and emotionally. I carried tissues; made sure I knew when to switch off the tape, and pause the interview and allowed time for closure at the end of the interview. In addition I made available information regarding access to support networks for participants, arranged for my own supervision, and followed university and research guidelines on lone researcher safety when undertaking domiciliary visits should the participants choose to be interviewed at home.

4.3 Sampling

The sampling in this qualitative study was context based as it comprised participants originally recruited into the hip/knee trial from a population of subjects aged between eighteen and eighty years with a diagnosis of hip or knee OA. This context had implications for the sampling process, which will now be discussed.

The logic underlying sampling in qualitative research is not one of representativeness of the wider population rather the sample is chosen based on the richness of the information available, and its relevance to the research question, area of exploration or the analytical framework be used. Initially purposive, the qualitative sample in this study focused on pain scores and stemmed from the design of the hip/knee trial and its interest in the non specific effects of acupuncture. It may be argued that an alternative starting point would have been more in keeping with a grounded theory approach, for example participants could have been sampled irrespective of their quantitative pain scores. I took the view of Coyne (1997) and Sandelowski, Holditch-Davis& Harris (1992), who advocate that purposive sampling is a realistic, if not the most reasonable option in the beginning of a grounded theory study.

Sampling commenced with the purposive sampling of four participants, who had completed all eight treatments offered in the trial. They were identified as having responded the most positively or negatively to treatment in terms of pain score reduction, irrespective of the treatment or consultation they received. This was so I could explore any differences, as well as similarities in the experiences that may have influenced their response to treatment. Only three participants were interviewed, as one gentleman had post operative complications following his operation and was un-contactable. All three participants had received placebo treatments, two with empathic consultations and one non empathic. I had not met any of these individuals before, however as I have already mentioned I was informed of their pain scores, what treatment and consultation type they had received, as well as who their practitioner had been.

The microanalysis and open coding procedure I employed on these first three interview transcripts led to a tentative emergence of codes that appeared to support the hypothesis that empathic consultations were associated with positive treatment outcomes, as the hip/knee trial's design had predicted. I decided to continue sampling participants who had improved pain scores in order to explore the impact of the consultation further. This resulted in my first possible 'deviant case' i.e. data that does not fit easily into the developing patterns or theory. During a review of the quantitative data, I found that a female participant who had received placebo treatment but with a non-empathic consultation had documented a noteworthy reduction in pain. The concepts that emerged from this particular participant's interview (Marion), led to the purposive selection of participants who had only received non-empathic consultations. I wanted to follow up on her experiences, and compare them with those of other participants who had received a similar level of interaction.

Following a further five interviews with participants who had received either real or placebo treatments with non-empathic consultations, the emerging data required a shift of focus onto those individuals who had received 'real' treatment only. This was to explore if the emerging concepts were related to treatment type, rather than consultation. As recruitment into the hip/knee trial slowed,

interview participants were recruited from the second trial site to explore for any influence of setting, and eventually participants were selected just as they were completing due to time constraints. By this stage however factors relating to participation were emerging and these were specifically explored further in these latter interviews.

The sampling finally moved in the direction of theoretical sampling. This refers to the sampling of ideas from a variety of sources such including observations and relevant literature that is driven by the emerging data (Glaser & Strauss 1967). It develops as the study proceeds and is not planned beforehand. Rather it is based on the need to collect more data in which to examine emerging categories and concepts for full range and variation in order to guide theory development. This 'testing' can lead the researcher in search of varied sources of data including that from settings often very different to the initial one (Chenitz & Swanson 1986). For example I drew on my own observations from working as a practitioner on the hip/knee trial, field notes; memos and previous research into trial participation in general.

4.4 The Interview process

Qualitative interviews were chosen as a method of data collection as they offered a potentially powerful means of exploring the intricacies of CAM, through the eyes of the recipients (Broom 2005). Unlike the reductionist approach of clinical trials, qualitative methods of investigation allow the researcher to gain insights into the thoughts and feelings of individuals. In particular they explore the experiences and processes of a phenomenon, and are also a means of gaining information into the understanding and meanings constructed by individuals regarding the events and experiences of their lives (Grbich 1999; Holloway & Wheeler 2002; Strauss & Corbin 1998). Although subject to 'recall', interviews allow the researcher to gain information on beliefs and perspectives of the interviewees, and the emergence of such data collection is inextricably linked to the interpretivist tradition associated with Glaser & Strauss (Broom 2005). I undertook face to face, semi- structured interviews, using open ended questions and probes for this study. This was with the hope that a narrative may develop

offering a process of meaning- making (Labov & Waletzky 2003), which would facilitate greater exploration of the phenomenon under investigation.

As I have mentioned in section 4.2, I contacted the participants to arrange an interview once they had been identified as willing by their practitioner. A choice of location was offered however all of the interviews were conducted in the participants' homes. Most interviews were carried out within four to eight weeks of the participant's completing the trial. The timing had to be flexible as many participants, especially at the early stages of data collection were due to go into hospital for their joint replacement operation. Therefore they had to be scheduled either before or after it, as not to impact on their preparations for the operation or impede on their recovery. I recorded field notes prior to entering the houses i.e. their demographic details and treatment codes. In the very early stages of my study I had still been recruiting participants onto the hip/knee trial and in three cases had met the interviewee at an initial assessment for the trial, and two during their treatments[3].

This blurring of roles was a concern as even some of the participants who I had not met before, were aware that I was part of the trial and knew their practitioners. As a result, I must concede that the information shared during the interviews may be influenced by this knowledge, or be in response to my behaviour in such situations. Previous research by Hamberg & Johansson (1999) sees the authors reflect on their grounded theory study of women seeking consultation for biomedical, undefined long-term musculo-skeletal pain in which the interviewing researcher was also the participant's family physician. The authors mention their access to the participant's medical records as data for the analysis, and I became aware that I may have been influenced by the interviewees' trial documentation. One of my roles as researcher was not only to work as a practitioner on the trial, but to input the quantitative data. I was aware of their treatment randomisation and written responses prior to hearing their

[3] Section 5.3 presents brief narrative descriptions of the 27 participants interviewed. My aim in including these is to give a sense of these individuals, and their differing experiences relating to the practicalities of the hip/knee trial. I also make explicit any previous contact with myself, prior to their interview in order to share the foundations of the qualitative study before discussing the emerging concepts.

verbal thoughts and experiences, which may have influenced my approach to the interview. Although this was the basis of my initial purposive sampling I did not consider at the time the influence this may have on subsequent data, and the importance that I acknowledge it as a means of potential prior assumption on my part.

Some of the interviews were conducted with spouses, grandchildren and pets present. Formality varied greatly from offerings of home made cakes in the lounge, to an area set aside in a quiet room with instructions to not be disturbed. The domiciliary visits varied in length from between a minimum of 30 minutes to a maximum of just over two hours. Interviews rarely started immediately on arrival to the house, first was introductions and organisation of refreshments, if offered. I did not set a time limit for the visits, but I became aware of my own limitations of beginning to 'switch off' after two hours. I started the process by introducing my study and explaining again the privacy and confidentiality issues regarding the interview data. I also requested permission to record the session. Only one participant declined to be recorded, explaining that she did not like the sound of her voice. I was also conscious to keep the recording equipment out on display, and remind the participants that they could request it being switched off if they so desired.

The interviews were open ended in nature to encourage a free flowing response (see example in appendix 7). No schedule was drawn up, apart from the opening question where the participants were asked to comment on their experiences of taking part in the trial. It may be argued however, that by commencing an interview with a question focusing specifically on a topic, the starting point is forced, thereby biasing the interviewee's story telling to a subject initiated by the researcher. This is in contrast to the flow of speech being independent from the interviewer, with the researcher's role confined to that of an attentive listener (Bauer 1996). In response to this I found during the interviews that once a response had been given regarding the trial, the individuals' own story then appeared to emerge.

However there has been long running criticism of interview based qualitative research, in which warnings have been offered as to the limits of what may be inferred from the data. Hammersley (2005) focuses on whether informants are telling the truth, the differences between what people say and do; social desirability and the incompleteness of the data, when compared to other qualitative data collection techniques such as participant observation. Kvale (1996) also discusses the trustworthiness of interview data, and argues for the evidence of spontaneity from the interviewees. In other words to what extent an informant's statement would be the same if given spontaneously rather than directed from the researcher. Other factors to take into consideration are the balance of interviewer/interviewee time and the achievement of clarity from the data, which can be inferred during the analysis process.

The implications of what people say and do within a specific context were an issue for this qualitative study, along with the 'power' relationship in the research process due to my role in the hip/knee trial. Most of the participants were keen to ask their own questions about the research, often using the interview to address their own need for further information that might not have been available during the trial. Reflecting upon this led me to realise that my interview technique varied from individual to individual. I tended to respond to them and the situation at the time, finding it difficult not to respond to their questions as I would have done in practice. At the outset of the study I had planned to follow the interview techniques guidelines of authors such as Patton (2002), who recommends the answering of any participant questions at the end of the interview. However in reality this wasn't quite so easy, and at times I did respond during the interview. This adjustment of interaction between my self and the participant could be viewed positively. For example my observations were that if the interviewee's questions were answered at the time, it appeared that the participants felt more at ease to open up and discuss freely their thoughts and experiences.

Yet this expression of views by the researcher is clearly seen as a source of bias, and Oakley (1988) has discussed this dilemma from a feminist research perspective. She acknowledges the recommendation that in a 'proper' interview,

researchers must pretend not to have opinions, or possess any information that the interviewee wants, due to the potential bias of it. But she argues that her own experiences of interviewing women have persuaded her that these prescribed techniques are open to challenge. Oakley's rationale is that, the best way to find out about someone through interviewing as a researcher is, to invest one's own personal identity in the relationship (Oakley 1988). With this in mind I chose to be aware of my own interaction within the interviews and consciously note it. Thereby allowing me the freedom to respond should the flow of the interview desire and allow for it.

My interview technique was not the only issue to exert potential influence on the interview process. Lewith (2004) argues that the education process of training as a practitioner produces individuals who have a strong belief in their chosen therapy and particular therapeutic role associated with it. This means that CAM practitioners may find it harder to step back from their therapeutic involvement and become effective researchers. In terms of data collection my method of interviewing did appear to be influenced by my previous occupation. Regarding my therapeutic involvement, the fact that the hip/knee trial was investigating western acupuncture may overcome this as it is not essentially my chosen therapy. Yet it is just as important that because my training is in TCM, that I did not inflict bias during treatments or interviews by comparing the two interventions. I tried to manage this by reinforcing the western approach to acupuncture and the mechanisms behind it if asked about the process of acupuncture during the interviews, for example the transcript extract overleaf is my response to a question asked by one of the participants – Betty, who wanted to know how acupuncture reduced pain (see Figure 2).

Figure 2 Interview example of participant enquiry

"Um, no I don't think so because I feel, well, I don't know exactly what's happening in there but the joints have worn away, even if you have the proper acupuncture, if it's actually worn away I don't feel that you're going to feel any better really, the pain… how can that stop the pain?

It's more that, when they've scientifically looked at the process of stimulating acupuncture points it seems that it releases your body's natural pain-killing analgesics.

Oh… Oh

And that's how it can be of benefit.

Oh I see, yes"

Betty (line 107-120).

Immediately after an interview had finished I would return to the car and document my observations of the interview situation e.g. my perceptions of the participant, the setting, and feelings of how the interview went. My first interviewee raised many aspects concerning the trial, which I recorded in my field notes as her comments ranged from parking at the hospital to what she thought of the paperwork. This participant also shared the fact that she had worked for many years in the field of research. This initiated my desire to see if similar comments would emerge in future interviews or if her experience was influenced by her previous personal and professional experiences.

Using issues from my field notes as probes also allowed me to keep an unstructured approach to subsequent interviews but facilitated the drawing in of such topics if not mentioned, which may then be asked at the end. Kvale (1996) asserts that interviews are conversations where the outcome is a co-production of the interviewer and the subject, as appears to be the case in my interviews. Such

adaptations to the interview process are the basis of grounded theory, due to the 'testing out' of emerging data.

I transcribed all but two of the participant interviews. This process proved extremely insightful as I listened to the tapes first, roughly transcribing then typed them up. This method enabled me to hold the voices of the participants in my mind as I read over the transcripts, along with the visual memories of the encounters. I aimed to transcribe the interviews within a week of my recording the interview, and begin the analysis once the participant summary had been written. Transcribing the interviews caused me to reflect upon the information being shared with me by the participants and the ways I facilitated or curbed this with my responses during the interview. At times I have thought, "why did I not follow up on that?" or "how would I ask that next time?" The transcribing process highlighted most interestingly that the balance of power is not necessarily in my favour, as was my initial concern. It appeared from my transcripts that the participants told me what they wanted me to hear, often not answering my questions but following their own agendas for speaking to me. This observation is not purely my own but was also noted by colleagues who kindly reviewed my preliminary analysis, and a secretary within the primary medical care department who transcribed two of the interviews for me.

At the natural close of each interview I arranged with the participants that a summary or copy of their interview would be sent to them within the following three weeks. I asked them to read these and contact me within two weeks of its receipt should they have any queries or wish that the data not be used. This type of participant feedback can be described as a 'member check', its aim being to assess the credibility of the data (Creswell 1998; Schwandt 2001). The value of member checks though has been questioned due to the limitations regarding change of perspectives over time and the differing agendas held by researchers and participants (Sandelowski 1993). A recommendation to overcome this is the use of repeated interviews over time, therefore allowing for such changes. Although considered, this was impractical for my study due to the circumstances of the participants and their future planned operations. Despite the potential bias of the single interview, this method of data collection was still believed to be the

best option for this study due to its explorative nature and the constraints of its aim, context and funding.

4.5 The Analysis Process

My initial attempts at analysis were very much influenced by my preoccupation with the coding procedures I was following (Strauss & Corbin 1990; 1998). This resulted in the development of categories too early in the analysis process, making them appear 'forced'. I also chose to focus my attentions on one particular category I had interpreted, without discussing the other concepts that had emerged, again giving an impression that the data was sparse. This process taught me that the analysis of qualitative data is a complex, and time consuming, as well as a rewarding experience. In this section I will discuss the challenges I encountered in the analysis process as a result of my involvement in the trial, and the impact that this may have had on the data.

> *"Coding represents the operations by which data are broken down, conceptualised and put back together in new ways. It is the central process by which theories are built from data". (Strauss & Corbin 1990)*

Analysis in grounded theory necessitates the coding of data at different levels (see Table 3). This process facilitates the emergence of conceptual categories in the data. The analysis then focuses on finding relationships between these categories and culminates in the generation of a core category to which all the categories are related. The emerging categories from the data are compared to subsequent data collection in a process known as 'constant comparison'.

Table 3 Coding procedures of grounded theory

Coding	Description
Open – the reading & re- reading of each line, sentence or paragraph in search of breaking down the data, naming and categorising emerging concepts of the phenomena.	The formation or naming of initial concepts about the phenomenon found in the text. These may be '*in vivo'* i.e. drawn from words in the text e.g. "I'm curious", or events and instances of phenomena e.g. desire for acupuncture. This is followed by the classification of such concepts, which seem to pertain to similar phenomena when compared against each other, resulting in a category. Subsequent open coding seeks out properties of these categories, the aim being to determine how categories vary dimensionally.
Axial - movement between open & axial coding is fluid.	This is the process of relating codes (categories & sub-categories) to each other in order to begin reassembling the data that is fractured during open coding. This results in more precise and complete explanations about the phenomena.
Selective - It is not until major categories are finally integrated that research findings can take the form of a theory.	The process of integrating and refining the theory. Categories are organized around a central idea or 'story line'.

The rationale for using this method is that it acknowledges the overlapping of emerging categories which in turn allows their evolution, and theorizing to occur.

My analysis of the data commenced with line by line microanalysis of the transcripts. My aim at this stage was open coding, as a means of identifying key phrases or issues described by the interviewees which may provide initial insight

in to the processes at work. This phase is often described as conceptualisation (Strauss & Corbin 1998).For example when asked to share their experiences of the trial; some of the participants spontaneously discussed their meaningful motivations for taking part. An initial '*in vivo*' code resulting from this in my study was titled "I'm curious". Below are excerpts of transcripts highlighting this concept:

> "….this was the first thing of this nature that I had come across and I want to know what it is, I'm curious, my curiosity is." (Arthur lines 18-19)

> "It struck me as being an interesting thing. I'm from a slightly technical background but I knew nothing, I know nothing about medicine and this was a great opportunity to perhaps find out a little bit myself." (Norman line 6-9)

> "I would have liked the acupuncture because everybody says "Oh needles being stuck in you". We're all like that and it would have been nice to have known what it actually would have been like." (Elizabeth line 17-19).

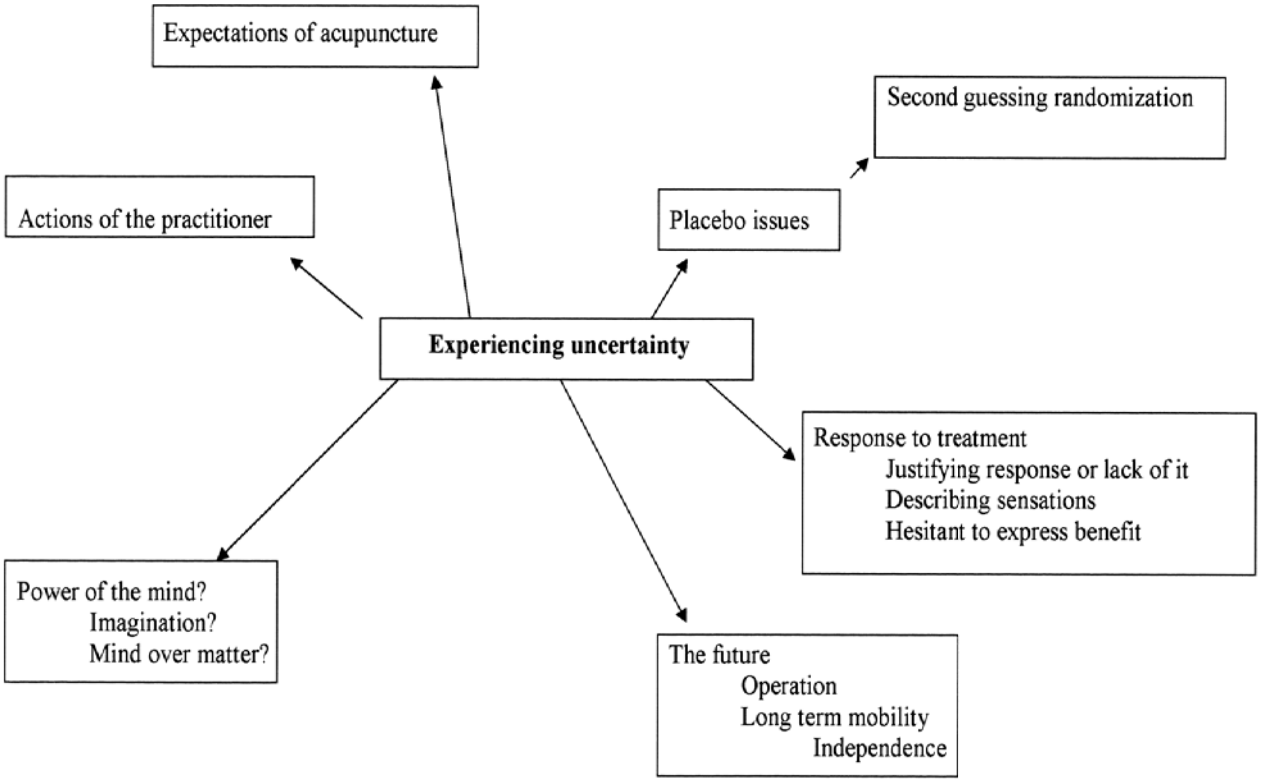
The concept of curiosity was repeated by some participants throughout their interviews and it is for this reason that I have chosen to use it as an example. On occasion I noticed that participants often gave more than one justification for why they agreed to take part in the hip/knee trial. For example Elizabeth's excerpt above gives the impression that it may have been due to her desire to have acupuncture treatment. Yet early on in the interview she rationalises another reason:

> "Well I've done another trial, that was injections and when I did this one I thought it won't probably benefit me but it might help somebody in another generation." (Elizabeth line 5-6)

As a result of these questions I began to document the tentative concepts in flow charts. Once initial categories relating to the issues coded in this stage emerged, they were then explored in terms of their properties and dimensions. To this extent, additional data was collected to facilitate this exploration, an example of which is detailed in section 4.3 when I described the sampling process. At that time the emerging initial concepts from the first ten interviews, necessitated the collection of data from participants who had received real acupuncture, so as to examine the differences or similarities of these concepts between real and placebo treatments in the hip/knee trial.

Whilst reanalysing the first 10 transcripts I was immediately struck by the realisation that in terms of issues being expressed in the interviews, I was dealing with a vast array of potentially relevant data that I had previously overlooked. The transcripts spoke of the individual's views, not on only the trial, but their condition of OA and life in general. The open coding process highlighted just how different each participant was, and that a number of other concepts appeared to be clearly emerging from the transcripts. These related to the level of commitment the participants undertake to participate in the hip/knee trial, their valuing of it and feeling valued, comparisons of the trial and other hospital based experiences, and a sense of uncertainty. Within these concepts were many properties and dimensions. For example the emerging concept of uncertainty appeared to be expressed as a diversity of doubts regarding many aspects of the trial e.g. the issue of placebo, self doubt, actions of the practitioner, response to treatment, documentation and even the future relating to their operation (see Figure 3 overleaf).

Figure 3 **Illustration of coding flow chart – Experiencing uncertainty**



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The examples shared in this thesis are intended to illustrate how data from the interviews was open coded for concepts, which may have had the potential to develop into a category or categories. It does not however convey the complex influences of my theoretical sensitivity and reflexivity on the research process.

As my early attempt at analysis taught me, initial concepts may, in fact be a result of a novice researcher's own prior assumptions or preconceptions, rather than truly emerging from the data. It is for this reason I recommenced my analysis, employing a more cautious and critical approach to it. In light of this I decided to seek the views of my peers and colleagues regarding any emerging concepts in my reanalysis. This was a very positive and productive decision as it was pointed out that I had overlooked an important potential influence on this data namely the power of knowledge and information sharing. An example of my assumptions was in relation to my knowledge of the treatment randomisation in the trial, and how this 'power' may alter the interaction of the interview process. This was especially relevant for my interpretations of the concept of uncertainty. Early on in the study one of the participants (Cynthia) had been informed of the treatment she had received prior to the interview. This was due to the final appointment of the trial being used as an opportunity for the participant's to ask what treatment they had received once all documentation had been collected. As it was our policy to not withhold information, the randomisation was shared. At the time I did not consider this to be an issue for the qualitative study, but my early interview with Dorothy altered all of that.

Dorothy decided not to attend her final appointment and therefore did not know prior to the interview what treatment she had received. Her response to this information caused me to discuss the possibility of sharing this information with the participants during the interview with my supervisors, as it may have shown differences in opinion pre and post information. This became the format for the interview, in that those sampled for the qualitative study are told that they will be told of their randomisation during the interview, should they wish to know. For some participants the issue of being un-blinded did not arise (Sidney, Marion, Linda, Elizabeth, Hester and Helen) and this decision was respected. On one

particular occasion (Susan) I could not remember what treatment she had been given, but she declined the opportunity to receive the information later that day.

With this potential for sharing of knowledge, I had to consider the alternative reasons why some of the participants were non committal about their experiences. Rather than appearing to have a sense of uncertainty, it could be that they were second guessing their treatments, as to not appear foolish for responding to a placebo treatment. This may be especially so if the person sharing this information was known to the running of the trial and their practitioner as is my case. In response to this, I presented this issue at a post graduate seminar at the School of Nursing within the university. The feedback and recommendations I received were very insightful. I was advised to be interviewed myself to 'see what it felt like', and record my preconceptions of the trial and interview process. I was also asked to consider interviewing participants I had treated, so that they could feel that they were informing my practice rather than judging that of my colleagues on the trial. Indeed I was interviewed about being an acupuncture practitioner and felt conscious of what I was sharing. The analysis process can therefore be shown to have an undeniable influence on the research process as a whole, as its feedback can alter the direction of future data collection. Together with fellow students I joined a grounded theory group, in order to discuss our analysis so as to minimise the risk of 'going off' in a direction based on personal assumptions, rather than emerging concepts.

The next step in the analytic procedure of grounded theory was axial coding. Axial coding requires the researcher to reassemble the categories around concept categories or a one core category which have been identified during the open coding process. The aim was to discover how these categories relate to each other, thereby promoting more theoretical ideas about the data emerging from the analysis (Strauss & Corbin 1998). What became apparent at this stage of analysis was that the emerging concepts appeared to relate to both the process of acupuncture and the issues of being in a clinical trial. Such was their entwinement that it was not possible to distinguish the two. As a result further analysis required an examination of this particular context i.e. findings to emerge regarding participation in a specific acupuncture trial. The final stage of coding

was selective. Selective coding results in the integration and refining of the theory to identify a central idea that incorporates all the categories identified in the prior coding procedures. It is from this 'story line' that a hypothesis may be generated. As the study progressed, continued analysis of the data highlighted a core category, and led to the development of a substantive theory.

4.6 The use of Grounded Theory

As previously discussed in section 3.4, grounded theory comprises a number of analytical processes, with the aim of generating a theory from data. Throughout this chapter I have highlighted my sources of data collection (semi-structured interviews, field notes and personal observations) and briefly described the analysis process I undertook. This section will detail the specific grounded theory processes I used and the rationale.

4.6.1 Theoretical sampling

As a grounded theory study progresses, so it's sampling becomes theoretical (i.e. is guided by concepts and constructs which have significance to the developing theory). Theoretical sampling continues throughout the study as data collection and analysis interact. This type of sampling is often a distinctive feature of grounded theory and highlights both its inductive and deductive elements. The dual nature of this process is exactly what attracted me to grounded theory as I thought it the most appropriate methodology for this data set bearing in mind my research questions.

4.6.2 Constant comparison

Constant comparison is another prominent characteristic of grounded theory. Working on the premise that 'all is data' constant comparison allows the researcher to compare qualitative information from various sources e.g. interviews, observations, notes and literature for similarities and differences. This process facilitates the generation of memos, coding and categorizing of data which in turn can direct theoretical sampling. Constant comparison also helps to establish explanatory power of the data and the development of a theory. I chose to use this method as it a core element of the analysis process in grounded theory

and offered me a constructive start and thoughtful framework that guided me through the maze of data analysis.

4.6.3 Coding and paradigms

Strauss & Corbin (1990:1998), describe coding as a fluid and dynamic process. However they offer a sequence of coding (open, axial and selective) that enables the researcher to carry out the steps of theory building. I have already described the differences in the types of coding earlier in this chapter but will now give examples of each stage. Open coding allowed early exploration my interview transcripts, breaking the data down and labeling portions of the text (see Figure 4).

Figure 4 Open coding of interview transcript

Interview transcript sections - Ursula	Open coding
…well I've had acupuncture on different things before so	Use of CAM
I thought it was a good way of easing some of my pain if I was given the right acupuncture.	Opportunity/belief
So that's when I felt…sometimes I felt I could have been given the placebo because she didn't come back in the room and twiddle the needles, and a couple of times she did and I could feel the throbbing after.	Second guessing
So I wasn't quite sure at the time whether the treatment was the real thing or not but it has definitely helped.	Uncertainty/doubt
I'm not conscious now of being in pain so much so that was good.	Response to treatment
I thought it was a good thing to do.	Experience of trial

As my analysis and data collection progressed, I began to consider the open codes in terms of concepts that represented social processes for example *in vivo* codes highlighted by the line by line open coding were compared and describing labels attributed (see Figure 5).

Figure 5 Conceptualization of open codes

Interview transcript sections - Lillian	Open codes	Concepts
Well when I got the letter saying about the trial I thought "Ooh lovely there's just a chance …".	Hope	Rationalizing Motivation
Umm so that's how I came to do it and it was only for four weeks. Twice a week so it wasn't for long.	Time factor	Justifying commitment
But umm…some days I thought it was helping and some days I didn't.	Doubt	Experiencing uncertainty
I wouldn't think it's done anything overall to be honest.	Response to treatment	Considering outcome

Continuing this analytical process helped me to highlight emerging concepts and subsequently categories, defining their properties in order to give meaning to them as well as reducing the number of 'units' with which I was working. The numerous and varying codes and concepts are compared and grouped into categories, which continue themselves to be categorized with other categories in line with axial coding as a more focused means of data interpretation, conceptual development and theory generation. Early categories to emerge from the open codes and concepts became encompassed into redefined categories which eventually became abstract categories that appeared to explain to varying aspects of the data (see Figure 6)

Figure 6 Example of conceptualization of categories

Early categories	Final abstract category
Being committed Conveying commitment Justifying commitment Valuing Being valued Differentiating the experience Distinguishing the setting Sharing	Maintaining the commitment

In the early stages of coding, data is fractured, but the use of a coding paradigm or a theoretical coding family can assist in the reassembling of data to offer complete explanations about the phenomena under investigation. This I found was especially helpful when exploring my final and core categories. With the guidance of one of my supervisors and the grounded theory peer group, I explored my data and the literature using the six C's coding family – context, causes, consequences, covariates and conditions (Hutchinson & Wilson 2001). This allowed me to determine the range of circumstances or settings (context) in which my theory may apply and the independent variables which may exert an effect (causes), the effects or consequences and the possible variables that may modify the relationship between cause and effect and lastly the conditions or limits of the theory and the overall context in which it is set.

4.6.4 Memoing

Throughout the various stages of research I wrote memos, in addition to keeping a reflexive journal and field notes taken post interview. The writing of memos is important for the capture and recording of both description and the important theoretical ideas. As Strauss & Corbin (1998) attest to they are essentially records of analysis notes, thoughts and research questions and also offer direction for further data collection. As the study progresses they can become more theoretical in nature, incorporating diagrams and helping again in the development and formation of a theory. It is for this reason that I used memos

many of which became diagrammatic as my analysis progressed. The next chapter provides a background to the main findings.

Chapter 5 Background to main findings

5.1 Introduction

This aim of this chapter is to contextualize the findings presented within this thesis. The findings describe a theory of 'active participation' which has been derived from the qualitative data. In terms of grounded theory definition, it is essentially a substantive theory of active participation embedded within a trial of western acupuncture for chronic pain. However it has the potential to develop into a formal theory of active participation in randomized controlled trials designed to explore any physically based therapies, complementary or conventional in nature.

The findings are presented in the following four chapters. Chapters' six to eight conceptualize the 'story' of the hip/knee trial from the participant perspective. While chapter nine, discusses the materialisation of the core category. The first three findings chapters each discuss one of three stages related to the emergent theory of participation:

- Making a commitment (chapter 6)
- Maintaining the commitment (chapter 7)
- Producing an outcome (chapter 8)

Each of these stages represents categorized concepts grounded in the data that describe the participants' experience of acupuncture within the perspective of being in a trial. By choosing to conduct open ended, semi structured interviews the transcripts often contained a 'storyline' through which the participants contextualized their individual participation. This composition often took the form of reasons for their involvement, their experience of the hip/knee trial and ultimately the outcome.

Chapters' six to eight of this thesis includes analysis and data pertaining to the categories that have been formed from recurrent concepts arising from the

participant interviews. Quotes from interview transcripts are used to further illuminate the issues; reflexive prose and memos are also included to provide a closer and more contextualized understanding of the analytical process, and to disclose a transparent account of how these findings emerged. Finally theoretical literature and its relationship to the concepts will also be discussed throughout the conceptualisation and presentation of the data, as a means of supporting the substantive theory.

The concept of '**making a commitment'** describes the influences underpinning the participants' participation in the trial and the way in which they justified their choice to take part. **'Maintaining the commitment'** illustrates the way in which the participants talked about their commitment to the trial once the decision to participate had been made, and how they justified their subsequent participation. Finally the concept of **'producing an outcome'** represents the issues expressed by the participants in terms of completing outcome measures, and how outcomes are produced not merely reported.

The three concepts described above, although qualitatively different are all related to another category that frequently emerged from the interview data. This core category is **'forging a conviction'** and has been identified as central to the data. Discussed in detail in chapter nine, it appears to relate to all of the descriptive concepts presented and also offers explanation regarding the vast majority of variations within the data. In essence the core category comprises descriptions of the established or acquired influences underpinning research participation in terms of the participants' motivations, commitment and outcome production in the hip/knee trial. The emergent theory of participation will be finally discussed in chapter ten along with conclusions and recommendations for future research.

This background chapter also includes discussions pertaining to the interview participant characteristics and some of the variables of the hip/knee trial. These variables (location and sample characteristics relating to CAM use) are by no means definitive; neither do they exist in isolation. Rather they have been presented as a means of describing the context of the emergent theory and

acknowledging some of the inherent influences that may be argued to have influenced the qualitative findings. This will be followed by a table of the interview participant demographics (see Table 4) and brief narrative descriptions of the twenty seven participants interviewed. My aim in including these is to give a sense of these individuals, and their differing experiences relating to the practicalities of the hip/knee trial. I also make explicit any previous contact with myself, prior to their interview in order to share the foundations of the qualitative study before discussing the emerging findings.

5.2 Context of the emergent theory

The theoretical and methodological underpinnings of qualitative research, as discussed in chapters three and four, have highlighted the potential contextual influences and implications that nested qualitative research can be exposed too. It would be naïve to deny that the research findings presented within this thesis are not inexplicably context bound to the western acupuncture randomized controlled trial in which the study is positioned. However this does not imply that this undermines the value of the emerging data. Rather by being transparent as to the nature of the contextual influences, the findings may be enhanced in terms of authenticity and trustworthiness. Therefore the purpose of this section is to illustrate some of the 'variables' within the trial that may be argued to have influenced the findings, or be thought of as potential predictors of outcome.

5.2.1 Location

Previous research exploring participation in CAM trials including acupuncture, has highlighted the importance of the research culture of an institution, proffering that potential participants are encouraged by a university setting and an openness to evaluating CAM (Paterson, Zheng, Xue & Wang 2006: Smith & Coyle 2006). The hip/knee trial was conducted by the Complementary and Integrated Medicine research group within the University of Southampton. The university is a well known institution with a long history of research, including CAM research. Both of the trial sites were situated within city hospitals. One was a designated clinical research facility in a teaching establishment, and the other a separate area of a physiotherapy department in a district general. Both localities

also fell under the same research area, and many trials in both primary and secondary care were regularly advertised within the region in the local media and press. Possibly as a result of this 'research saturated' environment, approximately a third of the interview participants had previous personal or professional experience of research.

5.2.2 Sample characteristics

All of the twenty seven participants interviewed in the qualitative study were Caucasian. Females, out numbered males by eighteen to nine, however, it must be acknowledged at this point that the participants were sampled depending upon the emergent data and that the final gender ratios of the hip/knee trial participants are still unknown at this time. From personal observations the majority of participants who completed the trial were over 50 years of age. The mean age of the interview participants was 68.4 years (range 52-78 years). It has not been clear from previous research whether age influences recruitment and retention in clinical trials (Adams, Silverman, Musa, & Peele 1997), but availability of time to take part is a potential influence to consider.

Nineteen of the participants were officially retired but many gave the impression of leading full lives, some continuing to do voluntary work. The other eight individuals were still working on either a full or part time basis. Educational levels and socioeconomic factors were not recorded as part of the trial data. Yet on personal reflection of conducting the interviews the majority of the participants appeared to conform to a high socioeconomic and educational background. These factors may be important when comparing the characteristics of the individuals interviewed, in regards to whether they are representative of the general population with osteoarthritis, or those who use CAM.

Research exploring the characteristics of individuals that use CAM believe common attributes to include female gender, higher educational and economic standing, poor health status (Shmueli & Shuval 2006), holistic philosophical orientations to health and life (Hyland, Lewith & Westoby 2003), and non-black ethnicity (Eisenberg, Kessler, Foster, Norlock, Calkins & Delbanco 1993). The substantial use of acupuncture amongst individuals with chronic musculoskeletal

conditions such as osteoarthritis has also been documented (MacPherson, Sinclair-Lian and Thomas 2006: Paterson & Britten 2003). Willison & Andrews (2004) argue that chronic health conditions and disability act as reliable predictors of CAM use. This in turn may help to explain the issue of choosing CAM in response to dissatisfaction with orthodox treatment be it ineffectiveness, side effects or frustration with the conventional medical clinical encounter (Furnham & Smith 1988). All but one interview participant recounted a chronic pain history of at least two years. In terms of their arthritic conditions fourteen were awaiting knee replacements and thirteen new hip joints. For some of the participants the wait was for a second joint replacement surgery, having already had 'the other side' operated upon.

Many of the participants had been on long term analgesics and, or non steroidal anti-inflammatory drugs for their osteoarthritis and were concerned by the potential implications of this. To this extent some never took 'pain killers' preferring to 'work through' or distract themselves from the pain. Others rationed their drug intake, while some felt unable to manage without regular medication and would take up to the recommended limit and on occasion exceed it. Concerns appeared to pertain to dependency, side effects, interaction with concomitant medications and alterations to regular treatments. During data collection the analgesic under the brand name Coproxamol was withdrawn from general supply and became available only under special rules in 2007. This was a common analgesic for osteoarthritic pain, and it was at this point that one particular participant decided to manage the pain with out being reliant on a particular prescribed medication.

Searching for an alternative was common place and participants continued the use of supplements mainly cod liver oil and glucosamine for self treatment of their condition. Manual therapies and magnets had also been sought as a possible treatment. This raises again the question of participant characteristics. In one qualitative study, differences were found between the decision making processes of adults with chronic rheumatological disorders with respect to CAM use, indicating the possibility of 'alternative patients' not just 'alternative therapies' (Caspi, Koithan & Criddle 2004).

Table 4 Interview Participant demographics

Pseudonym	Demographics	Trial data	Personal
Dorothy	Female 75 years of age Caucasian	Completed 03/04 Non needle placebo/ Non- Empathic Female practitioner SGH site*	• Single • Retired • Hip • Mobile & drives • Pre operative • Professional experience of research
Sidney	Male 75 years of age Caucasian	Completed 03/04 Placebo needle/ Empathic Female practitioner SGH site	• Married • Retired • Knee • Mobile & drives • Post operative • Personal experience of research
Cynthia	Female 69 years of age Caucasian	Completed 04/04 Placebo needle/ Empathic Male practitioner SGH site	• Married • Retired • Knee • Mobile* • Pre operative • Personal experience of research
Marion	Female 69 years of age Caucasian	Completed 07/04 Non needle placebo/ Non-empathic Male practitioner SGH site	• Married • Retired • Hip • Mobile • Pre operative • No previous experience of research
Linda	Female 61 years of age Caucasian	Completed 08/04 Placebo needle/ Empathic Male practitioner SGH site	• Married • Works part – time • Hip • Mobile & drives • Pre operative • Professional experience of research

Martin	Male 59 years of age Caucasian	Completed 10/04 Real acupuncture/ Non Empathic Male practitioner SGH site	• Married • Works full time, but signed off at present • Hip • Mobile & drives • Pre operative • No previous experience of research
Betty	Female 72 years of age Caucasian	Completed 10/04 Non needle placebo/ Non empathic Female practitioner SGH site	• Widowed • Retired • Hip • Mobile • Pre operative • No previous experience of research
Arthur	Male 76 years of age Caucasian	Completed 10/04 Non needle placebo/ Non empathic Female practitioner SGH site	• Married • Retired • Hip • Mobile & drives • Pre operative • No previous experience of research •
Susan	Female 63 years of age Caucasian	Completed 10/04 Placebo needle/ Non empathic Female practitioner SGH site	• Married • Retired • Knee • Immobile*** • Pre operative • No previous experience of research
Elizabeth	Female 65 years of age Caucasian	Completed 10/04 Non needle placebo/ Non empathic Female practitioner SGH site	• Widowed • Retired but volunteers • Knee • Mobile • Pre operative • Personal experience of research

Ursula	Female 61 years of age Caucasian	Completed 02/05 Real acupuncture/ Non empathic Female practitioner SGH site	• Married • Works one day a week • Knee • Mobile • Pre operative • No previous personal experience of research
Hester	Female 79 years of age Caucasian	Completed 03/05 Real acupuncture/ Non empathic Female practitioner SGH site	• Widowed • Retired but volunteers • Knee • Mobile • Pre operative • No previous personal experience of research
Lillian	Female 70 years of age Caucasian	Completed 05/05 Real acupuncture/ Empathic Male practitioner SGH site	• Married • Retired • Hip • Mobile • Pre operative • No previous personal experience of research
Norman	Male 67 years of age Caucasian	Completed 04/05 Real acupuncture/ Non empathic Female practitioner SGH site	• Married • Works • Knee • Mobile • Pre operative • No previous personal experience of research
John	Male 77 years of age Caucasian	Completed 11/05 Real acupuncture/ Empathic Male practitioner SGH site	• Married • Retired • Hip • Mobile • Pre operative • No previous personal experience of research

Melanie	Female 62 years of age Caucasian	Completed 11/05 Placebo needle/ Empathic Male practitioner SGH site	• Married • Works & studying • Hip • Mobile • Post operative • Professional experience of research
Agnes	Female 67 years of age Caucasian	Completed ?/05 Non needle placebo/ Empathic Male practitioner SGH site	• Married • Medically retired • Knee • Mobile • Pre operative • Previous personal experience of research
Stella	Female 70 years of age Caucasian	Completed 02/06 Non needle placebo/ Non empathic Female practitioner SDH site**	• Married • Retired • Hip • Mobile • Pre operative • No previous experience of research
Beatrice	Female 66 years of age Caucasian	Completed 02/06 Non needle placebo/ Non empathic Female practitioner SDH site	• Unknown status • Works nights in NHS • Knee • Mobile • Pre operative • No previous experience of research
David	Male 78 years of age Caucasian	Completed Mar/06 Non needle placebo/ Empathic Female practitioner SDH site	• Married • Retired • Hip • Mobile • Post operative • Personal experience of research

Emily	Female 78 years of age Caucasian	Completed 03/06 Real acupuncture/ Empathic Female practitioner SDH site	• Married • Retired • Knee • Mobile • Post operative • No previous experience of research
Margaret	Female 73 years of age Caucasian	Completed 05/06 Non needle placebo/ Non empathic Male practitioner SGH site	• Married • Retired • Knee • Mobile • Pre operative • No previous experience of research
Roy	Male 68 years of age Caucasian	Completed 05/06 Placebo needle/ Empathic Male practitioner SGH site	• Married • Works part time • Hip • Mobile • Pre operative • No previous experience of research
Helen	Female 52 years of age Caucasian	Completed 05/06 Placebo needle/ Empathic Female practitioner SGH site	• Separated • Works • Hip • Mobile • Pre operative • No previous experience of research
Wendy	Female 62 years of age Caucasian	Completed 05/06 Placebo needle/ Non empathic Male practitioner SGH site	• Married • Unknown work status • Knee • Mobile • Pre operative • No previous experience of research

Colin	Male 71 years of age Caucasian	Completed 05/ 06 Real acupuncture/ Empathic Female practitioner SGH site	• Married • Retired • Knee • Mobile • Post operative • No previous experience of research
Peter	Male 61 years of age Caucasian	Completed 05/06 Non needle placebo/ Empathic Male practitioner SGH site	• Married • Retired due to disability • Hip • Mobile • Pre operative • No previous experience of research

(*) SGH site is Southampton General Hospital

(**) SDH site is Salisbury District General Hospital

(***) Mobile indicates the ability to walk independently or with the aid of a stick/crutch. Immobile indicates the need to use a wheelchair.

5.3 Participant narrative descriptions

5.3.1 Dorothy

Dorothy had a previous professional background in research, and was the first participant that I interviewed. She was sampled due to her negative response to the RCT in terms of no improvement in pain scores. She had received a non needle placebo and non empathic consultations, from the practitioner who had recruited and consented her onto the trial. I had not met Dorothy prior to the interview. During the two hour process, she admitted that she had made a judgement of her practitioner at their initial meeting, and when her subsequent behaviour was different during the treatments this provoked a negative experience for Dorothy. This impact resulted in Dorothy deliberately choosing to not attend her final appointment with her practitioner as she did not wish to see her. These final trial appointments were arranged as a part of the RCT to collect

any outstanding quantitative data and as an opportunity to inform and discuss with the participants which treatments they had received, should they wish to. Therefore Dorothy did not know which treatment she had been given and it was important to her that this information was shared during the interview.

5.3.2 Sidney

Sidney was a gentleman who had a two year history of pain. He was the first participant to be interviewed post operatively, and had recently had his joint replacement at a local private hospital as an NHS patient. At the time of his interview he was recovering at home from a post operative complication. Sidney was sampled due to his reduced pain scores, in response to a needle placebo treatment and empathic consultations. His practitioner had recruited and consented him on to the trial. The interview was my first meeting with Sidney, and this was comparatively short at 30 minutes. Sidney rarely expanded on his thoughts about the RCT, but he did talk freely about a previous trial he had been involved in. At no point during the interview did Sidney ask about what treatment he had received, neither did he request this information from his practitioner on his last appointment.

5.3.3 Cynthia

Cynthia was a lady with a two year history of pain. She was a sampled because of her reduced pain score after receiving needle placebo treatment with empathic consultation. Cynthia had asked her practitioner about her treatment at her final appointment, and had been informed that it was a placebo. As a result, I documented in my interview field notes about ‘the need to give reassurance that she hadn’t been duped’. I even ask myself if this is Cynthia’s need, or my own? Cynthia asked me many questions during the interview, all of which have been kept on tape but were not fully transcribed at the time. I had not met Cynthia prior to her interview.

5.3.4 Marion

Marion was a lady who had experienced pain for the last five years and was interviewed just prior to going into hospital for her operation. Marion was

sampled due to her potential as a ‘deviant case’. She had noticeably reduced pain scores, from receiving a non needle placebo and non empathic consultations which challenged the hypothesis of the hip/knee trial that empathic therapeutic encounters benefited outcome. Marion was very impressed with the setting of the trial and the staff within it, and her practitioner. I first met Marion during her participation in the trial, when I treated her twice on behalf of her allocated practitioner. On reflection the interview process did feel like being invited into her house as a ‘new friend’. Marion never directly asked what treatment she had received, despite discussing the issue of placebo with me. By this point I had decided to share the treatment randomisation during the interview, so she was unaware of this information unlike Cynthia.

5.3.5 Linda

Linda was a lady who had professional experience of clinical trials due to her part time work. She reiterated during the interview what a good opportunity the hip/knee trial was to try acupuncture and find out if it worked. Linda’s joint pain had been increasing over the last four years, but admitted that she was reluctant to have the replacement operation. Linda received a needle placebo and empathic consultations, and was sampled due to her improved pain scores noted in the quantitative data. I first met Linda at her initial assessment, when I consented her onto the trial. Despite this it was not a first meeting that stuck in my mind, and I actually forgot that I had met her before. The interview was relatively short in duration- 30 minutes, and I documented in my field notes that Linda appeared surprised that I did not ask her more questions. I have considered whether this was partly due to the fact that Linda’s interview was arranged just prior to the discovery of Marion, who challenged the hip/knee trial’s empathy hypothesis. I decided to still interview Linda however my own curiosity was drawing me to talk to participants who had received non empathic consultations. During the interview Linda did not ask me to confirm which treatment she had received, therefore I myself did not raise the topic as I was conscious that some participants may not wish to be informed.

5.3.6 Martin

Martin was a gentleman with a five year history of pain. At the time of his participation in the trial he had been signed off sick from his physically demanding employment. This appeared to be a concern for him as he repeatedly mentioned his work situation during the interview. Martin was sampled because he had received a non empathic consultation, and the purposive sampling was focused in this direction. Martin's interview was one of the longest at 90 minutes. I had met him previously at his initial assessment having consented him into the trial, and on the odd occasion in passing at the research unit during his treatment. He was also randomised to have real acupuncture, and was extremely keen to know which treatment he had been given. He physically relaxed when I informed him that it had been a real treatment, however his verbal response regarding the benefit of the treatment, following this remained neither positive or negative.

5.3.7 Betty

Betty's pain started after an injury three years ago, and she was experiencing a lot of referred pain. Betty shared that she had been recommended acupuncture initially after her injury, but she only considered it an option when her mobility became impaired and she had trouble walking. Betty was sampled according to her consultation type which was non empathic. She received non needle placebo treatment from the practitioner who had consented her. I had not met Betty prior to her interview, and as soon as I arrived through the door she wanted to be told what her treatment type had been. This was even before I had set up the recorder for the interview, but I respected her request and shared it with her. Betty raised the issue of 'what others were getting', as she had received treatments when other trials were being conducted in the research unit. She assumed that these individuals were also part of the hip/knee trial, and when overhearing their positive responses to the 'their treatment' decided they were having the real thing, whereas she wasn't. During the interview Betty asked me a numerous questions about the trial and research.

5.3.8 Arthur

Arthur was a gentleman in his mid seventies, with a five year history of pain. Arthur was sampled due to his receipt of non empathic consultations from his practitioner, whom he was very impressed with. Arthur was also randomised to a non needle placebo and he expressed that he experienced pronounced benefit during the trial. I had met Arthur at his initial assessment and had consented him, into the trial. When informed of the randomisation he questioned how the treatment could have been inactive, due to his response and the sensations he had felt. I felt very uncomfortable during this interview, which may have been due to Arthur's defensive response to being told he had received a placebo.

5.3.9 Susan

Susan had a five year history of pain. Susan's pain was bilateral and she required a wheelchair when outside of the home. Susan's mobility was also impaired by her weight, which she was trying to reduce prior to her operation. This was a challenge for her, as well as other medical complaints which she discussed throughout the interview. Susan was sampled because of the non empathic consultations she received, in conjunction with needle placebo treatment. I had seen Susan in passing at the research unit but we had not spoken prior to her interview. I was unprepared for Susan's interview, in the fact that I could not remember whether she had received a needle or non needle placebo. Despite this Susan did not directly ask me about her treatment, and when I mentioned that I could find out for her she declined the opportunity.

5.3.10 Elizabeth

Elizabeth was a lady with a thirty year history of pain. It appeared that Elizabeth's concern was that OA was hereditary and her children and grandchildren would inherit the condition. She committed herself to the trial around her part time work and often talked of 'playing truant' to attend her appointments. Elizabeth was sampled due to the non empathic consultations she received with a non needle placebo. She was treated by the same practitioner who had consented her into the trial. Susan did not ask if her treatment was real

or not, although she did ask me about ‘the operation’. She had just received a letter offering her a pre assessment for a private hospital. I had not had not met Elizabeth prior to her interview.

5.3.11 Ursula

Ursula had a 3 year history of pain. She had tried acupuncture before with good results and worked part time within a CAM setting. Ursula was sampled due to a change in the focus of my purposive sampling. I wished to explore the emerging concepts from the previous interviews but felt in order to do I required data from participants who had received real acupuncture. This was irrespective of their consultation type. Ursula actually received non empathic consultations with her treatment. I had not met Ursula prior to her interview but she talked freely for nearly an hour. Once the tape had been stopped we talked for a further 25 minutes. Ursula was keen to be told what treatment she had received, but it appeared that her other concern was the behaviour of the practitioner – I noted in my field notes that Ursula’s interview reminded me some what of Dorothy’s.

5.3.12 Hester

Hester was a lady in her late seventies, very independent, driving, and still working three afternoons a week. Hester had already had one joint replacement in 1999, and took part in the trial whilst waiting for the ‘other side’ to be done. Hester was sampled as she had received real acupuncture, and her consultations were empathic in nature. I had not met Hester prior to her interview, and it was clear from the start that she knew what she wanted to say. Hester talked little of her experiences of the trial, preferring to discuss the effect of OA and her other ill health on her daily life. She shared with me that she had decided to postpone her forthcoming surgery, so that she could attend a pilgrimage abroad – her faith seemed very important to her. The interview lasted an hour and Hester drew it to a close.

5.3.13 Lillian

Lillian had a three year history of pain. She was sampled as she had received real acupuncture, again in conjunction with empathic consultations. Lillian appeared very keen to be able to ride her bike again, and was hopeful that she would be able to do this after her operation. I had not met Lillian before, but she thought she may have seen me at the research unit. Lillian was very interested in the research trial and she did enquire outright if her treatment had been a placebo or not. Lillian shared with me that her response to the treatment had been limited and that she felt that she had 'let us down'. The interview itself lasted about thirty minutes but again I was there chatting for over an hour.

5.3.14 Norman

Norman was retired but his professional background was in engineering and by his own admission he was very skeptical of alternative medicine, as it did not fit his need for exactness. Norman had bilateral pain in his joints for sixteen years. The previous year he had a joint replacement operation on the other leg and was pleased with the results. Norman received 'real' acupuncture and was sampled according to this. He had non empathic consultations, with a practitioner who had recruited and consented, him onto the trial and was disappointed that he was unable to discuss the treatment in a much detail as he would have liked, repeatedly mentioning his curiosity for acupuncture. My first contact with Norman was by letter as we continued to miss each other on the telephone. He wrote a formal letter confirming his willingness to take part in the qualitative study, and dates he could be contacted. In fact Norman's approach to the interview did appear quite formal, in that he prepared a list of his own questions to ask me during the process. I had been informed by Norman's practitioner that he was keen to know what treatment he had received and as a result was reassured that he would be told during the interview. Norman requested a copy of the whole interview transcript rather than a summary.

5.3.15 John

John was my oldest interviewee and a gentleman with a military background. He was sampled due to the fact that he received real acupuncture. His wife remained with us throughout his interview and at the end asked her own questions for up to 45 minutes. It was during this that John's wife informed me that he himself very rarely noticed an improvement in his condition, whereas she recognized that 'he was better'. John had previously had his other hip replaced a few years ago, and since taking part in the trial had decided to postpone his scheduled operation – he felt the risks outweighed the benefits. He was very interested in the history of acupuncture, having read books on it and seen it overseas in the early seventies. John was very impressed with his practitioner and the running of the trial, and I had no previous contact with him prior to the interview.

5.3.16 Melanie

Melanie was a lady who worked for the health service and was herself in higher education. At this stage sampling for interviews was based on the practitioner allocated to them, and I had not met her before. She had already had one hip replaced a few years ago and was interviewed postoperatively. Unfortunately she too had developed complications whist in hospital which was restricting her recovery. Melanie compared her pain experiences of both hips, which were different in their disabling factors. She discussed her faith and expressed a positive view of placebos, rationalizing her experience on the trial when informed that she had received one. Melanie also requested a copy of her interview transcript. She even rang me to say it had arrived and was happy with the content but there were typographical errors.

5.3.17 Agnes

Agnes was registered disabled due to her OA and pain. Interestingly she had already participated in a CAM trial for her OA (Devils Claw study), which was also based in our research unit. I had not met her previously and was unaware of this at the time. She joked that she was concerned we would think 'Oh no, not

her again'. Agnes was interviewed with her husband present and again due to her allocated practitioner, who she had a lot of time for. Her family members worked in the health service and had encouraged her to take part. Her forthcoming operation was due within the week and she was keen that this would allow her to travel again. In the past she had been overseas to China and spoke of this during our time together.

5.3.18 Stella

Stella was a participant from the hip/knee trial's second site, and was sampled according to this. We had not met previously. Throughout her interview Stella talked of 'acupuncture' however during the trial she had been randomized to the non needle placebo. Her husband was retired from the Navy and encouraged the management of her pain. Stella was always reluctant to take pain killers and preferred natural 'products'. She lived an outdoors life and was keen to maintain this. Stella was informed during the interview that she had received a placebo. Although initially shocked she decided to keep this information to only herself and her husband (he joined us at this point), as had been recommending 'it' to all her friends. She was happy to be contacted again if required.

5.3.19 Beatrice

Beatrice worked for the health service and it was difficult to arrange this interview due to her work commitments. She was sampled due to her trial site and was the only participant interviewed to request that it not be audio taped. We had not met before but had spoken repeatedly on the phone to arrange a convenient date and time. Beatrice had already had two arthroscopic washouts to her knee in the past, and informed me at interview that she had postponed her forthcoming operation. Her mother had similar surgery in the past and had ended up with an infected prosthesis that ended up being removed. Beatrice expressed that she felt disappointed when she did not receive 'needles' on the trial as it had been promoted as an acupuncture trial. Although she had no previous experience of acupuncture but had heard positive accounts of acupuncture from family members, and had associated the treatment with needles.

5.3.20 David

David was a retired medical scientist whose wife and daughter had worked for the health service. He was sampled due to his trial site and I had no previous contact with him prior to his interview which was postoperatively. He had originally had acupuncture for a different, referred pain complaint and experienced great relief from this treatment and as a result compared the effects of the randomised trial treatment (non-needle placebo) with this previous occurrence. By the end of the eight trial sessions he had concluded that the treatments given were placebo due to a lack of response and prior knowledge. The fact that the treatment was a placebo was confirmed during the interview. David admitted that when first offered ‘acupuncture’ he was some what reluctant to pursue it, despite its ancient background, witnessing its use in Asia and the understanding that it is an invasive treatment. However since initially receiving it he is a firm believer in its benefits and now recommends it to others. David doubted the use of real acupuncture treatment as a complete alternative to joint replacement surgery, as he felt the benefits would be ‘relieving’ rather than curative. He was also aware of the physical and structural changes caused by osteoarthritis and how these would not be altered by acupuncture.

5.3.21 Emily

Emily’s interview was conducted post-operatively and we spent a portion of the interview discussing the surgical experience and the complications which arose following the operation. She was sampled due to her trial site and she started off by discussing the documentation and how it was felt not to be entirely applicable. Emily’s response to the treatment offered on the trial was positive, with a noticeable reduction in swelling around the joint and pain relief, during the day. Mobilizing was also easier. These benefits continued the short time from the end of the treatments to the operation date. It was confirmed during the interview that the treatment received was real acupuncture. She decided to take part in the trial due to own perceptions and other peoples’ positive accounts of acupuncture. Despite this she did not see acupuncture as an alternative to joint replacement surgery as was unconvinced that the benefits are long lasting, especially if

internal structures are altered for example lack of cartilage. Overall Emily found the trial a positive experience, was impressed by the practitioner and would be happy to take part again should it be needed. We had not met before.

5.3.22 Margaret

Margaret had a long history of the knee problems which she attributed to complications of prolonged bed rest whilst hospitalized with a serious medical condition as a teenager. Her husband, who has a scientific background sat in on her interview as Margaret is hearing impaired, and it was he himself who enquired about treatment type rather than Margaret. I had been informed that this scenario may occur by her practitioner on the trial, but had no other knowledge of Margaret prior to her interview. She was aware of acupuncture as it was a treatment used by a close family member, and feels this may have influenced her decision to participate in the trial. However she had long been interested in the effect of diet on health, and has taken other health supplements for many years. Margaret's pain and disability fluctuated and she had postponed the replacement operation for a further three months.

5.3.23 Roy

Roy had already had one hip replaced and had considered acupuncture prior to being contacted for the trial. He felt the research was a free opportunity to try something that was already of interest (he had lived previously in Singapore). I arranged the interview date with his wife who sat in with us, but had not met Roy prior to this. Roy's main priority was not the hip joint but the referred pain to the knee. He expressed disappointment that the response from the intervention was not greater, and did consider if it was placebo. However he wondered how this would be possible with needles and the realistic actions of the practitioner. Confirmation was given during the interview that it was placebo, but Roy viewed this encouragingly as it meant that acupuncture may still be a method of pain relief in the future, even after his operation. However he later expressed on my leaving that it was a shame as he had participated around his work commitments and had had to alter his days in order to take part.

5.3.24 Helen

Helen was the youngest participant to be interviewed, and had the shortest pain history of only nine months. I had no contact with her prior to arranging and conducting her interview. Helen valued her practitioner on the trial and felt that her care enhanced her commitment to attending the treatment sessions. She did not enquire as to whether the treatment was real during the interview and I did not offer it. Helen had heard about acupuncture from friends but did not expect a cure. She was requiring a large amount of analgesia and was keen to try and reduce her intake if at all possible prior to her surgery. Helen requested a copy of her interview as was interested to know what she had said.

5.3.25 Wendy

Wendy's father had to have his knees replaced and in her late fifties she had the other knee replaced privately a few years ago after waiting two years with pain. Her first prosthesis lasted five years but she felt she wore it out cycling London to Brighton, golf and swimming and she over used it. She had to have a revision after the five years (nine month wait for this) and was advised not to leave it too long to have her other knee done as to protect the revision. i.e. she was compensating due to pain. She was disappointed to be told that she had received a placebo but asked about follow up treatment as she had actually postponed her surgery for three months when called in order to give the trial a chance. Towards the end of the interview Wendy began to ask me questions about how acupuncture worked. Overall she was impressed with the running of the trial, and despite having concerns over drug trials would be happy to participate in this kind of trial again.

5.3.26 Colin

Colin had already had a joint replacement operation on his other leg and this was done privately the previous year. His interview was conducted postoperatively and he was recovering from post operative complications of anaemia. We had not met prior to this. Colin had not considered acupuncture in the past but had

heard positive views of acupuncture prior to taking part in the trial, and his wife had received acupuncture from the GP with good effect for an upper limb condition. He wanted to give the trial ‘a chance’ therefore he restricted his analgesia intake whilst receiving the treatments. He did feel that there was a response from the treatment, and it was confirmed during the interview that it was real acupuncture that was given.

5.3.27 Peter

Peter admitted to initially being skeptical of acupuncture however his perceptions changed a few years ago after witnessing the effect of veterinary acupuncture on the family pet. He took part in the trial as he viewed research as a way to help others. Peter was registered blind and I had seen him in the trial setting but we had not officially met prior to the interview. He did feel that there was some benefit from the intervention given on the trial in the form of decreased pain when putting leg to the floor after standing up. Peter requested to know what type of treatment had actually been given and it was confirmed that the intervention was a placebo. He was disappointed at the news of the placebo but understood why research requires a placebo aspect. Peter’s operation date was scheduled for the end of the summer and was he was hopeful that the benefit of his ‘treatment’ lasted until then.

5.4 Summary

This chapter aimed to provide a background to the findings which will be presented in the following chapters. By contextualizing the demographics and narratives of the participants it is hoped that this added transparency of the data will enhance the qualitative findings.

Chapter 6 Making a Commitment

6.1 Introduction

This chapter discusses the category 'making a commitment' and presents the emergent data conceptualizing the interview participants' explanations behind their decision to participate in the hip/knee trial. The concepts underlying motivation to participate are of particular interest in this qualitative study, as the recruitment rate for the trial was only 19% of those individuals approached. Furthermore it is well documented in the field of clinical research that recruitment of 'enough' patients into trials is a demanding challenge (Carter, Edward, Malgren, Martin & Larson 1991).

One explanation for the difficulty is the inclusion of placebo arms in order to be considered 'gold standard' in terms of biomedical research (Richardson, Post-White, Singletary & Justice 1998). Therefore recruitment of patients into CAM RCTs may be just as problematic despite the popularity and widespread practice of CAM (Richardson et al 1998). Recruitment rates among CAM research appears to vary greatly, as does the nature of the sample group and therapy under investigation. Randomised trials investigating acupuncture for OA knee illustrate differing recruitment rates of 27% (Witt, Brinkhaus, Jena, Linde, Streng, Wagenpfeil, Hummelsberger, Walther ,Melchart & Willich 2005), and 65% (Scharf, Mansmann, Streitberger,Witte, Kramer, Maier, Trampisch & Victor 2006) of those initially identified to take part in their trials. Both these trials included three arms one of which included needling of defined non acupuncture points. Therefore one could argue that recruitment rates in acupuncture may differ irrespective of placebo arm inclusion thereby challenging Richardson et al (1998).

The issue remains unclear and warrants further research. However the findings of this qualitative study may offer an explanation as at some point within the interview each participant discussed the reasons behind their participation. For some this justification came at the beginning of the interview as if they were

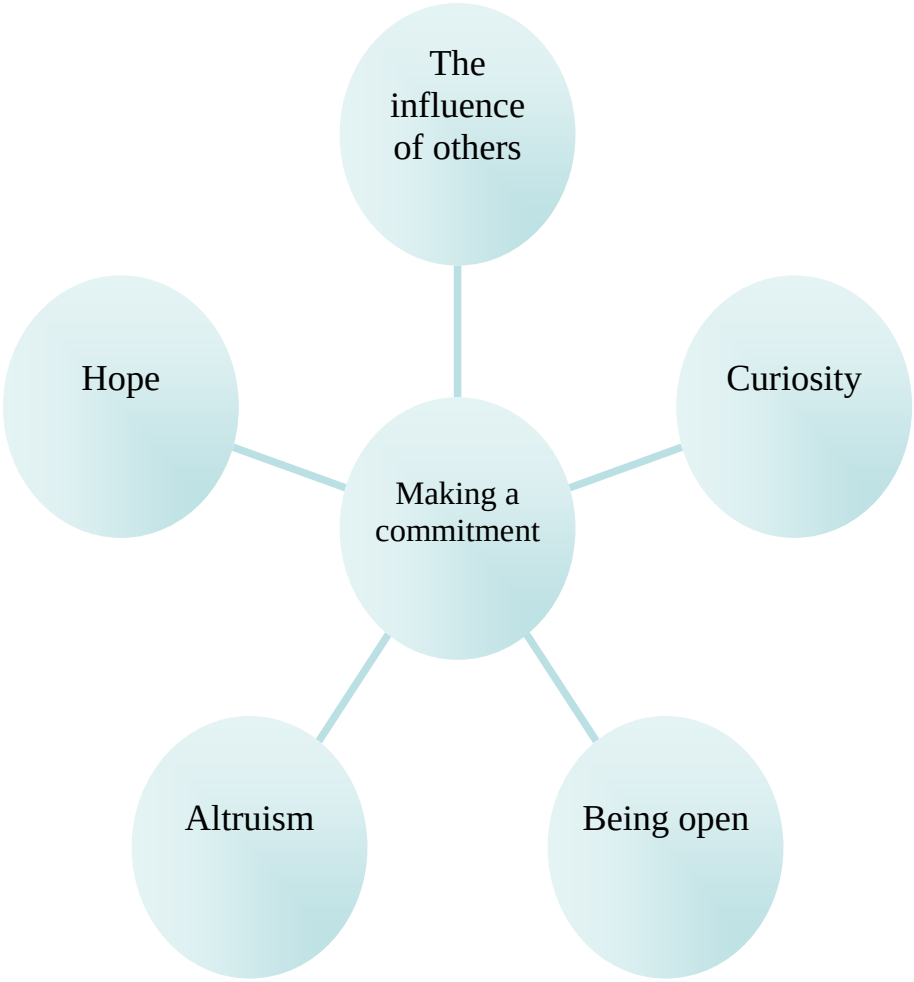
setting the scene. Others focused on an alternative starting point, recollecting the onset of their osteoarthritis; its clinical course, and how it led to the point of participation. On occasion I was required to enquire about their reasons as the subject did not naturally arise. However this was rare.

Open coding of the interviews highlighted numerous codes often *in vivo* in nature that enabled me to label the differing motivations behind participation in the trial expressed by the participants. They were varied and personal to the individual including opportunity, hope, curiosity, responsibility for own health, positive views of research, dissatisfaction with orthodox medicine, own personal experience or that of others (see Appendix 8). I explored these terms for their definitions, creating memos so as to capture conceptual descriptions and explain why I had coded the data in such as way.

As further interview data was collected and compared with these concepts so I found that these issues did not exist in isolation and could therefore be integrated. Tentative categories formed e.g. an early label was 'Rationalizing Motivation' because of the justifications offered in the interviews, and subsequent memos focused on the conceptualization of groups of codes rather than on an individual basis. The addition of new data and the subsequent integration of the analysis led to the category being redefined on numerous occasions, to the point where it became 'Making a commitment'.

Despite the abstraction of the category there remained key dimensions that persisted from the open coding stage. These dimensions consisted of recurrent concepts that appeared to underpin and explain an individual's decision making process in terms of deciding to participate specifically in the hip/knee trial. (see Figure 7). These were the influence of others, altruism, hope, curiosity, and being open. Each of these concepts will now be discussed in greater detail.

Figure 7 Making a commitment



6.2 The influence of others

The concept of other peoples' experience, and the affect that such events had on the hip/knee trial participants in terms of motivation, appeared to be a commonality in the data. However, the 'other' often differed from individual to individual, and included spouses, family, friends, and even pets. Such influence appeared to primarily relate to acupuncture or CAM in general rather than research.

For some of those participants who had not had acupuncture before, it was as a result of family or friends experiences of acupuncture that appeared to have an impact on their decision to take part in the trial. John, Colin, Marion and Margaret appeared to have been influenced by a spouse or relative's own use of acupuncture, citing this as a motivational factor. For example Margaret talked of her daughter's use of acupuncture:

> "I know she's had acupuncture I think for asthma…But she has had acupuncture needles so I thought oh it's worth a try…"
> (Margaret- non needle placebo/non empathic)

The use of acupuncture by friends appeared to have a similar motivational effect. Dorothy for example, justified her participation by a friend's experience:

> "In my friend's case they had to go to a Chinese medicine… where they practiced Western medicine and Chinese and they wanted volunteers. So all the group who knew about her shoulder said "well go on Pauline – you go and have your shoulder done" And she had acupuncture on her shoulder and it was perfect afterwards."
> (Dorothy – non needle placebo/non empathic)

Ursula's comment was also comparable:

> "Well I have actually been to a Chinese place with a friend, you know in a shopping mall. Chinese herbal remedy things and she went there for headaches and they gave her some stuff and she felt fine so it does work."
> (Ursula – real acupuncture /non empathic)

However it was not only direct experience that appeared to influence, but second or third hand knowledge as this quote from Agnes' interview highlights:

> "Then when this acupuncture thing came up I thought oh I wouldn't bother. But then our eldest grandson is training to be a nurse, him and his fiancée and when he came I said 'What do you think about alternative therapies?' They both said it depends as long as you are going to a good one it's alright, and I said about this and they said go for it because they'd heard you know from different patients that it is good. So I thought oh well if they say it's good I'll give it a go".
> (Agnes- non needle placebo/empathic)

It appeared for some of the interview participants that another individual's positive experience of acupuncture could be interpreted as a form of evidence of the treatment's benefits. This in turn was then possibly used in the decision making process concerning whether to take part in the hip/knee trial or not. However, I wondered if it depended upon whom the experience or the convincing recount of it came from. On one occasion the experience of another was an unusual factor. Peter had formed an opinion of acupuncture through witnessing its 'positive effect' on his pet dog who was receiving the treatment for arthritis from their vet.

The influence of others predominantly friends and family on an individual's rationale for trying CAM has been previously noted (MacPherson et al 2006; Shmueli and Shuval 2006). Indeed one of the motivations to participate in a trial about acupuncture that did seem to emerge was anecdotal evidence about the benefits of the treatment as asserted by family or friends. Verhoef's qualitative research of CAM patients showed that RCT evidence was bottom of the hierarchy of proof and anecdotal substantiation from friends and family rated the highest (Verhoef et al 2004). However a possible negative case among the acupuncture trial participants raised the notion that acknowledgement of the experiences of others may not be motivation enough to prompt participation.

Betty for example, initially dismissed acupuncture despite her daughter's recommendation:

> "Well, in the past my daughter has had acupuncture, I forget what that was for, and she suggested I have it but, this was sort of fairly…before this started and it wasn't the sort of thing I wanted to do at the time, but I don't know, two years ago, to be honest, I mean only six months ago I wasn't anything like I am now". (Betty - non needle placebo/non empathic)

It may be argued that something changed for Betty and I had to ask myself if the hip/knee trial participants were more susceptible to the influence of another at a particular point in their condition, for example waiting for a joint replacement operation. Of course it is necessary to acknowledge at this point that the majority of interview participants appeared to describe the influence of another's positive experiences. It may be that for some of those individuals that did not respond to the trial's recruitment process, that their decision had been informed by another's negative experiences. This highlights the issue of how potentially influential an individual's perceived experiences can be on behaviour. Not only through the reports of others but their own encounters and knowledge. Many of the hip/knee trial participants spoke of their own personal experiences on the trial during their interview, and the impact that these occurrences appeared to have on their participation in the trial. However these emerging concepts seemed to describe commitment to the trial rather than initial motivations, and will be discussed in the next chapter.

6.3 Altruism

Altruistic reasoning as a rationale for participating in clinical trials is a recurrent subject that appears in a broad spectrum of publications exploring individuals' reasons for involvement in research (Baker, Lavender& Tincello 2005; Harris Interactive 2004; Roberts, Warner, Green & Geppert 2006; Saunders &

Wainright 2003; Smith & Coyle 2006; Terry, Olson, Ravencroft, Wilss & Boulton-Lewis 2006; Tolmie Mungall, Louden, Lindsay and Gaw 2004). To be altruistic is likened to being unselfish or selfless. The notion of altruism first arose in my earliest interview with Dorothy. This excerpt illustrates her response when I enquired as to her reason for participating:

> *Why did you choose to take part?*
>
> Well. I worked at the university you see, so I was used to research and umm… anything that research, I would be willing on the whole to help.
>
> (Dorothy – non needle placebo/non empathic)

Initially I coded this response as a positive view to research, however as I conducted further interviews and the analysis progressed this transformed into the more abstract concept of altruism. Batson (1991) defines altruism as a motivational state with an ultimate goal of increasing another's welfare. Indeed it appeared that for some of the trial participants, the benefit of 'others' was a factor influencing their participation. Betty and Elizabeth are two examples:

> "Well, you're doing research you see, and this is all part of it, I knew it wasn't all part of getting me better, well I mean, had I had the real thing and it helped me then OK, but no I knew this was research and it all goes to help whatever you're doing, doesn't it, whatever you are trying to find out and help other people if you can…" (Betty - non needle placebo/non empathic)

Elizabeth was a grandmother and expressed concern during her interview about the possible hereditary features of osteoarthritis:

> "I thought it won't probably benefit me but it might help somebody in another generation."
>
> (Elizabeth-non needle placebo/non empathic)

Elizabeth's apparent apprehension for her grandchildren highlights a hypothesis that altruism may be evoked by empathy. Stocks (2006), discusses the claim that empathy elicits an altruistic motive to increase the welfare of the person for whom empathy is experienced. For some of the participants this may be a family member, but I also considered if empathy could be felt for peers with the same diagnosis. Some participants seemed to discuss altruistic participation in a more general sense, often referring to the trial in terms of protracted outcomes and future possibilities. Linda's view appeared to exemplify this:

> "Also if things are going to progress people have got to do these things, haven't they? And if something's non-invasive there's not a lot you can lose anyway. If it all comes together and helps in the future, and someone can perhaps have acupuncture rather than coproxamol then it would be good. And you can always put the operation off as well. You're better of with your own bits probably rather than all the artificial bits they can put in you these days."
> (Linda – placebo needle/empathic)

Sidney had taken part in a trial before and also appeared to rationalize his participation in the acupuncture trial in similar terms:

> "Well I suppose long term it's doing somebody a bit of good isn't it? They've got to find these things and there's nothing like the real thing is there? You've got to try it you know, yeah but I enjoy doing it." (Sidney - placebo needle/empathic)

However Sidney's closing words slightly confused the issue in that he expressed altruism in addition to another motivating factor e.g. enjoyment. This early memo illustrates my thoughts on these somewhat contradicting rationales:

Figure 8 Memo on participation

MEMO 22/09/2005- Rationale for participation is often dichotomous in nature e.g. due to personal needs e.g. pain and curiosity or an altruistic attitude regarding research and wanting to help others. For some participants it is personal need only whereas others mention both reasons– do they think they should tell me this?

Sidney was not the only participant to express altruism in a dichotomous way. Both Martin and Stella initially appeared to justify their participation as their due to their own need, but then consolidate their reason with an expression of altruism:

> *"What made you want to take part in the trial?*
> Well the state I'm in. If I could help anyway to measure if this sort of treatment works to um…help other people."
> (Martin – real acupuncture /non empathic)

> "I decided to take part because I was experiencing so much discomfort, and I knew of other ladies who were waiting for it (the operation) who were experiencing even worse pain than I was. And I thought if I can go and get involved in this research programme that may bring it into the National Health to help these other ladies. Or the ladies of the future that, you know, would be waiting for the operation."
> (Stella- non needle placebo/non empathic)

This duality seeming to underpin motivation to participate among some of the participants may be explained by exploring altruism in terms of egoistic incentives. It has been suggested that altruism is possible and indeed facilitated if the expectation of coming gains exceeds the immediate cost (Nowak & Sigmund (2000). However, Dawes (2004) challenges this view arguing that this supposed

necessity has not been shown in order for altruistic behaviour to occur. Instead he suggests that what could be inferred is that when the expectation of future gains increases, then behaviour benefiting others increases as well (Dawes 2004). The expectation for something is often described as hope, and this was another recurrently emerging concept.

6.4 Hope

When justifying their motivation to participate in the trial, the participants appeared to express the concept of hope in many forms. These ranged from hope about what acupuncture may offer them whilst waiting for their surgery, to postoperative future dreams. Hope is a complex phenomenon that seems hard to define. Literature within nursing for example has likened it to expectations and goals, positive future orientations, possibilities and even life force (Lohne & Severinsson 2006). In terms of participation in the hip/knee trial, hope may be explained by Edey & Jevne's assertion that hope can be the spark that moves people towards seeking help (Edey & Jevne 2003). Initial codes were both 'in vivo' containing the word hope, as well as more abstract quotations such as having 'a last chance before surgery' and 'it might work'. Susan exemplifies the concept of hope in this quote from her interview:

> "You always think I'm sure something else can be done, said or whatever." (Susan – non needle placebo/ non empathic)

Acupuncture or the chance of receiving this intervention on the trial seemed to offer hope in terms of personal gain such as potential pain relief and/or the ability to reduce analgesic intake. For Ursula, who had a previous positive experience of acupuncture, hope appeared to be expressed as a means of being able to reduce her pain:

"…well I've had acupuncture on different things before so I thought it was a good way of easing some of my pain if I was given the right acupuncture."
(Ursula – real acupuncture/non empathic)

Another participant David explained how he was experiencing side effects from his analgesia use:

"…what I was hoping was that even if it took half the pain away I could reduce my intake of paracetamol and ibuprofen."
(David- non needle placebo /empathic)

Symptom relief and an alternative to medication are reasons found to emerge in previously published qualitative research exploring participation in CAM trials (Walker et al 2004; Paterson 2006).However, in this study some participants seemed to hesitate when expressing hope, and I asked myself if it was because they were uncertain of what they hoped for or were possibly reluctant to say. The following quotes from Lillian and Dorothy highlight this emerging factor:

"Well when I got the letter saying about the trial I thought Ooh lovely there's just a chance …"
(Lillian - real acupuncture/empathic)

"I tried, well I uh hoped it would be, because I'm not against complementary medicine. Umm and I thought Ooh it will be nice if it, if there was any…"
(Dorothy- non needle placebo/non empathic)

There may be a number of explanations for this emerging data, one of which is that the sharing of hope can leave an individual feeling vulnerable (Simpson 2004). This may be especially so for those taking part in a trial with a placebo

randomization. On the other hand it may be that individuals have different goals to which their hope is directed. Participant's such as Lillian and Dorothy may be less clear about their hopes, whereas others appear to be more succinct about their expectations. This latter option appears to be the most grounded in the participant interview data. For example some of the participants talked openly about hope in terms of a 'reduction' in pain or changes to medication, mobility and independence. However not all of these hopes pertained to the acupuncture trial; some were expressed in terms of the forthcoming operation. For example Roy talked of hoping to reduce his referred pain:

> "So when I have this hip done (***points to left hip)*** and I hopefully get reduced pain in this knee I intend to leave it a few months, let the whole situation settle down and stabilize". (Roy–placebo needle/ empathic)

Norman articulated similar sentiments about his hopes for after his operation but in terms of disability:

> "Well I'm very lucky I have a disabled badge, although if you can call that lucky …I don't like the idea of being disabled and I hope when I have the next knee joint done I shall be able to hand it back". (Norman - placebo needle/empathic)

I began to analyze the interviews for emerging data pertaining to expectation and became aware of a possible contradiction relating to the trial and surgery. This following excerpt from Emily's transcript illustrates both hope for acupuncture and a seemingly fixed view on surgery:

" *Why did you choose to take part in the trial?*

Well I've heard of it obviously many times and everyone I've spoken to has had great results…you know whether it was pain in the neck or headache that sort of thing. So I thought well it can work for them why can't it work for me.

Yeah.

But I was still wanting to go ahead with the operation, because after I had the washout a few years ago … (*Consultant's name*) said 'there's hardly any cartilage in there and you will need an operation but see how you go, you might need to come back in six months'…" (Emily- real acupuncture/empathic)

Could it be that for the majority of the participants 'ultimate hope' lay in the operation and that the hip/knee trial offered a temporary solution? Acupuncture as a treatment for OA certainly did not appear to be seen as a potential cure for the condition, and the promise of a cure was at no time offered during the recruitment and consenting process of the trial. In fact, many participants seemed to be under the impression that the only possible alleviation at this stage in their condition was a new joint. It appeared that hope was emerging in relation to short term alleviation of the lived experience of OA. Wendy had already undergone both an initial joint replacement and revision on her 'other side' but was hoping for pain relief and the possibility of delaying her surgery:

"I'd hoped it was going to be an alternative, and I realized that it wouldn't be a cure. It would help and err… prolong the time when I'd need to have surgery. I hoped that's what would happen and I think I was sensible enough to understand that it wouldn't cure it, because bone on bone I'm going to have to have the operation. But if it alleviated pain I wanted to go for it". (Wendy – placebo needle/non empathic)

Helen also talked of hope whilst waiting for her operation:

> "I never had it in my mind at all that it would make me pain free… at all. I went in thinking that because I'd been told damage is done and nothing will cure it, but I used to go in hoping … well it's got to help it, got to help ease it and it did." (Helen – placebo needle/empathic)

Paterson & Britten's qualitative research supports this notion. Of the twenty patients interviewed in their study all sought symptomatic relief from CAM, yet for most individuals with more chronic conditions, cure was not an expectation rather it was help of any kind that was being required (Paterson & Britten 1999). This fits with the views of previous research that hope and help, or help seeking are aligned (Daufault & Martocchio 1985: Van Hattum 1997 cited by Turner and Stokes 2006).Yet despite this support a contradiction still remains. Paterson & Britten's (1999) research is entitled 'Doctors can't help much: the search for an alternative' – one could therefore argue that this does not fit with some of the acupuncture trial participants' thoughts on joint replacement surgery. An explanation may be that there is an underlying insecurity about acupuncture in regard to long term benefits, and the fear of not being able to have surgery when it is needed is a superseding factor for this particular sample of participants.

As I have already mentioned, the concept of hope is multi dimensional and can encompass a spectrum of explanations. To discuss hope in detail is not possible in the confines of this thesis. However, the role of hope in relation to its therapeutic value on health and well being has been well documented (Moore 2005). Furthermore, it has been proffered that it is possible to 'choose hope' (Jevne & Williams 1999), and that others (for example practitioners) can themselves be sources of hope.

6.5 Curiosity

The issue of curiosity and its impact on motivation to take part in the hip/knee trial emerged recurrently from the participant interviews. Early open codes highlighted in the analysis process related to 'being interested', wondering or seeking knowledge. However, over time, such codes became conceptually coded as 'curiosity' as this was an 'in vivo' code that noticeably reappeared in the transcripts. For example, in Norman's interview the word curious is used on five different occasions e.g.: "In a sense for the first sort of two weeks I was curious". The concept of curiosity presented within this chapter appears to relate to both acupuncture as a treatment and the process of research.

Curiosity about acupuncture appeared to be expressed in relation to the treatment process and the Chinese association with it, notably the historical and practical contexts. Some of the trial participants had received acupuncture previously within a variety of settings. Yet for those individuals who were acupuncture naïve there appeared to be a general curiosity about the treatment, how it worked and what it would be like to receive needle treatment. One participant Sidney, when asked if he'd had any previous experience of acupuncture justified his participation as due to curiosity:

> "No, never had it before. I wondered what it would feel like and how it would work." (Sidney – placebo needle/empathic)

Other participants also expressed curiosity in terms of what the needles would be like. So much so that some participants that had been randomized to the non-needle placebo intervention arm expressed disappointment at their allocation. Arthur and Elizabeth are two examples:

> "I was initially disappointed because I wanted to see what acupuncture was…"
> (Arthur - non needle placebo/non empathic)

"I would have liked the acupuncture because everybody says 'Oh needles being stuck in you'. We're all like that and it would have been nice to have known what it actually would have been like." (Elizabeth- non needle placebo/non empathic)

It also appeared that the historical and cultural aspects of acupuncture treatment prompted curiosity as to what the treatment may offer. Many of the participants interviewed acquainted acupuncture to be 'Chinese'. Issues relating to it being an ancient therapy and its use as a method of anaesthesia were more likely comments than issues pertaining to the release of endorphins. Melanie acknowledged the history of acupuncture and raised the 'possibilities' of such an intervention in this excerpt of her transcript:

"I understand that there are points that are used and also that it's a very ancient medicine.

Yeah.

And if it's been going that long…there's got to be something to it." (Melanie – placebo needle/empathic)

Some of the participants had lived overseas in Asia and had witnessed the practice of acupuncture in the East. This experience also appeared to have an influence on curiosity. David, a gentleman with a professional scientific background, compared acupuncture favourably to other therapies and described how acupuncture is used in China as a justification for his participation:

"It does seem to work doesn't it . . . they can start open heart surgery with it." (David – non needle placebo/empathic)

Previous qualitative research has explored the experience of individuals receiving TCM acupuncture treatment and has also highlighted 'being curious' and feelings of intrigue and fascination as some of the emerging responses (Walker, de Valois, Young, Davies & Maher 2004; Griffiths & Taylor 2005).

Although the sample group in Walker et al's study were all female; undergoing cancer treatment, and the presenting conditions of the acupuncture recipients are not documented in Griffiths and Taylor's research, it appears that the views of the hip/knee trial participants concur with such reports. One could therefore argue that a curiosity about an intervention is a precipitating factor in seeking it.

However not all of the interview participants had heard of acupuncture before and the issue of curiosity about research may have been an additional or independent motivating factor. For example although when asked why she took part in the trial one participant, Marion, expressed a desire for acupuncture she also admitted that it was quite nice to see what happens inside of these places. Often described within the interview transcripts as 'interesting', the trial itself appeared to incite curiosity. I even considered if the sample of interviews participants had a positive bias towards research, as exactly a third of those interviewed (9 out of 27) had taken part in research before or had connections to it professionally. Curiosity pertaining to research seemed to be a personal inquisitiveness. One gentleman, Arthur, justifies participation as due to his curiosity:

> "It was something that I'd never done before, something entirely new, and I've always wanted to see what the other side would be, I don't want to go back, I'm not interested in going back, over past history of my life or anybody else's for that matter, the other side of it, is what matters."

He continues:

> "…this was the first thing of this nature that I had come across and I want to know what it is, I'm curious, my curiosity is". (Arthur - non needle placebo/non empathic)

As previously highlighted in chapter 4 another participant Norman also expressed the concept of curiosity as a motivating factor:

"…the research said you're at the general hospital and umm I was happy to go along. It struck me as being an interesting thing. I'm from a slightly technical background but I knew nothing, I know nothing about medicine and this was a great opportunity to perhaps find out a little bit myself."
(Norman – real acupuncture/non empathic)

Curiosity has been identified previously as a motivator for participation into a clinical trial (Mattson, Curb, McArdle& Bhat and Amis research groups 1985; Tolmie et al 2004). Matteson et al acknowledged curiosity however, other motivational factors occurred in greater numbers (1985). Whereas Tolmie et al, found that curiosity prompted the most positive response in the early stage of recruitment (2004). This was in their two stage retrospective survey of Scottish participants of the PROSPER trial which aimed to explore why elderly recruits at risk of vascular disease responded to an initial trial invitation letter, and subsequently enrolled in the study. They also explored their overall perceptions of PROSPER. They concluded that curiosity is an important pre-enrolment motivator which should be fostered to optimise recruitment into any research study. This argument appears to be supported not only by the acupuncture trial participant's interviews but also a general response on the trial once a recruitment letter had been sent out. From my own observations and that of a colleague also working on the trial, it became apparent that those individuals who took part in the research were those who responded often on the day or soon after of receiving the initial letter and patient information sheet. Therefore, one could consider if for these individuals their minds had already been made up in some way. However, Tolmie et al (2004) acknowledge an important limitation, the fact that these motivational factors have emerged from an analysis of participant recruitment responders. The views of recruitment non-responders cannot be ethically identified, leaving an unknown perspective.

Consideration of the sample groups in both the PROSPER and the hip/knee trial show some similarity. In terms of age, the participants of the PROSPER trial

(mean then range 70 – 82 years of age) appear comparable to that of the acupuncture trial participants (mean age range 68.4 years). This may be of importance as curiosity has been considered as a predictor of health in older people by Swan & Carmelli (1996). They propose that curiosity is made up of two components - the seeking of both information, and stimulation. The higher the levels of curiosity an older person exhibits, the better their ability to respond to challenges with active coping through new experiences, social interactions and problem solving. One example of a 'novel experience' the authors offer is participation in a research study. However Swan & Carmelli also argue that the construct of curiosity is subsumed by a factor universal in human personality- openness (1996). The issue of openness will be discussed in the next section, as the concept 'being open' has also emerged from the participant interviews.

6.6 Being Open

To be 'open' to something can be described as being receptive, amenable; willing or ready. To be 'open minded' is thought to mean unprejudiced, unbiased or objective. Both these adjectives were initial codes to emerge from the interview transcripts as the participants often spoke of their willingness to try new things, openness, or open mind when justifying their participation in the trial. For example: "I'm sort of open minded" (Roy–placebo needle/ empathic) and "I was very open to it" (Melanie-placebo needle/ empathic).

The concept of 'being open' was identified when these codes of comparable content were grouped together conceptually. Being open was expressed not only in relation to issues surrounding CAM, of which acupuncture was just one of many therapies mentioned, but the trial and research as well. These two differing aspects will be discussed separately in the following sections.

6.6.1 Being open to CAM

One participant worked within the field of CAM, and some of them had a history of CAM use. This included acupuncture, other therapies such as chiropractics, magnets, supplements or over the counter remedies. Usage varied between ongoing (e.g. supplements were continued during the trial) and irregular; as needed. However openness to CAM did not appear exclusive to those individuals with prior CAM experience. Participants who had no prior experience still appeared to be open to it, justifying this by the stories they had heard about particular therapies. Dorothy is an example:

> "I suppose I'd heard enough about it to not think it was quackish. I was predisposed to it…"(Dorothy–non needle placebo/non empathic)

Some participants expressed the view that they would have liked to try acupuncture but had been constrained by the financial implications of private treatment. For others the timing had not been right. Yet for some the trial appeared to change that. The hip/knee trial itself appeared to be viewed as a 'free' opportunity for putting one's openness into practice, for example Margaret spoke of the invitation to participate in the trial:

> "Well I had this letter and I thought well I could try it". (Margaret – non needle placebo /non empathic)

Linda appeared to feel similarly:

> "Well I'd never had anything to do with acupuncture or alternative type things before but I was fairly open minded about it, so I thought this was a good opportunity to give it a go." (Linda – placebo needle/empathic)

Roy had already looked into finding an acupuncturist in his local area when he received his recruitment letter:

> "I went into the trial because I'd already made up my mind that it might be worth trying. Then along comes a free trial so I grabbed it." (Roy – placebo needle/empathic)

Roy's comment is an interesting one. There was a sense among the interview participants that they were convinced that the trial was worth trying. This was often in relation to their 'stage' of OA (i.e. awaiting surgery) or their intrinsic views on medicine, as these quotes exemplify:

> "I was getting to that stage where in fact I was in a lot of discomfort …" (Stella – non needle placebo/ non empathic)

> "I've got to a stage I'm so fed up with it…"(Elizabeth – non needle placebo/ non empathic)

> "I just don't like taking anything. I have painkillers prescribed but I have to be in real pain before I take it, and I suppose perhaps I've got a higher pain stress level than other people…I don't know. So you know from that point of view I just think I wouldn't want to take any drugs." (Wendy – placebo needle/non empathic)

> "I don't take any drugs, I take glucosamine." (Margaret - non needle placebo/ non empathic)
> "….a natural therapy any thing like that is better than tablets." (Helen – placebo needle/ empathic)

These additional justifications were often expressed contextually as if the participants were talking about their general ways of building meaning in their lives, part of which being the influences on their decision making. It appeared that the potential treatment offered by the trial may have been viewed as an additional coping strategy for those individuals with chronic disease.

Research has previously discussed the notion of openness and its links to CAM use (Honda & Jacobson 2005; Lombart 2003), and has even looked at willingness to participate in a CAM trial (Schneider, Vuckovic & DeBar 2003). Honda & Jacobson (2005) examined the associations between CAM use, personality, coping strategies and perceived social support in a representative sample of US adults. The use of acupuncture was analyzed in additional to fourteen other CAM therapies over a one year period. They found that openness was positively associated with the use of all types of CAM except manipulative therapies (osteopathy and chiropractic) (Honda & Jacobson 2005). Lombart (2003) also surveyed the use of acupuncture and nine other 'Unconventional Therapies' among a sample of 160 adults from the Louisville area. The age range of these participants was18-73; being older and scoring higher in the personality factor 'openness to new experience' were associated with having tried more unconventional therapies (Lombart 2003). Certain aspects of the results from both these studies could be related to the emergent findings from the participant interviews. In terms of openness to all types of CAM except manipulation, a number of the participants mentioned how they favoured some therapies over others, often justifying their views in terms of perceived credibility of the treatment. Therefore it is important to consider if personal judgements of credibility influence an individual's openness to an experience such as CAM. This following excerpt is from Melanie's transcript. Melanie had been talking about the historical aspect of acupuncture and how she thought it worked:

> "*Do you think then that that's what gives it…*
> Credibility…? Yeah I think it probably does. I said I was open to it but err…there are some things that I think sound a bit dodgy to me and I probably wouldn't go for some of the things.

She continues:

> Yeah, there are other alternative medicines that I would be happy to … I think chiropractics is a licence to print money. I've never ever met anybody who has just been twice they seem to be going for ever. Whereas osteopathy… it worked for me so alternative medicine is not a problem. It's got a place."(Melanie – placebo needle/empathic)

Lombart's (2003) research focused on age and openness. Indeed the average age of the hip/knee trial participants interviewed (68.4 years) would appear to be within the upper end of his particular age range, indicating the classification of 'older'. Similarly with regard to openness to new experience and the use of more than one therapy, some of the participants had indeed tried more than one CAM. However, consideration must be given to the underlying condition for which CAM is being sought, and its history. Openness to new experience must be interpreted with caution. This is especially so when the factors 'older' and 'suffering a chronic condition' may be related to a combination of factors underlying and potentially confounding the issues. For example, desperation and hope may also be synonyms for openness rather than curiosity alone. Schneider et al's (2003) study supports the emergence of openness to CAM among individuals with no prior CAM use. Their research was conducted in focus groups involving 85 participants with cranio-facial disorders to determine their willingness to join a CAM research study, and aid in the design of three RCTs for the conditions. Acupuncture, chiropractic and massage were the most frequently accessed therapies, and participants who had not used CAM treatments for their condition expressed interest and openness to experiencing CAM within a research study (Schneider et al 2003).

6.6.2 Being open to the trial and research

The hip/knee trial and research in general had already appeared to emerge as factors in relation to the impact of curiosity on participation. Issues pertaining to openness to the research process were also beginning to surface from the

interviews. Although one cannot truly infer as to the thoughts and views of individuals who did not respond to the invitation to take part in the hip/knee trial, it may be fair to propose that they were less open to the research than those individuals who did take part and were subsequently interviewed. Could this then imply that those individuals who did participate in the hip/knee trial were all open to research? Or had the emergence of such a possibility from the interviews actually been due to another factor, namely the questions I was asking and I wondered whether I had any impact on this data being present in the transcripts?

Early on in the study, one of the participants (Cynthia) had been un-blinded to the intervention type (placebo needle) she had received prior to the interview. This situation resulted in a discussion about the placebo aspect of the trial, and I began to enquire about this during my subsequent interviews. For example at Ursula's interview I asked how she felt about being in a trial:

> "Oh it didn't worry me at all. I thought well ok it's a trial they've got to try and find out. So if I get acupuncture out of it it's a good thing. If I got the placebo it was just one of those things but if I actually got the acupuncture that was good". (Ursula -real acupuncture/non empathic)

Other participants appeared to feel the same when I enquired if they had felt any concern over the possibility of receiving a placebo intervention. Here are a couple of examples:

> "No I know you've got to do that and ***(practitioner's name)*** did say that you learn from people who have had the dummy. You learn quite a lot from them don't you? No it didn't bother me if I had it or not."
> (Lillian – real acupuncture/empathic)

"I understand why you've got to do it, and if you'd told me now that I didn't have the proper treatment I would still understand why" (Martin –real acupuncture/non empathic)

These excerpts appeared to highlight openness to the design of the trial and the nature of randomized controlled trials. I was also aware however, that the emergence of openness to research may be questioned in relation to one of the criticisms of interview based qualitative research i.e. 'truth telling'. For instance, Hammersley (2005) asks whether informants are telling the truth and highlights the differences between what people say and do in response to social desirability. A possible illustration of this is from an excerpt of Melanie's interview:

"When you first read the information sheet were you put off by the placebo?
No not at all.
Can you expand on that?
Maybe I'm a natural gambler?"
(Melanie – placebo needle/empathic)

I had asked a closed question initially to which an answer was given. However I continued to pursue the issue, the result being Melanie's answer about gambling. This potentially offered a new perspective on being open, as in order to take a chance on something doesn't one have to be open and willing to do it? Yet her expression of this information may have been given as a means of addressing the further issues I was probing. I decided to follow the advice of Kvale (1996) and look for spontaneity from the interviews. Indeed, it appeared that other participants also expressed similar sentiments around taking a chance that seemed to arise more naturally than in response to a statement directed from the researcher. The following quotes are examples:

"How did you feel about the possibility of having a placebo treatment?

Well that was a gamble you had to take wasn't it."

(Marion – non needle placebo/non empathic)

"Not really because I thought well I'd give it a go anyway. I mean it might have been the real stuff and not worked or it could have been a placebo and I would have thought 'Oh because somebody's doing something…..No I thought I'd take pot luck, and I wouldn't be any worse off if it was a placebo than I was before I gave it a go."

(Linda – placebo needle/empathic)

"It did make me think, is it worth going, but you don't know do you, till you try it…" (Susan – placebo needle/non empathic)

Research exploring recruitment issues and participation in clinical trials has documented responses of participants relating to randomization and receiving a placebo (Harris Interactive 2004; Smith & Coyle 2006). Data obtained from on line interviews with nearly 6,000 adults across the US investigated a number of questions pertaining to public awareness of clinical trials and the views of patients who had participated in such experiences. When asked about the greatest perceived risk of participating in a clinical trial, 10% of the 5,822 responders attributed this to receiving a placebo (Harris Interactive 2004). Of this sample 656 individuals had participated in at least one clinical trial. However, it is unclear whether any of these individuals made up the 10%, or if this view was held only by members of the public who have not participated in trials. Smith & Coyle investigated recruitment strategies among randomized controlled trials of acupuncture and herbal medicine. The client group was women's health, and the data explored CAM use in pregnancy. Five trials were looked at and over 1500

women participated and were followed up. The results indicated that 16% of the women across five trials did not like being randomized to a study group (Smith & Coyle 2006). In comparing these two sets of findings with the views from the participant interviews, a possible explanation may be offered. This being that the risk of receiving a placebo is for the majority of trial participants a gamble which can be subsumed by other motivating factors such as the aforementioned altruism or hope for personal gain.

The participation stage of making a commitment appears to be inherently linked to recruitment. When considering participant recruitment, researchers are acutely aware of the challenges within this process. Poor recruitment in quantitative studies will impact upon the generalizability of the research, and may even threaten a trials' completion if bound to time and funding constraints. Literature identifying why individuals participate in clinical trials suggest justifications such as to please the professionals, a feeling of obligation to help after care, genuine interest in science and altruism (Saunders & Wainwright 2003); to advance medicine, earn extra money, help others and obtain better treatment (Harris Interactive 2004); and self motivation (Aitken et al 2003). Little existing research focusing on recruitment and patient retention within clinical trials appears to exist however in the field of CAM. Only two recent studies with regard to participation in acupuncture trials (Paterson, Zheng, Xue and Wang 2008; Smith & Coyle 2006) have been published. It has been suggested that, in general, investigators are not very concerned with reasons behind an individual's decision to participate (Saunders & Wainright 2003). Yet given the literature exploring how to promote recruitment and adherence in clinical trials this may be an area of study researchers have previously overlooked. If researchers can identify the motivations and influences underpinning an individual's decision to participate in research, it may enhance not only recruitment but adherence too.

Previous research suggests that medical trials offering treatment benefits for an active complaint should expect 1 in 5 (20%) screened patients to enroll (Spiker & Cramer 1992). It has been proposed that the effort required to recruit patients into a trial that includes CAM may be greater than that required for medical trials (Cambron 2001). Cambron's randomized controlled trial of spinal manipulation

for a non musculo skeletal condition found 1 in 17 (5.8%) patients screened, enrolled. However there is little discussion with regard to why this may be the case. Is it as a result of lack of credibility in CAM or the nature of randomized controlled trials? The hip/knee trial's recruitment rate was 19% (n279), a figure appearing to exceed Cambron's expectations and mimic those outlined by Spiker & Cramer (1992). In comparison to other randomized placebo controlled acupuncture trials there is also variation. Documented recruitment rates vary from 15 % (Linde et al 2005) to 65% (Scharf et al 2006). The findings of this qualitative study however offer a possible explanation of how individuals are convinced to take part in a specific acupuncture trial.

6.7 Conclusion

When expressing motivations for taking part in the hip/knee trial, the participants that were interviewed for this qualitative study appeared to place emphasis on a variety of influences. The main ones to emerge were the influence of others, altruism, hope, curiosity and being open. Although of stand alone importance, these influencing factors were often expressed by the participants in combination with each other, blurring in relation to an individuals' beliefs and prior experiences. The supporting literature pertaining to this complex category of concepts is also multifaceted encompassing the fields of CAM, osteoarthritis and research methodology. Despite this the interview participant's views do not appear to be significantly different from other individuals who have sought acupuncture treatment or taken part in research trials.

Overall, making a commitment to participate in the trial appeared to be in response to a combination of transferable influencing factors and these were expressed irrespective of intervention or the consultation type participants had been randomized too. Interestingly though in the hip/knee trial one influencing factor was not expressed in relation to making a commitment, this being the participant/researcher relationship. Aitken et al (2003) describe intangible incentives that determine trial participation. These incentives include the interpersonal skills of the research personnel responsible for recruitment, citing in particular elements of courtesy, respect and time devoted to an individual. By

comparison the findings of this qualitative study found that this was not the case for the hip/knee trial. It was other persuasive forces that influenced the decision to participate, and practitioner influence was limited to playing a part in maintaining a commitment to the trial only. The next chapter will discuss the issues underpinning this next stage in the theory of participation and the ways in which the participants' justified maintaining their commitment to the hip/knee trial.

Chapter 7 Maintaining the Commitment

7.1 Introduction

Following on from chapter 6 where the motivations behind participation were presented, this chapter presents the differing justifications expressed by the participant's as they discussed their reasons for staying in the trial. These issues may be important given that strategies among the research industry to minimize attrition are seen as vital, with methods described to achieve retention including reimbursements and gifts within the confines of ethical approval (Wyse 2006). Furthermore within the context of the hip/knee trial there was a relatively low drop out rate (4.9 %) and the participants received no such reimbursements, and were even required to pay for transport or hospital parking in order to attend their sessions.

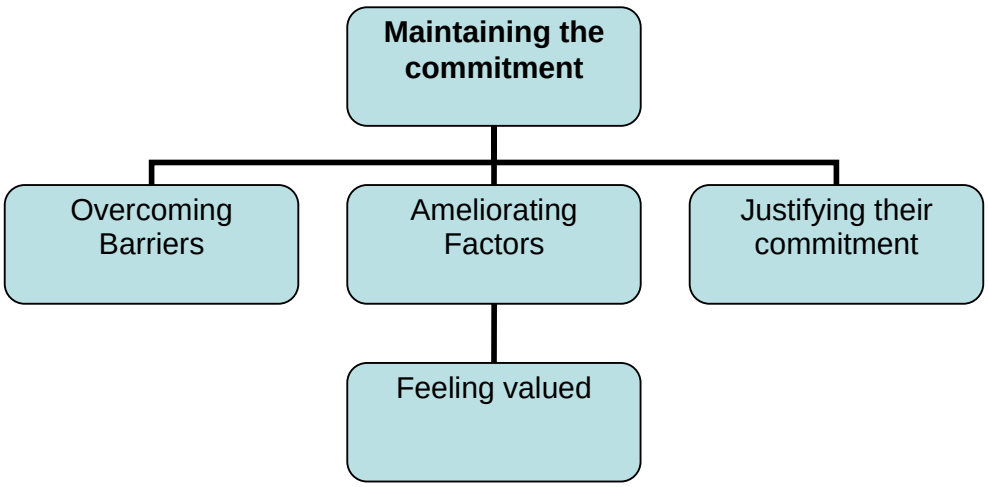
In terms of commitment, participation in the hip/knee trial required the participants to attend treatment sessions twice a week for four weeks. This was after an initial assessment visit at the relevant trial site, at which they were asked to keep a weekly diary in order to record a baseline assessment of their pain. Daily treatment sessions were prohibited as per the protocol, and evening/weekend appointments were also unavailable. Concomitant medications were allowed but participants were asked to refrain from starting any other new therapy during their time in the trial. There was no financial reimbursement for any aspect of the research.

Early in the analysis I considered issues relating to continued participation as akin to adherence. There appeared to be a sense in which the participants, who completed their participation, adhered to the specific trial process (hip/knee trial) and trials in general. Emerging open codes included enjoyment, and "taking part again", flexibility and running to time, positive views of environment and feeling benefit. Issues around feeling valued were also expressed. I considered at this point whether their ongoing participation was related to satisfaction. However I was concerned by a number of 'complaint' factors also emerging that appeared to

challenge this notion .Further open codes highlighted difficulties with access, transport, and timing. Financial costs also emerged (see Appendix 9). I discussed these conflicting aspects with my supervisors and colleagues and considered if these complaints may be explained as the participants conveying their commitment. In other words despite such difficulties they continued their participation.

Early categories included ‘conveying commitment’, ‘being committed’, valuing and differentiating the experience. Over time these were refined into an abstract category labeled ‘maintaining the commitment’ that appeared to capture the bipolarization of the participation process e.g. enjoyment ranging on a continuum to disappointment and dissatisfaction. The following sections of this chapter will now focus on the recurrent factors expressed when the participants were asked to share their experiences of the study that may have influenced the relatively high level of adherence to hip/knee trial (see Figure 9). These were overcoming barriers (complaints), ameliorating factors, feeling valued and justifications for their commitment.

Figure 9 Maintaining the commitment



7.2 Overcoming barriers

The interviews highlighted a number of perceived barriers to participation, primarily related to potential difficulties travelling to the study site; the locations' parking and associated costs, as Martin and Ursula's quotes illustrate:

> "Well the thing about it was being so far out as I am here in the forest you can meet a load of cows and it can hold you up. Plus the fact that down in the hospital itself its rather expensive as you've got to park in the multi storey." (Martin – real acupuncture/non empathic)

> "The only gripe I had about the trial was that it was in the general hospital. From here it's quite a way over there, that's why I usually had a very early morning 9-9.30 …umm…because of the parking. It's the parking at these hospitals, especially the General that was a bit of a bug bear, but apart from that it was fine." (Ursula – real acupuncture/non empathic)

Despite these factors only 11 participants out of 270 dropped out during the course of their participation in the trial. Interestingly ten of these eleven had received non-empathic consultations, eight of which were in conjunction with placebo interventions. Documented reasons for withdrawal included being called for their surgery, exacerbation of symptoms, and a newly diagnosed medical condition (see appendix 6). For four individuals the rationale given was practical in terms of transport difficulties and/or time commitment issues, concordant with the issues raised in the qualitative interviews. Arguably it is impossible to truly know the real reasons for drop out, and it may well be that these were the explanations participants felt most comfortable giving the research team at the time of discontinuation.

Barriers such as inconvenience, travel and additional expenses have previously been highlighted as demands that may influence an individual's decision not to participate in research (Aitken, Gallagher & Madronio 2003; Ross, Grant, Counsell, Gillespie, Russell & Prescott 1999). Moreover it is also suggested that such additional demands may lead to attrition (Ross et al 1999). The findings of this qualitative study suggest that the specific barriers of travel, parking and costs were in existence for the hip/knee trial. Yet analysis of the interviews offered an additional perspective. It appeared that regardless of the potential barriers to participation in the hip/ knee trial (travel, parking & costs), there were possible ameliorating factors that influenced continued participation. The interviews not only highlighted possible hindrances, but also perceived advantageous aspects of the trial that seemed to facilitate the participants' ability to overcome these concerns. These ameliorating factors included the flexibility of appointment times and the perceived efficiency in the running of the hip/knee trial, evidence of which will be presented in the next section

7.3 Ameliorating factors

Most of the interview participants shared their justifications for continued participation in the hip/knee trial despite potential practical barriers. The justifications appeared to be a combination of ameliorating factors, both practical and emotional in nature.

Although the majority of the interview participants were relatively mobile, the issue of travelling to the hip/knee trial was an important factor in maintaining the commitment. Many lived quite far away from the trial sites, and although based in hospitals, both locations were outside the city centre and were regarded as notorious for their lack of parking availability. Numerous participants described their initial concerns regarding this but then went on to explain how they overcame it with the help of the trial itself. For example Elizabeth travelled by public transport and often arrived early due to the unreliable bus service:

"I like to be early and often I was there and ***(practitioner's name***) used too take me in a bit early, you know."
(Elizabeth- non needle placebo/ non empathic)

Although appointments were limited to week days, the trial sites facilitated the ability to treatment multiple participants at the same time thereby, if two people wanted the 9am appointment this was usually feasible. These benefits appeared therefore, irrespective of the trial's location, which may be due to the environmental settings and/or the fact that the same practitioners worked at both sites, and this was their usual manner of working. Elizabeth's ability to be taken in early by her practitioner highlights how the flexibility of the trial appeared to provide her with a positive participatory factor that outweighed the barrier of public transport. Flexibility of appointments also appeared to encourage the car driving participants who had concerns over parking availability:

"Of course the only other drag was the parking up there. Fortunately most times I got an early appointment, nine o'clock start". (Sidney- placebo needle/ empathic)

"I think the big issue for me was that I could travel…the distance we are from the hospital, travelling in peak muster times is terrible and I was very glad that I could have the same time every day, every visit and it worked very well. It was in between everything. I valued that a lot and I think car parking is a big issue for me and not to be able to park comfortably would have irritated me I think. So I feel lucky in the way it proportioned out."
(Norman – real acupuncture/non empathic)

The fact that appointments ran to time also appeared to be deemed beneficial in terms of convenience:

> "The trial was very well run, very efficient and time wise you weren't kept waiting or anything like that. It was very good and I wouldn't hesitate to go on another trial of a similar nature. *Did you feel that made a difference?*
>
> I know that nuisance value would have come into it. I mean you knew you could park outside in the road, it's only an hour's parking and you knew you'd only be half an hour and that was it. I mean I know it was a trial and an opportunity to get relief and that but if you're hanging around for two or three hours you don't want that. (Wendy – placebo needle /non empathic)
>
> "Well it was err… simple, very, very easy going. We made our way over twice a week by car and didn't park the car there. My wife went off up the road I popped in, half an hour later I popped out". (Roy – placebo needle/ empathic)
>
> "…you were seen on time, there was no waiting around. The appointment system was very good you were seen too straight away. I would do it again, definitely do it again."
> (Ursula – real acupuncture/non empathic)

On occasion this efficiency was even compared favorably to other situations such as hospital outpatient appointments:

> "Yes, and it's not a rushed thing. You've got an appointment and everybody knows what is going to happen, what you are going to do and what your aim is. It's just different." (Linda – placebo needle / empathic)

Efficiency and flexibility also appeared to have an impact on costs:

> "A lot of the times I parked further up by the cemetery where it's a matter of 50p, or was given tickets with time left on them. It was good that appointments were to time…."
> (Martin- real acupuncture/ non empathic)

Some participants described being able to park for free on the road at one site, safe in the knowledge that their appointment wouldn't over run. While others, paid for parking but chose an appointment that allowed the inclusion of lunch or visiting patients/friends on wards during their allotted car park time.

Although the flexibility regarding appointments and the fact that they ran to time, seems to have eased the participation process thereby minimizing inconvenience and for some participants, even costs. They were not the only justifications offered. Other issues related to continued hope for personal gain, feeling valued and a possible sense of obligation. For example, Betty and Melanie both initially discuss their concerns about accessing the trial site, but subsequently describe other justifications for maintaining their commitment. Betty appears to talk about hope of getting better (see excerpt overleaf):

"I don't drive. I don't mind going by taxi one way because it's quite expensive from here. I can get a bus it will take me into town and just cross over the road and catch a number 5 right up to the General, so although with the way I get up it is embarrassing and I have to try getting up from my seat in the bus, before I want to get off, of course the bus is still travelling and I've got on to hold on really tight, it's awkward getting up and you know you feel embarrassed, you silly old woman (laughs) but anyway no, at one time there used to be a bus stop inside the ground, not far from the main door, but of course you have to walk on down through now and if the weathers not good, but anyway if the weather had been bad I would have got a taxi over, but cos I want, you know I wanted something to happen, so hopefully makes things better."
(Betty – non needle placebo/non empathic)

Whereas Melanie seems to maintain commitment out of a sense of contractual obligation, and a sense of feeling valued as a result of being allowed to withdraw for surgery:

"It was quite a long drag and as you say you have the furthest room possible. I don't think there was another room after that was there? (***/laughs***)

No!

Oh couldn't you come to me? There are times when I did think that if people are in certain degrees of disability that's probably quite a long way to go.

Can you tell me why you kept coming?

> Because I'd made a commitment, and I wanted to see it to the end and umm… as I told you I worked in the NHS for twenty years…when people are doing research. I know how I used to feel when somebody didn't turn up for a course or something, its just throws out your programme all together. I sort of made the commitment but I did say to him that you do realise that if I'm called in…because I had said I'd take a cancellation, I won't turn it down if I'm in the middle. And he said "Oh no, I wouldn't expect you to". So that's good."
> (Melanie – placebo needle/empathic)

Such notions of feeling valued and a potential sense of contractual duty felt by participants highlight that there are possible additional important factors that may help to explain the high levels of ongoing commitment to the trial. However it is necessary to acknowledge that these justifications were post hoc at interview and there is always the possibility that the interviewees felt a need to present a socially acceptable argument for their maintained commitment. With this in mind it is not possible to accept as gospel these reasons for keeping them in the trial. Rather they were the justifications presented to me as an interviewer, at a point in time in which I asked them to recollect. For some of the participants these justifications arose naturally in the course of the interview. While for others, they appeared to be expressed in relation to a topic in which they questioned their own continued participation.

7. 4 Feeling valued

A sense of feeling valued in relation to commitment to the trial was noted in many interviews. From early transcripts spontaneous comments emerged not only relating to the hip/knee trial's organization, but the impact of the practitioner and, interestingly for one site in particular, the research facility's environment and staff:

> "I like the way you were treated there. You were treated as an individual. Nobody could ask to see what you were doing. Everybody was polite to you even from reception – they were friendly walking about and that's what I liked about it". (Marion – non needle placebo/non empathic).

This was further explored in subsequent interviews where positive views of the environment continued to surface from the participants of one particular trial site but not the other e.g. Helen:

> "First impression was that I felt relaxed; the welcoming was good even from reception". (Helen –placebo needle/empathic)

The creation of a welcoming environment, that fosters a sense of feeling valued, has previously been suggested as a strategy to increase the likelihood of participant retention in research (Aitken et al 2003). It appeared that in the case of the hip/knee trial, one particular research site setting, and its staff, may have additionally influenced some of the participants' commitment to the trial. Feeling valued for some of the participants related to individual standards being be met, the result being that they were convinced enough to stay in the trial. An example of this is the perceived professionalism of the research trial, its staff and its locations. Participants seemed to judge professionalism in part with the cleanliness of the trial settings and clinical practice of the researcher/practitioners, as Ursula illustrates:

> "I did notice people put on gloves, I had wrapping around the pillow you know. I did feel fine but if I had seen things that weren't or I was treated differently I know it sounds terrible…but you notice it and I did notice that people were washing their hands, doing everything that I felt was right." (Ursula – real acupuncture/ non empathic)

Confidence in the competence, and 'attitude' of the practitioners were also convincing factors where continued participation was concerned. One participant's husband repeatedly commented during her interview (Margaret) that they felt the trial and researcher were genuine in their attempt to find out about acupuncture. The judging of practitioner's characters by participants seemed commonplace. So much so that for some participants who received non empathic consultations, individuals appeared to excuse the behaviour of the practitioners:

> "… she knew exactly what she was doing and what was expected of her, at the end I had the feeling that she sort of felt that you know, not being able to converse properly, that she felt a bit awkward about it."
> (Betty - non needle placebo/non empathic)

Recent qualitative research exploring the experiences of participants in a randomized sham controlled acupuncture trial for migraine (Paterson, Zheng, Xue & Wang 2008) identified similar findings. Paterson et al's study found that positive associations of the practitioner and setting appeared to make people feel comfortable and relaxed, prompting participants to suggest that this atmosphere had contributed to them staying in the study (2008). These findings seem to concur with those of the hip knee participants and may also help to explain another phenomenon of continued participation, which will now be discussed in the next section.

7.5 Justifying their commitment

On occasion, the hip/knee interview participants appeared to make justifications as to why they stayed involved even when their motivations for taking part in the trial had not been met. An example of this was Arthur who had not been randomised to acupuncture. This was interesting as he expressed disappointment at not receiving it, but justified his continuation in the trial as due to the personal gain he received with regard his reduced pain and decreased need for analgesia:

"I was initially disappointed because I wanted to see what acupuncture was, and then she said to me that they were going to put the needles in exactly the same place as the electrodes, which meant I couldn't ***(indistinguishable words)***…rolling over onto my left side, but there you go, that was my opinion and I am quite convinced that it did me some good."
(Arthur –non needle placebo/non empathic)

Personal gain was also an issue for Ursula, who justified this benefit when discussing her dislike of the non empathic consultation she had been randomised to receive. Even so, she appears to excuse this aspect of trial design and maintain her commitment:

"It was strange because people aren't really like that and then you saw her chatting away to somebody else and (laughs) I understood what was going on but I did think if I didn't I would have felt differently. Because I knew what was going on and I was told that could happen it was alright. But I think if it wasn't I think I would have said I'm not going to bother.
Can you expand on that?
Because I probably would have felt that she didn't care and you were just there as something for her to do, you know. Which as I said a couple of times I did come out of there and think "well this is a waste of time" (laughs). But there again if it is the real acupuncture it must be doing me good, so that's why you keep going …and I could feel the needles sometimes I thought they must be the right things. So I thought it was only a trial so I'd go ahead with it."
(Ursula – real acupuncture / non empathic)

It may be argued that Ursula's desire for personal gain was the influencing factor in her continued participation. However her acceptance of a situation she would not normally choose to endure raises the issue of behaviour modification in trial participants. Paterson et al's (2008) research also identified that participants appeared to be 'playing their part' as research subjects in a scientific experiment. In response to this their behaviour was altered such as having different expectations for that of the trial to usual health care setting. One example that is given is, the self imposed 'silencing' of discussion with the practitioner about acupuncture and other health problems (Paterson et al 2008).

This curbing of behaviour was also visible among the hip/knee trial participants, as Ursula's quote about it 'only being a trial' highlights. Other participants also appeared to act in a different manner than they may usually do. I remember speaking once to a participant I was treating on the trial with a non empathic consultation and being told that I had better not say much else as "I wasn't meant to be talking to him….". A couple of interview participants even mentioned how they had altered their behaviour during their sessions:

> "I took a book after the first thing, there was no point." (Dorothy – non needle placebo /non empathic)

> "I want to ask all sorts of things and I tried to obey the rule and actually shut up. I think I was with (***practitioner's name***) and umm we didn't say a lot at all…but she was extremely good in what she did. I was very confident in what she did but we maintained silence and I tended to read during the half hour or so." (Norman – real acupuncture/ non empathic)

It may be argued that the hip/knee participants were also 'playing a part' however it is unclear as to what extent this behaviour encourages commitment to research participation. Self interest on the other hand has been suggested as the most significant incentive for continued participation among participants of the

PROSPER study (Tolmie et al 2004). Supporting this finding is Wyse (2006) who highlights issues such as perceived lack of efficacy, and patients believing they are on placebo as reasons for poor retention in clinical trials. However these notions do not account for the participants who maintain their commitment to research despite receiving little or no personal gain. David had previous, positive experiences of acupuncture, and described his motivation for taking part as a desire for pain relief and reduction in medication:

> "… what I was hoping was that even if it took half the pain away I could reduce my intake of paracetamol and ibuprofen."
> (David – non needle placebo/ empathic)

However he had little response to the intervention on the trial and concluded from this that his was receiving a placebo. Nevertheless he remained in the trial justifying it altruistically as this excerpt illustrates:

> (Wife) "(***Practitioner's name)*** did say to you "do you want to give it up? " because you told her you thought you were having the placebo and it wasn't doing any good.
> *Oh right.*
> And I said "oh no, I'll do it to the bitter end just in case it helps someone else". (David – non needle placebo /empathic)

Another participant Lillian, who derived no benefit from the intervention yet also remained committed to the trial, expressed justification of her commitment in terms of her pain level:

> "The pain's not there now and it's not painful when I'm in bed so maybe mine wasn't bad enough for it to have an effect?"
> (Lillian – real acupuncture/empathic)

Whereas Roy appears to justify his ongoing participation in response to the actions of his practitioner overlooking his lack of response, as he still perceives the treatment to be real:

> "During one of the sessions because I didn't seem to be getting any significantly… he said "well it should be doing something by now". And that was the only perhaps give away, if that's what he intended to suggest that I was actually receiving acupuncture. I always believed I was."
> (Roy – placebo needle/empathic)

It may be possible to conclude from this that commitment to research can extend beyond the limits of initial motivating factors. For example disappointment at receiving a particular intervention or consultation type even lack of response may be overcome by hope for; or experience of personal gain or feelings of being valued. In addition motivating factors such as hope may also be subsumed by issues pertaining to altruism or the value of research. Yet it is important to consider if these convincing factors described by the interview participants may be a result of other explanations, namely social desirability bias and/or cognitive dissonance as there may well be differing views to maintaining commitment. For example Elizabeth was another participant who continued in the hip/knee trial despite having a lack of benefit. At the start of her interview she describes how she has participated in a trial previously and cites altruistic reasons of helping future generations of her family. She also appears to excuse her lack of response:

> "The only thing with this one is that within a fortnight I'd fallen over and hurt my knee. So I haven't really got a picture because it was very painful, so I'm not sure if it would have done any good."

However there was a possible alternative reason for ongoing participation that she alluded too a number of times in her interview, namely time off work:

> "I kept going over and seeing everybody. It was all right it wasn't uncomfortable. Actually a couple of hours off from work makes it alright (laughs) its like playing truant when you leave early".

> "And it was nice leaving at twelve. I felt like I was playing truant". (Elizabeth – non needle placebo

The issue of social desirability has been raised previously in section 6.4.2. Social desirability bias is when a respondent provides a socially desirable answer to a question rather than what they really think, believe or do. This preference for presenting oneself in a favourable manner to others has potential consequences for research in regard to interviews and self report measures. Qualitative interviews may be subject to social desirability bias in two ways. These have been suggested as 'impression management' and 'ego defence' (Nancarrow & Brace 2000). The first concerns being presented in a positive light to the interviewer, while the second is a function of self esteem preservation. Impression management may be an underlying issue for participants when discussing commitment, as to admit to continued participation solely in the hope of personal gain may be perceived as an undesirable response to share. Thereby to justify commitment to the hip/knee as due to of altruistic factors may be a more acceptable response to participants as well as one they feel willing to be associated with.

Alternatively, this behaviour may be explained by the theory of cognitive dissonance (Festinger 1957). Justification may be described as the result of acting against a set of beliefs, and beliefs are changed as in response to cognitive dissonance. Festinger's theory proposes that cognitions are pieces of knowledge that pertain to any variety of thoughts, values, facts or emotions (1957).

Most cognition is unrelated, but some are consonant and follow on from each other. Consonant cognitions are comfortable and 'make sense' e.g. I have a savoury tooth and I like cheese. However there are situations where cognitions are dissonant and the following cognition is opposite to the other resulting in a state of psychological tension e.g. I like cheese but I am trying to reduce my cholesterol. In order to reduce this problematic tension of dissonance an individual is motivated to lessen it. Reduction of dissonance can be achieved in a number of ways. These are by altering the importance of the cognitions; creating new cognitions that can overwhelm the original tension, or by ignoring them completely. In the case of the interview participants who maintained their commitment despite receiving no or little benefit from their participation, this creating of new cognitions may offer an explanation. If the hope of pain relief is not fulfilled despite an intervention being administered, the creation of new cognitions may reduce the tension felt in response to this outcome. Such new cognitions may be created in response to fresh knowledge, expressed in terms of the desire to help others, a sense of feeling valued or the belief that they received a placebo.

7.6 Discussion

Drop out rates in clinical trials are often allowed for, and in previous acupuncture research documented attrition rates have ranged from as low as 10% (Thomas et al 2006) to over 50% (Moroz, Spivack & Lee 2004).In comparison to these other studies the 4.9 % drop out rate of the hip/knee trial appears to be at the lower end of the scale.

Maintaining the commitment to the hip/knee trial appeared to be an important factor in the participation process, and is almost certainly a central issue in relation to retention for *all* clinical research. Continued involvement was not without the identifiable barriers of travel, parking and costs. Nevertheless participants repeatedly described ameliorating, practical, aspects of the trial such as flexibility of appointments and the efficiency of its running that helped them overcome such inconveniences. Commitment to participation was also justified

in a number of other terms including personal gain, feeling valued and altruistic reasons (contractual obligation).

There may be a number of explanations for this. One offering is an idea raised by Berman, Singh, Lao, Lagenberg, Li, Hadhazy, Bareta & Hochberg (1999) and includes the variables of age, pain and disability. In a randomized trial of acupuncture as an adjunctive therapy in OA of the knee, analysis of the participants that dropped out was compared to those who completed their participation. The results showed that the withdrawals had a higher mean on the WOMAC, longer history of OA and were younger than those who remained in the trial (Berman et al 1999). Similar data may be available with the publication of the hip/knee trial quantitative data, and in addition to the qualitative study, these findings may be able to provide greater clarity on this issue.

A second possibility is in the context of the hip/knee trial participants' not being healthy volunteers. There is a belief that there is poor understanding of research among chronically ill individuals or those with chronic conditions, which may lead to confusion when trying to distinguish research from treatment (Brown, Long & Milliken 2002; Terry, Olson Ravenscroft, Wilss & Boulton-Lewis 2006). Such confusion may influence a participants' adherence to a clinical trial in terms of not wanting to miss out on 'treatment'.

Finally it is important to acknowledge the potential effect of the practitioners/researchers. This factor has a number of components. Smith & Coyle (2006) noted a possible association of the high compliance and low drop out rates of their CAM study with the attributes of the researchers, i.e. they were similar in age and gender to the participants and worked in a supportive caring manner. This notion could be challenged by the hip/knee trial due to its design, and the age gap of at least 15 to 20 years between the practitioners and the participants. In a study of older participants in clinical trials, researchers identified interactions between themselves and the study team as an important factor in retention (Tolmie et al 2004). However it does not discuss the nature of these interactions. Wyse (2006) argues that patients show much better

compliance and retention if they feel the trial information is targeted precisely to their own patient group subsequently compelling them to stay in a study. The practitioners working on the hip/knee trial were all experienced professionals, used to working with OA patients as either an acupuncturist, NHS health professional or both. These clinical backgrounds may have provided them with such patient -centred skills thereby influencing retention.

The findings of this qualitative study however suggest another possible conclusion, this being that commitment to research may extend beyond the limits of initial motivating factors. In other words it appears possible that the trial participants were convinced to maintain their commitment to the trial because of their ability to overcome barriers; the fact that research staff behaviour led them to feel valued and individual personal gain reinforced participation. However it has been necessary to reflect on the influences of social desirability bias and cognitive dissonance that may underlie such data. These perspectives will be considered again in the following chapters, exploring the processes underling participation and the way in which participants described their production of outcomes.

Chapter 8 Producing an outcome

8.1 Introduction

The previous two findings chapters have highlighted how participants made their decision to enter into the hip/knee trial; then subsequently commit to continue in it irrespective of personal benefit. This third findings chapter discusses how the interview participants constructed meaning from their experiences on the trial in order to be able to report their outcome in both quantitative and qualitative ways.

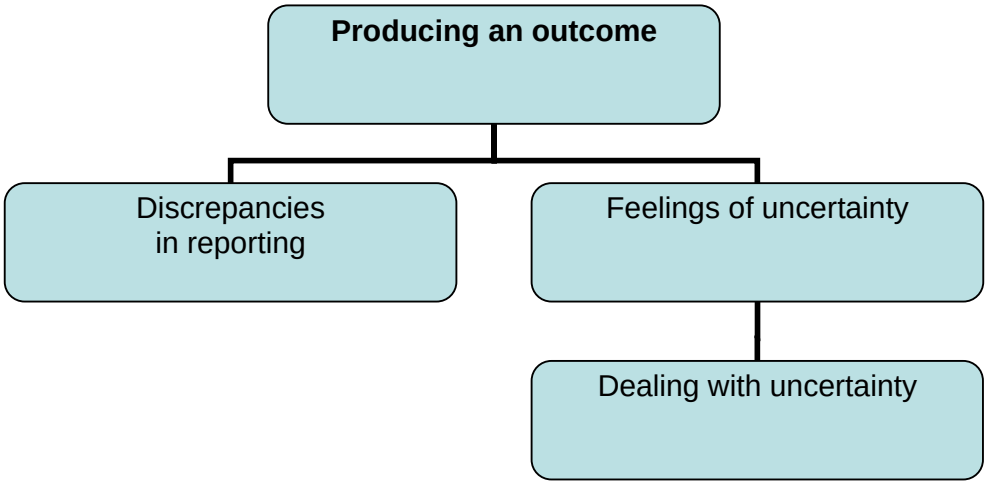
It is generally surmised that an outcome is a fact to be reported. Quantitative studies employ validated, reliable outcome tools to capture and evaluate the outcomes of their research. However the participant interviews of this qualitative study have highlighted a number of inconsistencies between the measured outcomes and the outcomes emerging from their accounts. The evidence from the interviews suggests that the term 'outcome' is complex, and rather than being reported, such outcomes are a product of complex interactions between prior expectations, demands of the study design and actual experience.

When it came to deciding upon outcome participants often appeared hesitant or cautious. Open codes of doubt or uncertainty were identified from the first interview transcript and remained a recurrent concept throughout subsequent data analysis. As presented previously in Figure 3, feelings of uncertainty related to a variety of elements within the trial e.g. the treatment, their response, and the behaviour of the practitioner. The impact of these 'unknowns' appeared to influence reporting and documenting of responses, prompting open codes to be labeled dislike of closed questions, criticism of outcome measures and "am I putting the right answer?"

Early categories further into the analysis process included "all in the mind?", reckoning randomization, having a sense of uncertainty, expressing outcomes and reporting outcomes. As the categories became more abstract it was possible to incorporate the differing early categories into one (producing an outcome).

This encompassed the varying issues relating to outcome and the processes underpinning it such as uncertainty and the challenge of outcome measures and appeared to explain the meaning making process experienced by the participants (see Figure 10).

Figure 10 Producing an outcome



The first part of this chapter presents the issue of discrepancies in reporting and the implications of collecting data from two entirely different social situations (primary quantitative questionnaire/diaries and domiciliary based qualitative interviews). Following this I will consider why this conflict may arise, in relation to the other influencing factors that emerged around 'producing an outcome'. This includes the general sense of uncertainty expressed by the interview participants; and how they dealt with this issue such as second guessing of intervention type and the impact that this appeared to have on outcome.

8.2 Discrepancies in reporting

As a practitioner/ researcher, I had access to the outcome measures recorded by the interview participants. In the majority of cases I was aware of any changes to an individual's pain score, analgesia intake or belief about intervention type on

my arrival at an interview. So it was with genuine surprise and perhaps naivety that I found, at times, discrepancies between such documented information and the accounts being relayed to me during the interviews. For example on occasion trial documentation recorded a negative response to treatment yet the experiences shared at interview contradicted this. Norman was an example of this as his trial documentation recorded a negative result. On paper he did not experience any alleviation of pain whilst participating in the trial, yet during his interview his narrative contradicted this outcome:

> "I reported that there was very little subsidence of the pain and even at the fourth week, the end of that I couldn't really detect. I felt that there was a shift from what I would regard as fairly intense pain back towards less intense and then miraculously suddenly I was sitting up in my computer room upstairs and I thought "Good heavens I'm sitting here normally as if…" You know you sit …with this arthritis you have an ongoing pain situation in whatever – sitting, standing, lying down, walking. Walking is almost out and umm it was suddenly "Good heavens what have I been missing for so long?" Literally it was gone and that was great, and it did have an effect." (Norman – real acupuncture/ non empathic)

One possible explanation for this change in outcome is the nature of acupuncture treatment, in that it is thought to have an accumulative effect. Lewith (2008) suggests that researchers are beginning to develop an understanding that CAM interventions can have increasingly beneficial effects the longer participants are followed up. Within the context of the hip/knee trial other participants who received real acupuncture described similar pain reduction patterns, with benefits developing towards the end of their trial participation e.g. Hester:

> "It was all very nice…as the course was coming to an end I was just beginning to reap the benefit then." (Hester – real acupuncture/ empathic)

However this was also sometimes the case for participants receiving a placebo intervention, such as Wendy:

> "I have to say that the first two or three sessions I was disappointed if you like. But then it was definitely the last week. Certainly the last session and for ten days after that it was very good, and then I felt 'I want some more of this now'…" (Wendy – placebo needle/non empathic)

It may be argued that such a situation may not have arisen if repeated interviews had been undertaken. Indeed this was considered as previously mentioned in chapter four, but methodological aspects of follow up in both the hip/knee trial and qualitative study were constrained by the prospect of surgery. Quantitative follow up was a week following the last treatment intervention due to the fact that participants were on the surgical waiting list and often given a date for their operation. Whereas repeated interviews offering a longitudinal approach, were similarly not appropriate as even some initial interviews were conducted post operatively, thereby sometimes changing the focus of the interview to surgical issues (e.g. Elizabeth and Colin)

Discrepancies between patients' assessments of outcome have been documented in previous, nested, qualitative research (Campbell, Quilty & Dieppe 2003). Campbell et al's research was an RCT exploring the effectiveness of physiotherapy for OA knee (2003). Twenty of the participants were randomized to have data collected both quantitatively (questionnaires) and qualitatively (in-depth interviews). Both methodologies focused on patient reports of changes in pain (worse, better or no change) and restriction of activities. Concordance between these two data sets was less than 50 %, and showed a troubling lack of agreement. The authors concluded that a likely explanation for these

discrepancies between standard patient based measurements and patients' narrative accounts was the context of data collection, i.e. questionnaires in a clinic setting with a practitioner present in contrast to being interviewed at home by an independent researcher. This explanation may have been of significance for the findings of this thesis, but for an important difference, as a researcher I was never independent and the participants were mostly aware of this fact. The following sections will now discuss the other influences on outcome to emerge from the participant interviews.

8.3 Feelings of uncertainty

Throughout the hip/knee trial the participants appeared actively engaged in the process of participation and this was no different when it came to reporting on outcome. However it seemed this task was a challenge as outcome appeared primarily linked to response to treatment. This was further complicated by a feeling of uncertainty expressed by the participants in relation to their own response and this was verbalized in a variety of ways within the interviews (see Figure 11 below for an early analysis memo).

Figure 11 Memo on uncertainty

MEMO (09/2005) - The concept of uncertainty shows in a diversity of doubts expressed by the participants during their interviews. The issue of placebo and which treatment was actually received is at the forefront; however issues relating to self doubt (judgement), actions of the practitioner, response to the treatment, documentation and their future including the operation are also present.
Is documentation affected by the desire to protect one's own pain as judged by others i.e. the need to be believed?
Some of the participants felt they were fools or had been duped if they had responded to a placebo treatment. Yet rather than be upset with the researchers, they appeared more upset with themselves.
Is the culmination of these uncertainties related to the trial a possible explanation for inconclusive results of acupuncture research?

The impact of these feelings of uncertainty appeared to have a number of implications for the interview participants. One recurrently emergent feature was the difficulty with documentation. Uncertainty appeared particularly problematic when reporting outcomes on questionnaires utilizing closed answers for example 'yes' or 'no'. Elizabeth's quote below illustrates this difficulty:

> "They asked you to put a yes or no but I wanted to put an in between. I think so but I'm not sure you have to do it as a yes or no. Whether you are in pain all day, the answers have got to be yes or no, and you have to put yes as if you put no they think well why are you here anyway. It's hurting now, but later on it may ease up a bit. But you can't put no it didn't hurt today because it did."
> (Elizabeth – non needle placebo / non empathic).

Difficulty completing questionnaires was also observed during the time I was employed as a practitioner for the hip/knee trial. Participants often asked the practitioners for advice on what to answer to put, or if they had 'done it correctly.' Previous research by Donovan, Frankel & Eyles (1993) found that the yes/no answers and ambiguous questions of the Nottingham Health Profile (NHP) severely constrained respondent's wishes to go into more detail. The interviews certainly appear to suggest that the participants didn't know what answer to put to this standard quality of life questionnaire.

A possible explanation for this is that the questions didn't fit with how they viewed their condition, and the questionnaire did not facilitate further explanation on this. Interestingly the NHP is one of a minority of questionnaires to use feedback from qualitative research to inform its design (Paterson 2002). However there has been limited previous research qualitatively exploring the issue of whether a questionnaire encompasses an individual's main concerns about their condition. Of the studies that exist, the qualitative findings suggest that in certain contexts outcome measures such as the SF- 36 can fail to report

quality of life changes of importance to patients' (Hill et al 1996), and questionnaires can be variable in their specific ability to reflect and measure patient derived outcomes from complex treatments such as acupuncture (Paterson 2002). This highlights another factor appearing to impact upon the interview participants' construction of an outcome, namely the nature of their OA.

Despite an inclusion criterion of predominantly single site pain, it became clear that some participants of the hip/knee trial had OA pain in other locations. It was not uncommon to find that the focus of pain shifted to other sites after an improvement was recognized in the original joint being treated:

> "To tell you the truth in some ways this leg (one treated) isn't so bad now as the left leg. So it may have relieved slightly the right leg – but I got both see."
> (Martin – real acupuncture/ non empathic)

The WOMAC, functional disability questionnaire used in the hip/knee trial appears to have been unable to capture any successful treatment of the original pain, and differentiate between the fact that this had now resolved but was replaced by pain in another location. This seemed particularly challenging for lower limb OA, as pain in one joint often appeared to impinge on the opposite side. As a result of compensating on the 'good side' as Martin's quote above highlights.

Similarly the WOMAC did not facilitate the recording of some of the improvements in daily living described by individuals such as mobility or the ability to 'keep going' and partake in social activities. This suggests that the narrative outcomes shared at interview were often based on an individual's perception of their condition as a whole, rather than isolated to a specific joint as the trial documentation required. This raises the issue of methodology and whether or not the hip/knee trial's recruitment criteria were strictly adhered too. Or if outcomes deemed indicative of change by researchers or clinicians are

contrary to those viewed significant by patients or trial participants. It would therefore appear that the uncertainties surrounding response to treatment could not be adequately captured by the demands for certainty imposed by the quantitative outcome measures used by the hip/knee trial. The qualitative interviews on the other hand offered a means by which the interview participants could share their uncertainties.

Another significant factor to emerge in relation to feeling uncertain over response to treatment was the participant's questioning of the power of the mind on their outcome, as the following quotes demonstrate:

> "It was quite helpful I found, whether that was in the mind actually I don't know but not at first probably but at halfway through I found I was much easier that side – not as stiff which is my main problem. I think the pain was reduced as well." (Linda – placebo needle/empathic)

> "I think it did, yeah. It think it definitely, it seemed to ease the pain a bit you know…whether it was all in the mind, or whether it was just…whether it lasted I wouldn't like to say but after I'd had it that day …As I say once or twice I struggled getting into the hospital but I walked out better than I walked in" (Sidney - placebo needle/empathic)

The notion of an individual's 'mind' playing a part in the outcomes of the hip/ knee trial emerged from as early on as the second interview. It continued to emerge throughout my data collection and appeared irrespective of intervention type or consultation type. Participants appeared unconvinced that benefits they were experiencing were real and not of their own making:

"Certainly the next morning it seemed to be better but this of course could be that (***points to head***) . . . brain rather than body. After all acupuncture's a bit mind over matter anyway . . . or is it? (David – non needle placebo/ empathic)

"…and I kept thinking well its getting better but is it really getting better or is it me?"
(Susan - placebo needle/ non empathic)

"For a while I thought perhaps it's in my mind, you get these mind over matter, talk yourself into thinking it was the real thing even if it wasn't."
(Ursula – real acupuncture/ non empathic)

The notion of events in minds causing events in bodies and vice versa is not new. The philosophers Descartes, Popper and Eccles supported this theory, known as 'psycho-physical interactionism'. Within the literature, the role of the imagination influencing the outcome of acupuncture has previously been considered, when compared to other case studies of 19th century 'scientific quackery' namely Mesmerism[4] and Perkinism[5] (Quen 1973). The rationale at the time for the comparison of acupuncture with these other suggestive 'techniques' was the recurring anomaly of anecdotal effectiveness, despite a lack of clear; and scientifically proven efficacy. It is interesting that this anomaly continues to date. In comparing this phenomena with the experiences of the hip/knee participants it appears that some initial uncertainty over which treatment they were having on the trial and their response to it, lead them to consider the potential impact of their 'minds' on perceived outcomes.

[4] Mesmerism (Dr Franz Anton Mesmer 1734-1815)- His clinical use of 'animal magnetism' an active agent composed of universal, magnetic, ethereal fluid with energetic qualities has evolved into the modern techniques of hypnotism.
[5] Perkinism (Dr Elisha Perkins(1741-1799) – The application of metallic instruments 'tractors' drawn over the affected body part as a treatment for conditions such as rheumatism, gout, pain and swelling (Miller 1935)

However another possible explanation for such uncertain participant responses may be social desirability bias. As mentioned in 6.3, Nancarrow & Brace (2000) suggest that qualitative interviews may be subject to 'ego defence'. This describes a situation where an interviewee preserves their self esteem by responding in a certain manner. For example if there is a possibility of receiving a placebo intervention, some individuals may wish to 'save face' by expressing doubt when describing outcomes in case they have responded to such a practice as Martins' quote below suggests:

> "And you're always a bit hesitant to say "well I think its doing me good" because you've got that feeling that perhaps what you're having done isn't…you know."
> (Martin – real acupuncture/ non empathic)

Previous research in the area of marketing and consumer behaviour has highlighted social desirability bias in response to 'threatening' questions (Blair, Sudman, Bradburn & Stocking 1977; Bradburn , Sudman & Wansink 2004).Threatening questions are described as those pertaining to behaviour or knowledge (Bradburn et al 2004). Or where there is un-easiness about answering the question (Blair et al 1977). Therefore it may be argued that the interview participants feel that they are required to justify their participation and outcome in the qualitative enquiry, which may elicit a social desirable response. For example they are requested to share their experiences of the trial and for some aspects of this there may have been uneasiness, as their knowledge of certain facts i.e. intervention type was limited until they were un-blinded. This could imply that social desirability bias was present in the qualitative interviews since the majority of participants wished to be informed of what intervention they had received.

Alternatively, uncertainty may be as a result of the hip/knee trial participants being informed from the outset that they may receive a placebo intervention as per the design of the trial. Their emerging uncertainty could therefore be as a response to being truly informed and therefore well aware that the treatment they

received may not have been real. If all the interview participants were conscious that the intervention may have been a placebo this may result in an element of uncertainty. Paterson et al (2008) however found in their qualitative study of participants in an acupuncture trial, that not all individuals were aware of the randomized design and sham acupuncture group. This therefore suggests that despite an initial recruitment assessment and the signing of a consent form, individual's participating in a trial may not clearly understand the process or even remember the explanation about it. The topic of informed consent was not specifically explored in my interviews and therefore this possible influence on outcome may be an area for future study.

Faced with uncertainty over response to treatment, the interview participants appeared to draw on convincing factors to produce an outcome. They then seemed to justify these factors during the interviews as a means of explaining how they second guessed the intervention, in order that they may document an outcome at the end of the trial. The next section presents how the interview participants dealt with their uncertainty.

8.4 Dealing with uncertainty

The process of having to producing an outcome, underpinned with uncertainty appeared to cause the interview participants to draw on a number of factors alluding to their intervention type. These factors were often used as justifications for their decisions on outcome and included sensations experienced during treatment or lack of them; and comparisons to previous experiences. These are a few examples:

> "…rightly or wrongly I've decided I was a placebo, because I felt absolutely nothing really from the treatment."
> (Dorothy – non needle placebo/non empathic)

"4 weeks that's right and there was no improvement whatsoever, so (laughs) I said I think I'm having the placebo (laughs)…" (Betty – non needle placebo /non empathic).

"…some obviously went in and I didn't feel them but others I did and I've had that experience before. And as I said when she actually came back and twiddled them as such I could feel it again then working – you know you felt something was happening and they weren't just put in."
(Ursula – real acupuncture/ non empathic)

"… also it was quite painful at times, you know they pricked or stung when he twiddled them. It wasn't very painful you know, but uncomfortable. That's it really. I mean I just felt that probably I was having it and whether that was because my attitude changed a bit because I thought it was the right treatment, perhaps that made me more positive and the pain was less for it – I don't know…"
(Cynthia – placebo needle/ empathic).

The participants' narratives illustrated a certain amount of second guessing of intervention type. Figure 7 details a vignette of participant, David's, experience of the hip/knee trial and how convictions forged during the study impacted on his outcome. There are a number of possible explanations for this second guessing. The first returns to the issue of cognitive dissonance (see section 6.3). Could it be that the for some of the participants tension due to cognitive dissonance causes them to minimize uncertainty by second guessing that they were having a placebo?

Figure 12 David's vignette

David

David was a gentleman in his late seventies with a medical background and professional knowledge of research. He had spent years living in the East and had previous personal experience of acupuncture. He admitted that he needed a lot of convincing when it came to CAM therapies and had tried acupuncture with a great deal of skepticism on the advice of his GP. On the hip/knee trial David received a non needle placebo and empathic consultation. He confessed that he was wanting the intervention to be beneficial and describes feeling electrical stimulation on his first session which he likened to the sensation of a TENS machine (which he had used in the past) and some improvement the next day. However he wasn't sure if the intervention was doing any good or not. Once he was informed that it had been a placebo treatment David rationalized that his perceived initial improvement was based on hope. As time went on he became less convinced of benefit and decided the treatment was a placebo, even to the point of informing the practitioner of his second guessing. His trial documentation showed an increased pain score from baseline to end point. He described the practitioner as so convincing she could "sell ice to the Eskimos". Despite his views on the treatment he was prepared to stay with it in case he was wrong and it helped someone else. He did feel though that had it been placebo acupuncture it would never have convinced him.

Richardson (1994) suggests that where uncertainty in relation to the possibility of receiving a placebo is concerned, the idea that there has been no improvement in symptoms is inconsistent with the experience of having received an intervention. This inconsistency can lead to cognitive dissonance .In order to reduce such dissonance an individual may be required to alter their perceptions of symptom change or belief about the intervention. Dorothy and Betty's previous narrative excerpts at the beginning of this section (8.4) may be examples of this. They both describe a lack of response despite receiving an intervention. In turn this may

have resulted in their need to second-guess receipt of placebo as a means of minimizing cognitive dissonance.

At times individuals sought other methods of external reinforcement to aid in their uncertainty over outcome. On occasion it became apparent in the interviews that the outcomes reported in the trial documentation were not based on the perception of the actual participant. Rather their response was based on the observations and opinions of significant others, as they themselves had not noticed or been totally convinced by the outcome. One participant John described how it was his wife's comments about how much better he was walking that prompted him to subsequently report a positive outcome. This following quote from Marion also illustrates how her justification of improvement appears reinforced by a neighbour's conviction:

> "…my next door neighbour said I'm walking better and I said I've been going to the hospital for research into acupuncture. She said she used to watch me go up the garden sometimes and think poor old…and now goodness does she walk well. I can do the stairs better too."
> (Marion – non needle placebo/ non empathic)

It appears clear that uncertainty about treatment veracity is closely linked to uncertainty about outcomes. Individual's who experienced no changes such as Dorothy and Betty, forged the conviction that they were having a placebo and confidently expressed it. Whereas those who did feel changes, appeared more circumspect in their assertions (e.g. Ursula and Cynthia) drawing on additional clues such as previous experiences or sensations felt to help them make and justify their decision.

There are of course exceptions, and on a couple of occasions the interview participants had been so convinced that they had received a real intervention that when informed otherwise they described feeling duped by the trial. These

excerpts from Stella's interview illustrate her dilemma at finding out her intervention was placebo:

> "…its' given me so much confidence I've told everybody it's absolutely wonderful I mean eh…so I can't believe that I haven't had it.
> …But I had so much confidence in it that (husband's name) was grumbling about his knee problem and I said "well look what acupuncture has done for me, we must get you acupuncture". I wouldn't…and I've said to my friends that I would not hesitate to go to an acupuncturist you know for help after my experience."
> (Stella – non needle placebo/ non empathic (calls it acupuncture throughout the interview)

The process of un-blinding the participants raised a number of issues for me as a practitioner/researcher. One participant Peter (see Figure 8) reacted to being told he had a placebo intervention in such a way that it left me feeling helpless and at fault. In contrast I observed that individuals who were un-blinded and their convictions confirmed, appeared to loose their uncertainty. A few of participants asked for information regarding their treatment type as soon as I arrived to do their interview. As provision of knowledge regarding intervention randomization is a potentially significant influencing factor on outcome I had to consider if such confident responses would have been expressed had I not un-blinded them until later in the interview. For example Norman's excerpt in section 8.2 detailing how his pain resolved after his participation in the trial despite a recorded negative outcome may not have been shared so eagerly had he remained uncertain. In light of the complexity of the un-blinding process I suggest this warrants future research into the impact that such circumstances may have on both participants and the researchers providing the information.

Figure 13 Peter's vignette

Peter

Peter was a gentleman in his early sixties, who is registered blind. Initially I interviewed him alone. He had decided to take part in the hip/knee trial based on his experience of his pet dog receiving acupuncture for joint problems. The interview did not record, but my field notes describe Peter reporting a benefit from his non needle placebo intervention and empathic consultations. This positive view was supported by his trial documentation which also reported a decreased pain score from baseline to end point. He was very keen to know what treatment he had received, but once I informed him that he had placebo the atmosphere changed. At this point in the interview his wife joined us. Peter became 'closed' both verbally and physically, and I felt the overwhelming need to reassure and explain. Peter admitted to me that he felt as if 'his illusions of himself had been shattered', following my disclosure. I felt unable to connect with Peter and the interview ended soon after. On leaving I called a colleague on the trial to discuss the situation. Despite informed consent, and patient information regarding the nature of the trial, Peter's experience had convinced him of benefit. By un blinding him to his intervention that benefit had potentially been destroyed. As a practitioner/researcher in this case I felt bereft. I was not able to assuage Peter of his feelings and felt that he didn't actually want me too. He was my last interview for this qualitative study.

8.5 Discussion

The findings presented in this chapter have highlighted how the majority of interview participants appeared to have a need to determine whether or not they were having real treatment. This may stem from their reasons for participating in the trial such as expectations about acupuncture, hope for personal gain and curiosity, but it may also be due to the context in which the treatments were

delivered i.e. a clinical trial. Uncertainty and outcome has been documented in previous research exploring response expectancies and placebos (Kirsch & Weixel 1988; Pollo, Amanzio, Arslanian, Casadio, Maggi & Bendetti 2001). The findings of these studies suggest that uncertainty about treatment type is more prominent in a double blind placebo administration, when compared to placebos which have been administered deceptively for example in association with varying verbal instructions. In the hip/knee trial however uncertainty was expressed in a single blind context, irrespective of which treatment type was given (needle or non needle intervention), and provoked concerns about treatment veracity which in turn appeared to impact on outcome.

Interview participants were repeatedly concerned with the influence of 'the mind' (see section 8.3) and the possibility that a specific outcome could be linked to an individual's imagination, which raises the notion of 'producing an outcome' in terms of suggestibility, expectation or belief. Suggestibility is one explanation for the reporting of positive outcomes. Individuals described the sensations they felt and imbibed the positive view of others regarding their response; it seems that these factors may underpin their perception of an effective therapeutic outcome.

The literature discussing the theory of suggestibility is historically linked to Mesmerism later described as hypnotism (Bernheim 1884; Braid 1843). Although there is no current, generally accepted explanatory theory for the phenomenon of hypnotism research into this area continues and has suggested that hypnosis is able to enhance a non specific therapeutic response that seems closely related to the placebo response.

There are many definitions within the literature of placebo and the placebo effect or response (see chapter 2). For the purposes of this thesis I have chosen to make comparisons to the placebo response which is defined as the "response of a subject to a substance or any procedure known to be without any therapeutic effect for the specific condition being treated" (Benedetti & Amanzio 1997). At the time of the hip/knee trial's design both the needle and non needle placebo controls used, were deemed to be physiologically inert. However I also wish to acknowledge Koshi & Short's (2007) interpretation of placebos; they suggest

that that the term placebo represents a psychosocial aspect of all treatments, and the study of placebo is essentially the study of psychosocial context that surrounds the patient and their therapeutic environment (Koshi & Short 2007). With this in mind I considered if the process of producing an outcome could be explained by the theories that seem to underlie the mechanisms of placebo response. There are two theories most supported by the literature in regard to this phenomenon - Expectancy (Goldstein 1962) and Conditioning (Gleidman, Gnatt, & Teitelbaum 1957; Wickramasekera 1980).

Expectancy theory suggests that placebo response is related to an individuals' expectation of improvement which is connected to the changes that take place within a therapeutic environment (Bootzin 1985; Evans 1985; Kirsch 1978 & Ross & Olsen 1981). Furthermore Harrington (1997) hypothesizes that bodily changes occur when an individual is exposed to a stimulus that has been linked in the past to active processes that could produce a therapeutic change. In the context of the hip/knee trial participants appear to be convinced by others' previous experiences or those of their own, in relation to acupuncture, which may itself be a stimulus for a positive expectation and may therefore impact positively upon outcome through the mechanism of expectation.

Previous experience is also a potential key factor in the theory of classical Pavlovian conditioning which proposes that the placebo response is based on conditioning created by learning through association (Gleidman et al 1957; Wickramasekera 1980). As with Pavlov's dogs, inducement of classical conditioning involves paired presentations of a neutral stimulus with a stimulus of some significance. For example individuals with a headache regularly take analgesia (unconditioned stimulus) and associate the shape color and taste of the 'tablet' with a reduction in pain (conditioned response). After several associations of this nature pain also decreases when an individual take a placebo tablet that looks and tastes like their regular and effective analgesia (Benedetti & Amanzio 1997). This has been described as a learning 'history' (Wickramasekera 1985). However the 'history' is variable and can include events from an individual's past medical history such as specific treatments; therapeutic environments and previously ameliorative events such as rituals which may in

themselves be therapeutic. These examples of ‘history’ could be compared to the experiences expressed by the interview participants and could account for the influences that convinced them throughout their stages of participation to remain committed to the hip/knee trial and aid in their production of outcome..

Any treatment real or placebo is carried out within a therapeutic context which may involve visual, auditory or olfactory stimuli a specific environmental setting, equipment or a particular human interaction. Context has already been shown to play an important positive role in the outcome of treatments (Di Blasi et al 2001) therefore there is potential for a placebo response to develop with any treatment process. Similarly there is also potential for such a placebo response to be either positive or negative (placebo or nocebo) depending upon its nature and context.

Following on from his work on predictors of outcome in CAM, Hyland et al (2007) argue that there are limitations to the theories underlying the mechanisms of placebo response. Instead he proposes a Motivational Concordance Theory. This is when the expectancies and the perceived value of getting better held by an individual can influence that person’s motivation and behaviour. If they think that acupuncture could help them and it’s it provided for them in a context they find appropriate then they are more likely to respond to the treatment positively; if the context of an intervention is in concordance between the therapy offered and patient a positive clinical effect is more likely to occur. This process has the potential to facilitate a positive therapeutic effect and thereby influence outcome. In other words one doesn’t need to believe in something for it to work, but it needs to ‘engage’ you so that you engage in the ritual and will then be helped. It is possible that in order to be ‘engaged’ by something you need to be initially (at least partially) convinced about it and this is an area that warrants further investigation.

8.6 Conclusion

It is often taken as read that the outcomes documented in a randomized controlled trial reflect an accurate report of what participants actually experienced. This qualitative study however challenges this assumption. This

chapter has highlighted that the use of mixed method approaches may uncover discrepancies in reporting between quantitative and qualitative data sets. There are a number of possible explanations for such discrepancies.

Firstly when it comes to exploring a complex intervention such as acupuncture, existing outcome measures may not be capable of capturing the totally of the participant experience. Research design itself may also have an impact on the reporting of outcomes for example the demands of the quantitative assessment for certainty in the face of uncertainty and doubt, and the potential for social desirability bias in the qualitative reporting. The issue of follow up also requires careful consideration if the intervention under examination has a potential accumulative or delayed response effect as in acupuncture. It also appears that participants' reporting of outcomes is influenced by a variety of convictions that together produce an end result.

In summary the evidence from the participant interviews appear to suggest that the term 'outcome' is not as straightforward as published trials would have us believe. Rather in the context of the hip/knee trial, outcome seemed to be a product of complex psychological and social mechanisms such as convictions underpinning making and maintaining the commitment to the trial in addition to factors influencing perceived treatment response for example sensations felt during treatment or changes to a person's mobility that seem to aid outcome production. There are also issues pertaining to expectancy and conditioning theories as well as the challenges of social desirability, cognitive dissonance and motivational concordance to consider. In other words outcomes appear to be 'produced' and not merely reported. The next chapter will discuss how 'forging a conviction' is the basic psychological process underpinning participation within the context of the hip/knee trial.

Chapter 9 The importance of 'forging a conviction'

9.1 Introduction

In this chapter I will discuss the core category to emerge from the data labeled 'forging a conviction'. The basic social psychological process of 'forging a conviction' refers to the beliefs of the participants in relation to their decision making throughout the hip/knee trial. It appears throughout this qualitative study, and flows throughout the three stages of participation (making a commitment; maintaining the commitment and producing an outcome), thereby linking the other categories presented in the previous three chapters.

The following sections of this chapter will discuss the importance of a core category in grounded theory demonstrating how 'forging a conviction' meets the criteria. I will also conceptualize how the core category is associated with the phenomenon of participation in this specific acupuncture trial and was used in the process of theory formation.

9.2 The purpose of a core category

A core category in grounded theory is said to evolve from the research to a point of abstraction that represents the main topic of the study (Strauss & Corbin 1998). In other words, it is the products of analysis condensed into an expression that appears to explain what 'the central concepts of the research' are. A core category is said to be a category that links all other categories, illustrating and underpinning the storyline; running like a thread that is woven throughout the whole of a study. Essentially a core category seeks to explain most of the variance associated with the emergent categories.

The process of 'forging a conviction' was revealed during a supervision session in September 2006 (see Figure 9 overleaf). It appeared to be central to the data, and capable of unifying and explaining all the concepts which had already emerged. It had the essential characteristics required of a core category in that it

recurred frequently and consistently and linked the data together coherently (Sherman & Webb 1988).

Figure 14 Memo on core category

MEMO 22/09/06 - During a session with one of my supervisors I discussed how I felt less connection with the data of interviews 15-27, compared to the first 14 interviews despite doing the same analysis process e.g.

- open coding of transcripts
- flow chart diagrams of individual interviews
- highlighting of repetitions

During this time I mention an example of David's repetition of the issue of being convinced. As we discuss it more we notice that convictions appear applicable to many of the concepts emerging – is forging of convictions a core category?

The analysis indicated that convictions forged before and during participation in the hip/knee trial influenced participants' decisions to commit to participation in the trial; their commitment to staying in the trial and the production of their reported outcomes. For example Roy's earlier quote in Chapter 6 highlights his already forged convictions about taking part:

> "I went into the trial because I'd already made up my mind that it might be worth trying.

Stella described how she kept on coming for treatment:

> "I went there and I just relaxed thinking well this is going to make it better".

Whereas Dorothy described how she drew on her convictions in a number of ways throughout her time in the trial:

> "…in the end I decided that she couldn't be a practitioner she was just being told where to put these things and was bored stiff with the job but needed the job"

She continues:

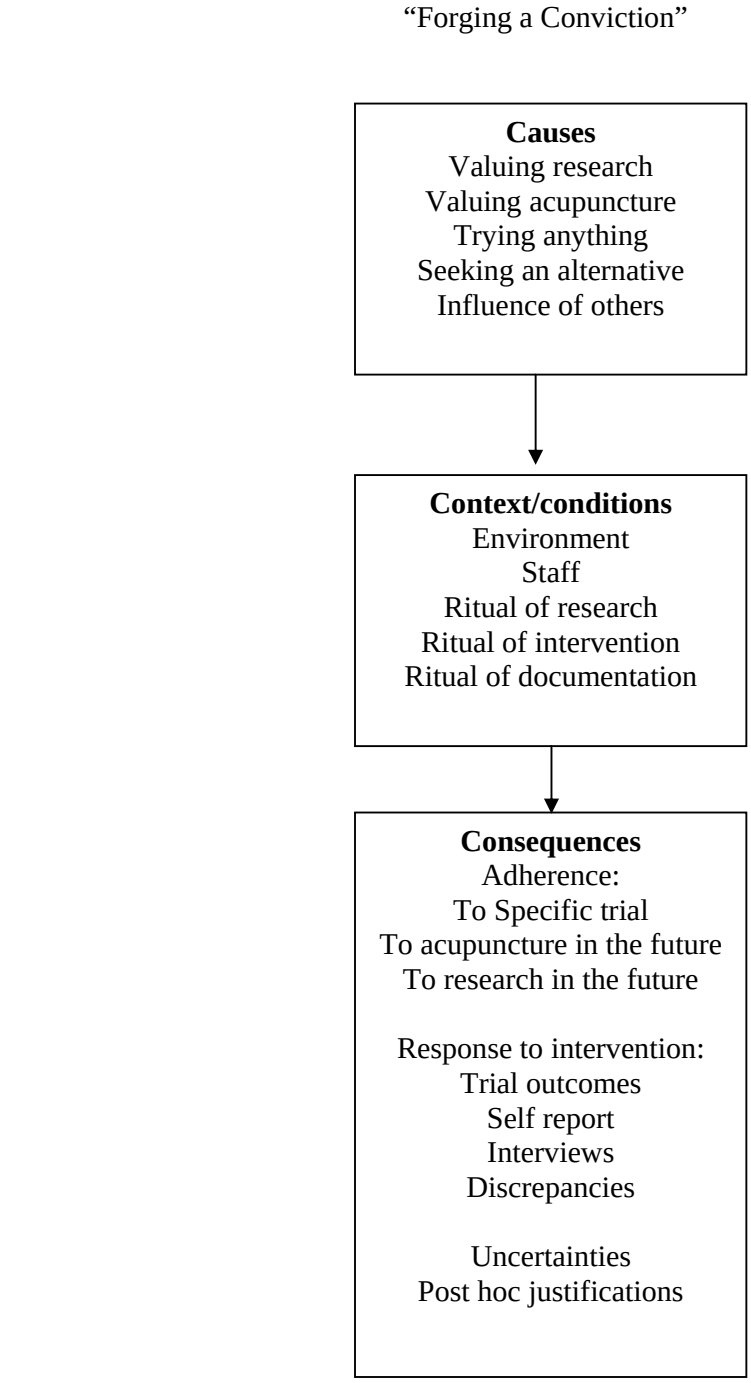
> "I decided in the end I was a placebo person".

When originally exploring the properties of the core category and how it linked and explained variations in the data I considered if it could be described by the process of 'being convinced' as the words convince or convinced had been identified in a number of interview transcripts as in vivo coding e.g.
"I'm quite convinced that …; Mmm I was never convinced; I wouldn't be convinced".

By utilizing dictionaries and thesauruses to explore the terminology I found that the root of the word 'convince' is '*convincere'* dating back to AD1520-30. Convincere was defined as to prove (something) false or true; or (somebody) right or wrong (Skeat 1993). This suggests that one individual is attempting to impose their version of the truth on another and is often interpreted in the context of persuasion. The issue of persuasion did not appear as a key concept during the analysis process; however throughout the interview transcripts the participants did justify their actions and behaviour describing influences on decision making, a continuum of certainties and uncertainty about their experiences and response to treatment. Throughout the transcripts participants used words such as I felt, I believed, I was sure, I was uncertain whilst making these justifications.

Developing on from asking if the participants had been convinced I therefore explored if they had developed convictions. In contrast to the word convince, the word 'conviction' pertains to belief, opinion, and even article of faith (Waite 2001) which may be forged from a variety of experiences. Drawing on grounded theory analysis techniques I sought to explore the core category using selective coding to ascertain if forging a conviction could integrate the other categories and refine the theory offering itself as a thread running through the data (see Appendix 10). I also used a theoretical coding paradigm to consider the causes, conditions and contexts within which this process could occur and the subsequent consequences of this process (see Figure 15).

Figure 15 Exploring the core category



It was not possible to saturate the data in terms of theoretical sampling of further participant interviews to explore the core category as by this stage my funding had expired. However theoretical sampling of existing literature was undertaken and integrated with the theory. Indeed it did appear that the process of forging a conviction was a core category that could explain the variations in the data and differing stages of participation in the trial, thereby being the basis of a substantive theory.

Review of the literature identified much already been written on belief with regard to CAM use (Bishop, Yardley and Lewith 2005; Hyland, Lewith and Westoby 2003). Yet whereas a belief or opinions are usually measured as a snapshot, the notion of 'forging a conviction' refers to a dynamic process of change. The following sections of this chapter will now discuss factors that influence the process of 'forging a conviction' in relation to the three stages of participation, as presented in the previous three chapters.

9.3 Making a commitment

In order to take part in the hip/knee trial the participants needed to have been convinced that it was a worthwhile endeavour. Chapter six highlighted how the interview participants expressed a number of key factors appearing to influence their motivation for participation in the hip/knee trial. For example some focused on the positive experience others had gained from acupuncture; while others had limited knowledge of acupuncture but expressed curiosity and an overall openness to CAM. For others there was openness to aiding research and altruism; and finally those who chose to participate out of self interest in the hope that they may derive some benefit from it. At first glance these influencing factors appeared unrelated, yet more detailed analysis revealed that they were all justifications for participation. Justifications that were expressed when participants spoke of how and why they had decided to take part

From the start the quantitative study was advertised as an 'acupuncture trial for OA', therefore it may be reasonable to assume that the individuals who enrolled already held some positive rather than negative beliefs about acupuncture or at

the very least were inquisitive about acupuncture. Research suggests that individuals who use CAM are more likely to hold positive beliefs in holistic health, holistic and natural treatments, as well as actively participating in treatment (Bishop et al 2005). In the case of individuals with chronic disease such as OA, it has also been well documented that such patients are usually selective about their choice of CAM treatments and that they use them in addition to conventional care (Fonnebo et al 2007; Willson &Andrews 2004). Furthermore this concurrent use occurs despite a lack of decisive evidence of efficacy. This scenario mimics the context of the hip/knee trial as all participants were awaiting conventional care in the form of surgery and at the point of early recruitment there was little conclusive evidence on which to base acupuncture treatment. The layman's perception of overall effectiveness rather than efficacy is complex and almost certainly attributable to the widespread availability of CAM and the perception and expectation that 'CAM works' associated with the patients' inability to differentiate between placebo and real treatment (Fonnebo et al 2007). Patients appear to make up their own minds about using CAM while the evidence remains inconclusive, yet how do individuals make such decisions?

One justification that appeared to aid the interview participants in forging their convictions was anecdotal evidence from family and friends. Many of the interview participants had decided to take part having heard about acupuncture and other CAM modalities from others, moreover this was perceived by the subjects who were interviewed as their most reliable source of information about these interventions. Tales of positive experiences and/or strongly held beliefs in favour of acupuncture from peers or loved ones were methods by which participants were convinced the hip/knee trial was worth their participation. For example Beatrice spoke of hearing positive accounts of acupuncture from family members. Margaret and Marion too appeared to draw on relative's use of acupuncture:

> "But she has had acupuncture needles so I thought oh it's worth a try…" (Margaret – non needle placebo/ non empathic)

> "Lots of people have acupuncture. My sister had it because she had a bad neck and used to get bad headaches".
> (Marion – non needle placebo/non empathic)

Whereas Roy although rather skeptical had lived overseas, and described the cultural influence of the Chinese use of acupuncture:

> "I didn't think there was a lot of likelihood that it would do any good, but then the Chinese for 2000 years can't all be wrong.
> (Roy – placebo needle/empathic)

Other participants talked about how they had heard of acupuncture from friends:

> "I've heard about it; friends have had bits and pieces done like they do…" (Helen – placebo needle/empathic)

> "I have got a friend who does…I don't know if she does acupuncture but she has had a lot of acupuncture herself."
> (Lillian – real acupuncture/empathic

> "Lots of people I know have had it, umm… for different varying reasons." (Wendy – placebo needle/non empathic)

Existing research supports this finding. A study exploring the priorities of patients of OA of the knee found that alternative therapies such as supplements, magnets and acupuncture were used frequently by many of the respondents (Tallon, Chard & Dieppe 2000). Furthermore lack of evidence for CAM and perceived dismissal by the medical profession did little to discourage these individuals as they said they were prepared to try anything that appeared to be safe and others had found helpful (Tallon et al 2000).

Barry's ethnography of homeopathy in South London arrived at similar conclusions, in that users of homeopathy drew on evidence of therapeutic benefit from not only their own embodied experiences but from witnessing effective treatment outcomes in others with whom they communicated (Barry 2006). In another area of chronic pain, migraine, an individual's self management of their condition has also been found to be subject to the influence of others. Peters, Huijer Abu-Saad, Vydelingum, Dowson & Murphy (2003) suggest in their qualitative study of decision making in migraine and chronic daily headache sufferers, that other people influenced the participants' evaluations and sometimes convinced or hindered people in their therapeutic decisions. Therefore the notion of forging a conviction based upon the influence of others in healthcare participation has already been considered both within (e.g. Tallon et al 2000) and outside CAM (e.g. Peters et al 2003).

The emergent findings from this qualitative study supported by examples in the research literature appear to sustain the notion that the positive experiences of, and encouragement from others in an individuals' support network, can enhance or possibly negate participation. This is a potentially important recruitment issue as it may explain why individuals may or may not take part in a study. However, it is not possible to compare the views of family and friends with those of individual's that did not participate in the hip/knee trial; one would need a broader qualitative study to develop this hypothesis further.

Previous personal experience of acupuncture did not appear to be a main influencing factor in making a commitment to the hip/knee trial; rather it was an interest that encouraged individuals to find out more. Only three of the interview participants had received acupuncture previously, but they all appeared open to and/or curious about it. John encompassed both aspects of this as he had personal experience of acupuncture years ago whilst in Singapore, and was aware of other's perceptions of the benefits of acupuncture. He described being:

> "Very interested in the historical aspects of acupuncture as a therapy and had read up on it."
>
> (John- real acupuncture/empathic)

A positive view of acupuncture was also reported among the German participants of four randomized controlled trials for chronic pain. In particular patients with OA of the knee considered acupuncture a very effective therapy, irrespective of their own prior experience presumably based on the experiences of friends and family as well as views that may have been expressed in the media, even though 80% had not received it prior to trial recruitment (Linde, Witt, Streng, Weidenhammer, Wagenpfeil, Brinkhaus, Willich & Melchart 2007; Weindenhammer, Streng , Linde, Hoppe & Melchart 2007)

Whereas prior experience of acupuncture did not appear to be an issue bound up with 'forging a conviction', previous participation in research may have been important. Some of the interview participants had worked in the field of research or had taken part in previous studies and seemed convinced that their participation was worthwhile for a variety of reasons. Halpern et al (2003) found that when exploring patients' willingness to participate in placebo controlled trials, those who had participated in research previously were significantly more willing to participate again. This finding concurs with a poll study of participants from the U.S and Europe (Harris Interactive 2004), and the views of the participants who had previously taken part in trials as this excerpt from Cynthia's transcript illustrates:

> "I quite enjoyed taking part.
>
> *Would you take part in a trial again?*
>
> Oh yes I did take part in one for, oh I think it was um…cholesterol.
>
> *Oh right*
>
> Yes, I had to go to the hospital. It was before they'd altered it all and um they just asked if I'd be interested in…it was only sort of like a blood test and just to monitor you know. It was only a one off. No I don't mind as long as it's not too unpleasant".
>
> (Cynthia – placebo needle/empathic)

Participants also appeared to have forged a conviction that the trial may offer them some personal gain in relation to their OA, in particular pain relief, improved mobility and/or reduced analgesia intake (see section 6.4)

Altruism (social responsibility) or the desire to help others in similar situations as well as personal gain, are repeatedly cited as quite contrary but equally valuable explanations for research participation. They were recurrent features of the hip/knee interviews, with both factors often being mentioned at differing points in the interview. However I question as to whether the issue of altruism is expressed as a result of the participants being convinced that they *should* provide a socially acceptable response. Indeed having been interviewed myself I would argue that this is a possibility and that participation may be more likely to be due to participants believing that some form of personal gain might be forthcoming as a result of their commitment. However these expressions of hope for personal gain and altruism concur with the consistent message conveyed by the current literature in the rationales provided to explain why individuals participate in clinical trials (Aitken, Gallagher & Madronio 2003; Halpern, Karlawish, Casarett, Berlin, Townsend & Asch 2003; Welton, Vickers, Cooper, Meade & Marteau 1999). This means that the more general findings from the existing clinical trial literature are transferable to the select sample that took part in the hip/knee trial.

Overall, 'forging a conviction' in relation to making a commitment to participate in the hip/knee trial appeared to be in response to a combination of transferable, influencing factors. Furthermore these factors were expressed irrespective of intervention or the consultation type participants had been randomized too. Interestingly though in the hip/knee trial one influencing factor was not expressed in relation to making a commitment, this being the participant/researcher relationship. Aitken et al (2003) describe intangible incentives that determine trial participation. These incentives include the interpersonal skills of the research personnel responsible for recruitment, citing in particular elements of courtesy, respect and time devoted to an individual. By comparison the findings of this qualitative study found that this was not the case for the hip/knee trial. It was other persuasive forces that influenced the decision

to participate, and practitioner influence appeared more relevant to maintaining a commitment to the trial.

The research presented in this thesis has identified influencing factors within its findings that appear almost entirely unrelated to any deliberate attempts of persuasion by the researchers. Indeed as mentioned earlier, persuasion was not an issue that emerged from the data. It would appear that decisions to participate in this clinical trial were influenced by a variety of external, social and personal influences that led individuals to decide it was worth doing. This has potentially important theoretical and practical implications for recruitment and retention in clinical trials. The process of 'forging a conviction' appears to offer additional understanding of participant behaviour in terms of decision making, as suggested by Peters et al (2003). Persuasive issues relating to the influence of others (primarily family and friends), openness to research, altruism and hope for personal gain may apply to any area of medical research. An understanding of the contextual issues underpinning a decision to take part in the hip/knee trial may be transferable in the first instance to other research trials investigating treatments for OA and or trials of a specific intervention, that foster openness and curiosity about them. The next section will focus on how interview participants forged convictions relating to maintaining a commitment to the hip/knee trial

9.4 Maintaining the commitment

The barriers to trial participation are well documented (see chapter seven), and it is therefore of great interest that participants continue to take part in clinical trials despite these challenges. The findings of this qualitative study offer some insight into why individuals continued to make a commitment to a specific research endeavour. Within the context of the hip/knee trial 'forging a conviction' related to how individuals appeared to weigh up the practical barriers of participation with the beneficial factors that appeared to keep them committed to the study. Individuals described influencing factors of flexibility of appointment times, and a system that ran to time providing structure and regularity to the sessions. These elements of participation appeared to convince them to stay the course despite challenging issues of travel, parking and associated costs.

These findings concur with previous research exploring barriers to trial participation. The impediments previously reported have been access to the research site (including transport issues), sufficient and flexible time for appointments and other miscellaneous difficulties such as language barriers (Aitken et al 2003). Flexibility of appointments has already been recognized as encouraging participation in previous qualitative work exploring participant's experiences of an acupuncture trial for migraine (Paterson, et al 2006) and research determining willingness to join a CAM study (Scheider et al 2003). In the hip/knee trial, this flexibility of appointments along with good time keeping, and the behaviour of the research staff appeared to have a positive impact on the participants and trial retention. They spoke of welcoming staff, both on the trial and in the research settings, and this also appeared to result in the participants forging a conviction that their participation was valued. Here are a few examples:

> "I said to the receptionist can you tell (***practitioner's name***) that I'm here because the first time I sat there for ages, and she (***practitioner***) said "next time you come tell them that you're here and I'll come and get you directly you're here because it makes the parking so expensive". (Hester – real acupuncture/ non empathic)

> "… you were seen on time, there was no waiting around. The appointment system was very good, you were seen too straight away. I would do it again, definitely do it again". (Ursula – real acupuncture/ non empathic)

One of the participants Marion described a number of convictions that appear to have impacted upon her views of the trial:

> "Everybody was polite to you even from reception – they were friendly walking about and that's what I liked about it"

She continues:

> "…one of the ladies there one particular day, I could hear a conversation about her rushing around and getting hot outside. It was nothing to do with how she was feeling. She was offered a drink of water. You were always made comfortable.
> (Marion – non needle placebo/ non empathic)

The interview participants had already forged convictions in order to make a commitment to the trial. Subsequent to this, convictions appear to be reinforced in relation to the running of the trial that leave them feeling valued which in turn reinforces their decision to take part as a positive choice. There has already been much published on the impact of environmental and social factors in CAM, and the potential impact it can have on both meaning with respect to health and treatment outcome (e.g. Kaptchuk 2002; Long 2002; Moerman 2002).

There is an important difference in this study, however, in that unlike clinical practice where most of this literature originates, in the hip/knee trial the specific therapeutic relationships were at times randomly limited by the nature of the non empathic consultations. For those participants who received non empathic consultations one could argue that their feelings of value may be less than those of their counterparts. Interestingly this did not appear to be the case even if the behaviour of the practitioner was non empathic, as the participants continued commitment was often justified by other convincing factors, such as the skill of the practitioner, their clinical professionalism and the manner in which the whole research project was conducted. These findings offer a new perspective to promoting adherence to clinical research where 'rewards' are often recommended (e.g. Wyse 2006). In the case of the hip/knee trial tangible rewards were lacking. There was no financial incentive or academic credit scheme to make participation worth while. Yet still the participants made a commitment to the trial so much so that only 11 out of 221 randomized participants dropped out.[6]

[6] See Appendix 6 for reasons for withdrawal from the hip/knee trial

The drops out rates of published trials are documented but often with little detailed explanation as to the reasons why participants fail to complete the study. One study of acupuncture as an adjunctive therapy for OA knee that did consider this issue suggests that those individuals who dropped out are on average younger or have a higher mean disability score (WOMAC) than those individuals who completed the process (Berman, Singh, Lao, Langenberg, Hadhazy, Bareta & Hochberg 1999). However it is unclear as to whether this means that younger and more disabled participants got less response from the acupuncture so were less likely to adhere to the study, or rather certain individuals were more prone to drop out irrespective of the intervention offered. The explanation of age and disability offered by Berman et al (1999) is a possibility that could be explored with the overall hip/knee quantitative data. Certainly our age range of participants was older and their disability variable, yet it may be that this low drop out rate in the hip/knee trial was due to participants being convinced to stay in it. Furthermore that which convinced them to commit is not by any means consistent. For example some participants forged convictions to remain in the trial despite initial motivating factors not being realized, i.e. not receiving their desired intervention (acupuncture). In these cases, individual experiences of personal gain or the perceived benefits of helping others were often the expressed reason, for example Elizabeth spoke of her disappointment at not receiving acupuncture but rationalized her commitment in terms of helping her family and time off work:

> "I would have liked the acupuncture because everybody says "Oh needles being stuck in you". We're all like that and it would have been nice to have known what it actually would have been like" (Elizabeth – non needle placebo/non empathic)

Beatrice (non needle placebo/non empathic) who declined to be recorded during her interview shared how she felt there was an element of compromise on her behalf as the trial was promoted as acupuncture, and this treatment was not given in her case. Despite this though she remained committed due to the hope of pain relief.

It may well be that such justifications are produced simply in order to satisfy the interviewer. However there is also the possibility that participants feel the need to recognize within themselves what factors convinced them to maintain a commitment during the research. This could be argued to a particular concern when they are ultimately required to produce an outcome, which may be based on how convinced they were about a responding to an intervention that might be placebo. The next section will now focus on how the process of 'forging a conviction' appeared to influence the participant's production of an outcome.

9.5 Producing an outcome

The analysis presented in chapter eight argued that study outcomes are not based simply on factual reporting, but are produced in response to a set of convictions forged before and during the study and constrained by the reporting process. Reporting their outcome was inherently bound up with how the interview participants forged convictions about their response to the intervention they received in the hip/knee trial. Melanie talked openly about how perceived response may impact on the end result:

> "…it's a question of belief and I'm as susceptible as anybody, we all are. Yeah I mean if you're in screaming pain and the doctor gives you something you don't argue, you think thank God for that something's going to help it."
> (Melanie – placebo needle/empathic)

That said the process of forging a conviction appeared on a continuum in which the strength of conviction varied. On occasion a few participants were so convinced by their experience that they were shocked to discover they had responded to a placebo, Arthur was an example:

"Well, you say it didn't work, but when (***practitioner's name***) switched and then put the electrodes on me, the tingling went all the way down my leg, now how can that be ineffective? Because I don't think it was, because after 3 or 4 of those treatments, I stopped taking painkillers"
(Arthur – non needle placebo/non empathic)

Others expressed uncertainty regarding outcome throughout their participation, and ended up 'second guessing' their intervention based on factors that had initially convinced them of their decision (see section 8.4). In these circumstances lack of certainty posed a challenge for reporting especially in relation to the dichotomous questions in the trial documentation. Nevertheless, participants appeared convinced that they needed to be accurate in this process and the interviews offered further explanation regarding this ever present dilemma in clinical trials of pain.

Depending on convictions forged before or during the study, some participants believed that any benefit that they experienced must be a specific response to a real intervention , while others were less certain (see section 8.3) and wondered if it was something that happened 'in their mind' for example:

"But the last 3 times I went it was sort of getting better for some reason. I don't know why you know, whether it was auto suggestion?" (Cynthia – placebo needle/empathic)

"Sometimes I don't know if it did or you're imaging it."
(Elizabeth – non needle placebo/ non empathic)

The extent to which these convictions were influenced by beliefs about placebo are an important issue for consideration. The previous chapter discussed issues relating to the placebo effect and outcomes, and it is clear that there are a

number of possible psychological theories that may help to explain the process of forging a conviction in regard to producing an outcome e.g. expectancy, conditioning, suggestibility etc. However there is no one theory that offers a concise answer, rather aspects drawn from a number of theories are required. That said, Hyland et al's (2007) proposal of motivational concordance, in which the expectancies and the perceived value of getting better held by an individual can influence that person's motivation and behaviour, appears to offer a possible explanation for the process of forging a conviction in all stages of participation within this study. Hyland et al predict that from a motivational perspective, the degree of involvement with a therapeutic ritual contributes to outcome (2007). This notion appears to correlate with the findings of this thesis. The participants of the hip/knee trial were open to the therapeutic ritual on offer (i.e. acupuncture and/or research) prior to participation. They became active participants within the trial, maintaining their commitment with the aid of ameliorating factors enhanced by the ritual of the trial process; and they actively sought to make meaning from their experiences on the trial which influenced their reporting of outcome.

Although of particular sensitivity within CAM, enhanced placebo response has the potential to occur with all treatments. For example Moseley, O'Malley, Peterson, Menke, Brody,Kuykendall, Hollingsworth, Ashton and Wray (2002) found that the placebo effect in arthroscopic surgery for OA knee can produce results equivalent to both lavage and debridement procedures, that continue throughout follow up. This appears to suggest that outcome may be linked to an expectation of having a 'procedure, which is reinforced by the rituals associated with in it for example in Moseley et al's study anesthesia, recovery, and visual wounds to the knee.

The process of forging a conviction cannot though be explained solely as having a positive expectation regarding outcome. Rather, 'forging a conviction' includes a range of subtle social influences that move beyond beliefs about outcomes. This active process of forging a conviction appears to have an important influence on the way in which individual's make and maintain a commitment to a study and report on its outcome.

9.6 Conclusion

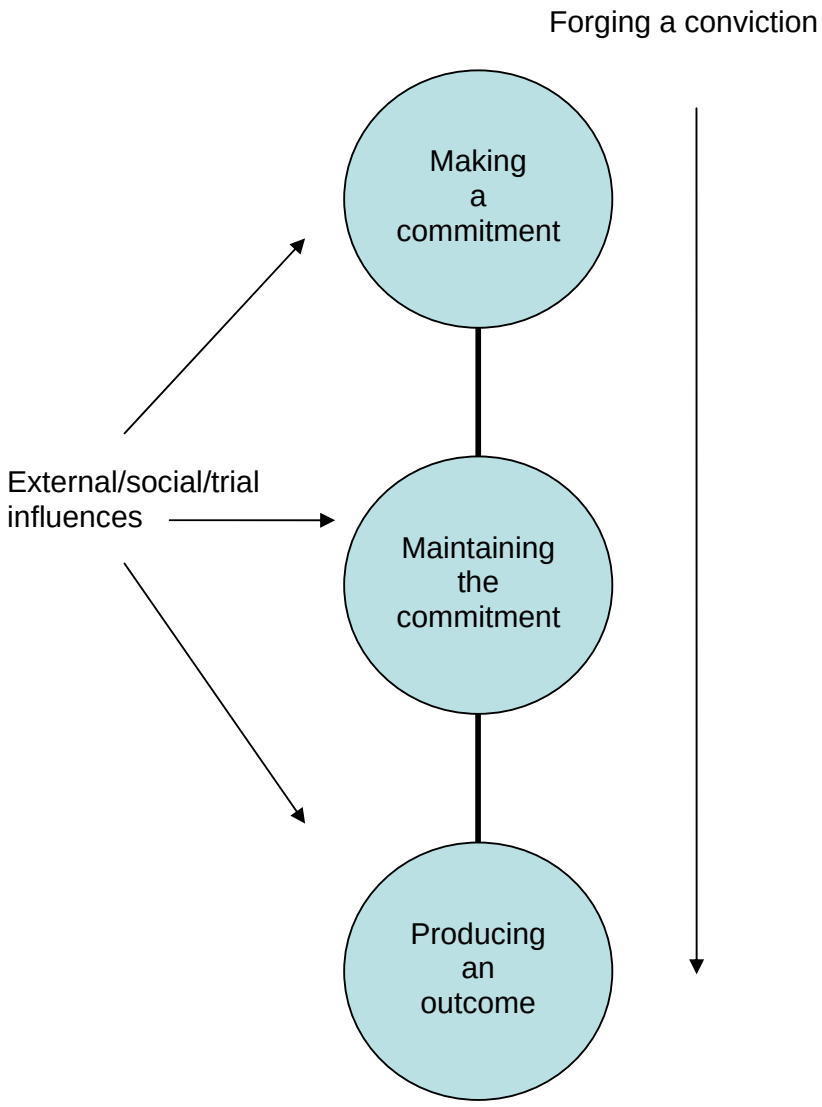
The concept of a basic social and psychological process of ‘forging a conviction’ is novel in terms of literature in both CAM and research participation in general. Within the context of the hip/knee trial, the core category of ‘forging a conviction’ represents a process whereby people make and maintain commitment to a study, and produce an outcome to report. Forging a conviction is an active process. In other words participants are convinced by a range of factors, mostly external and social to enter the trial. Whatever these reasons for agreeing to take part, they appear to facilitate a commitment to the study which is sustained by further convictions, based again on external social influences that their participation is valued. These convictions appear to help participants overcome a variety of barriers to continue their participation, further fostering a sense of commitment to the trial. At the point in which participants are asked to report on outcome, they appear to draw on convictions made in response to experiences on the trial, which aid in their second guessing of intervention type. This is an active process which in turn influences perceived outcome and an individual participant’s subsequent reporting of it. Thereby outcomes are ‘produced’ rather than merely reported

It may be argued that the veracity of ‘forging a conviction’ is challengeable, given that the interview participants were asked to retrospectively comment on their experiences of taking part in the trial, and are to some extent offering post hoc justifications for their participation. However the use of open ended semi structured interviews was specifically chosen to inspire a free flowing response to this opening question and reduce this likelihood, and the words convince, convincing, and believe were ‘in vivo’, emerging spontaneously from a number of participants. Therefore the issues underpinning participation which did emerge, and the relationship that ‘forging a conviction’ appears to have in relation to them, suggests that this core category is both universal in its range and robust in its veracity.

This concept of ‘forging a conviction’ and its implication on trial participation including outcome is new and original. Existing literature on research participation often considers recruitment and adherence as a separate from outcome, thereby overlooking the impact that the whole process can have on participation. The process of ‘forging a conviction’ is a continuum that may operate both positively and negatively. It is causative, initiating effects and meaning within the trial even before recruitment has begun. In turn it appears to continue to facilitate commitment to a study and produces consequences such as influencing the reporting of outcomes– see Figure 16 for a diagrammatic representation of this process.

In addition the process of ‘forging a conviction’ may extend to practitioners and this warrants further exploration with regard to staff conducting research studies. The question is whether ‘forging a conviction’ is a process that can be derived from a theory of active participation in an acupuncture trial and transferred to other clinical trials both within and outside CAM? The following final chapter with explore this possibility, answer the initial research question and discuss the key lessons learnt from this work that can taken forward into future qualitative and quantitative research.

Figure 16 A theory of active trial participation



Chapter 10 Discussion and Conclusion

10.1 Introduction

The aim of this thesis was to explore the non specific effects of acupuncture in a clinical trial setting within a qualitative context. The main reason for this being that acupuncture has become increasingly available within the NHS in both primary and secondary care, in spite of limited evidence that real acupuncture has a greater clinical effect than sham placebo controls. Furthermore individuals receiving acupuncture continue to anecdotally report favourable clinical effects (Lewith et al 2004) despite the lack of systematic evidence supporting a point specific effect for real acupuncture treatment.

The complexity of a process (e.g. acupuncture) under investigation is a major challenge to researchers when attempting to replicate pragmatic practice within a trial setting. We remain unsure what is specific and not specific about the whole process of acupuncture. Consequently it is clear that this lack of knowledge makes it increasingly difficult, if not impossible, to design an effective and convincing placebo without an understanding of the basic mechanisms involved in the treatment process. Therefore using placebo or sham controlled trial designs may lead to false negative results as the specific effects cannot realistically be separated from the non specific with our current level of knowledge about the mechanisms involved (Paterson & Dieppe 2005).

The hip/knee trial was specifically designed to explore the contributions of the specific and non specific effects of acupuncture quantitatively and allow this data to be interpreted within the context of the randomized controlled trial through a nested qualitative study. The trial itself had a number of research objectives (see appendix 1) but was primarily a comparison of acupuncture with both needle and non needle placebo controls. Birch et al (2002) suggest that acupuncture is partly effective because of the unique patient–practitioner relationship; therefore the impact of therapeutic empathic intent on outcome was also investigated in this study. The qualitative study nested within it used a grounded theory approach to

explore the non specific effects of western acupuncture in a trial context thereby adding new perspective to the small but existing body of qualitative work on acupuncture.

The previous chapters have presented the findings of this qualitative study, detailing the emergence of three stages of participation within the hip/knee trial linked by the process of 'forging a conviction' (core category). This developed into a substantive theory of active trial participation. Within this final chapter this theory of active trial participation will be discussed, along with its implications for researchers. Also included are my reflections on the research process, and imbedded within the text consideration of the study's strengths and weaknesses. Finally I will discuss my conclusions and recommendations for further study.

10.2 A theory of active trial participation

The findings of this qualitative study have identified a range of potential non specific influences related to recruitment, retention and outcome in the hip/knee trial. Namely the issues underpinning participants' rationale and influences for entering (see chapter six) and remaining in the trial (see chapter seven). These non specific factors combined to create a set of convictions about the nature and value of the hip/knee trial. The values and concepts forged before and during the trial appeared to influence the way in which participants perceived and reported the outcomes of the trial within an active and iterative process. This research has generated a substantive theory which I have chosen to label a '*Theory of Active Trial Participation'* (see Figure 16 in previous chapter).

This theory appears to challenge some of the basic assumptions of randomized controlled trials most notably that participants are passive recipients of an intervention and report factually on its effect. Rather individuals taking part in the hip/knee trial are recognised as active participants instead of passive recipients of research. This process of active participation begins at the moment they are approached to take part, continues to forge convictions and commitments throughout all stages of the trial and has strong potential to influence their reporting on the outcomes of the trial both quantitatively and

qualitatively. It is however important to acknowledge that the data from qualitative interviews in this study had the potential influence of social desirability bias, thereby highlighting those outcomes both quantitative and qualitative are equally prone to bias.

This theory however, offers a unique contribution to knowledge, and is important given the complex nature of acupuncture as a process under investigation, and possibly even more so when performed within a trial setting. It may help us to understand the process of acupuncture and, from a qualitative context, offer some explanation for the observed clinical effects we see in other randomised trials and indeed in clinical practice. The implications of these findings will now be discussed.

10.3 Implications for research

Emerging from this qualitative study was the core category labelled 'Forging a conviction', or in other words the construction of a belief or opinion. This basic social process occurs throughout an individual's participation in the trial, in which convictions forged before and during participation appear to directly influence the reported outcomes. This raises a number of issues for researchers.

Some of the non specific factors identified in the qualitative study are similar to those identified about recruitment issues for all research participation. This includes the factors influencing participants in relation to their decision to consent to be recruited into any study; curiosity (Mattson, Curb, McArdle& Bhat and Amis research groups 1985; Tolmie Mungall, Louden, Lindsay and Gaw 2004), altruism (Baker, Lavender& Tincello 2005; Harris Interactive 2004; Roberts, Warner, Green & Geppert 2006; Saunders & Wainright 2003; Smith & Coyle 2006; Terry, Olson, Ravencroft, Wilss & Boulton-Lewis 2006; Tolmie et al 2004) and hope are all well described and important patient perceptions that relate to and impact on research participation and retention. Patients willing to be recruited into studies of acupuncture appear not to be searching for the 'need for a cure' but rather an alternative source of help (Walker et al 2004; Paterson 2006) – see chapter six.

The findings of this qualitative study also identify these factors as well as the influence of family and friends in relation to trial participation. Such influence of others on an individuals choice of treatment has been described (Barry 2006; MacPherson et al 2006; Peters et al 2003; Shmueli and Shuval 2006), but it has not been considered as a positive factor that may influence research participation and study retention. Ross et al (1999) suggest that an "important person" is a considerable influence on the decision to participate, but as a barrier, with patients unlikely to participate if those close to them were against it. The findings presented here, add a new perspective to previous research acknowledging that other people close to the trial participant, may have a substantial influence on their consent to enter a research study and may help to explain why individuals do and do not take part.

Other considerations for recruitment are the possible theoretical influences underpinning forging a conviction on 'making a commitment' namely that of expectation & belief. Some participants appear to enter a trial with a pre existing conviction (expectation). This may well impact on outcome as Expectancy theory predicts that placebo response is related to an individuals' expectation of improvement and thus connected to the changes that take place within a therapeutic environment (Bootzin 1985; Evans 1985; Kirsch 1978 & Ross & Olsen 1981) – see chapter eight. In recent years there has even been the use of brain imaging to explore expectancy. Two studies, including one on acupuncture suggest that expectancy or belief can influence the cognitive processes that modulate perception and affect in areas of the brain associated with opioid activity (Wager et al 2007) and the reward system (Pariente et al 2005).It is unclear at this time what implications this may have for clinical pain syndromes, and their evaluation with regard to trials exploring them, but it appears to be an area in which future research is warranted.

In the context of the hip/knee trial participants appear to have forged convictions because of their own experiences and/or they had been influenced by the experience of other people to whom they are close, in relation to their perception of acupuncture. This may in itself provide the ideal context for a positive expectation and may therefore impact positively upon outcome through the

mechanism of expectation. If this is the case it could create a substantially different context when compared to a clinical trial involving a new pharmaceutical agent when knowledge, and more importantly patient and practitioner equipoise, cannot be based on prior experience or societal knowledge about the intervention.

The theories of suggestibility and motivational concordance may also contribute to our understanding of the process of forging a conviction with particular regard to making a commitment to participate. The hip/knee participants who were interviewed appeared to be 'open' in relation to both the process of acupuncture and or research. This openness supports the notion that suggestibility may explain participants' behaviour; for example individuals described the sensations they felt and imbibed the positive view of others regarding their response. It is possible that these factors may have underpinned their perception of and belief in an effective therapeutic outcome. Similarly Hyland et al's (2007) theory of motivational concordance, in which if a patient's understanding and belief about the context of the intervention is similar to that of the therapist then this may enhance the non specific effects of the intervention. For example, the patient who believes in a spiritual world view will have a better outcome if the therapy and the therapist create a spiritual context for the therapeutic intervention. Expectancies held by an individual clearly influence that person's motivation and behavior and through these processes engender an effect on the outcome of any therapeutic intervention.

The use of open ended, semi structured interviews in the qualitative study identified a wide range of influences on participant's experiences of not only entering, but being involved in the hip/knee trial. This data adds to the existing previous qualitative work on trial participation from a TCM study of migraine (Paterson et al 2008) which found that participants 'played their part', in which both their expectations and behaviour were adapted to the scientific requirements of the trial. It also highlights the possible effect of convictions forged throughout a participant's involvement in the trial on their continued commitment to a study.

Findings such as ameliorating factors to barriers to participation, feeling valued, personal gain and contractual duty expressed in the interviews suggest that rewards may not be essential to reduce attrition rates in clinical trials. This challenges the suggestions of previous research (e.g. Wyse 2006). Rather offering flexibility of trial appointments, running to time and a welcoming environment may be areas in which retention can be improved. Again however it is important at this point to acknowledge that these qualitative findings may be subject to biases such as social desirability (Nancarrow & Brace 2000) and these views may have been shared in order for the interview participants to present themselves in a favourable light.

Rather than being acquiescent subjects, trial participants in this acupuncture RCT (hip/knee) were very actively involved in the study and not simply passive trial participants. They appeared to come into the study with beliefs, hopes and expectations which continue throughout their study participation. These participant ideas evolved in an iterative manner in combination with behaviour that is shaped by the context of the trial and the participants experience whilst in the study. In addition outcomes are a product of a range of factors which are both variable and contextual. These are filtered throughout the participants pre-existing as well as their experience during the trial. These findings appear to have implications for both the interpretation of quantitative results and the design of trials. For example the hip/knee trial was in part designed to test for the effect of therapeutic empathic intent on the outcome of a course of acupuncture treatment as well as investigating the effects of needle and non needle placebos. This provided an opportunity to explore the experiences of participants under different therapeutic conditions. What was noteworthy from the interviews was the consistency of influencing factors across all randomised groups who consented to enter the study. The issues underpinning the theory of active participation in association with the core category of ‘forging a conviction’ emerged irrespective of randomised intervention (real acupuncture, placebo needle and non needle placebo) or consultation type (empathic or non empathic). If this qualitative finding is supported by the quantitative results of the hip/knee trial (i.e. that there is no statistically significant difference in outcome between all randomization types) it may help to explain why previous RCTs and systematic reviews of

acupuncture have been inconclusive as to its specific effect over ‘placebo acupuncture’.

With regard to trial design previous research evaluating the impact of prostate screening for cancer (Donovan, Mills, Smith, Brindle, Jacoby, Peters, Frankel, Neal, and Hamdy 2002), found that an initial qualitative study was able to identify areas for improvement with regards to recruitment and the presentation of clinical equipoise prior to randomization. Analysis of these findings led to changes in the ‘presentation’ of the trial and as a result recruitment was enhanced. Indeed my findings offer factors that may have enhanced recruitment that as a research team we could have utilized had this information been known earlier. This could have been beneficial given that out recruitment rate was relatively low and slowed over time. It may be worthwhile for researchers to consider incorporating qualitative interviews at differing points throughout a trial to identify non specific influences which could be recognized and taken account in the analysis and interpretation of the study outcomes This may be especially so within trials exploring complex interventions, not only to enhance the trial process but to explore the participant’s perspective at differing time points and enable effective trial design.

10.4 Reflections

Throughout this PhD I have attempted to address the subjective beliefs I held about acupuncture when starting, in order to develop an objective stance towards the research I was undertaking. Not only have I gained new skills as a researcher but as a practitioner my outlook and practice has also changed. Within this section I will discuss the main issues to arise from my ‘research journey’ and consider their impact for future researchers. These are the challenges of being a practitioner researcher, finding a balance when working within two paradigms i.e. quantitative and qualitative research, negotiating contradictions from two differing data sets and finally the professional and ethical task of un-blinding participants as to their intervention. Throughout these sections I will highlight the strengths and weaknesses of the study.

10.4.1 Being a practitioner-researcher

As a practitioner of CAM an individual's practice is often guided and shaped by the training undertaken and the propensity to immerse oneself in the rituals, theories and even the dogma of a chosen therapy. This 'right of passage' on the journey to becoming a practitioner has the potential to create challenges if a practitioner then decides to become a reflexive researcher in their own field.

There is longstanding recognition that the choice of a research topic often has personal significance for the researcher, whether conscious or unconscious (e.g. Devereaux 1967). My previous personal and professional experiences of acupuncture were certainly responsible for my desire to research this topic. Yet I entered the process naive as to what would be required to facilitate the experience, especially with regard to methodological rigour. It would be fair to say that at the start of my thesis there were a number of '*a priori*' assumptions, both personal and methodological, that were initially overlooked. Firstly I was a professional acupuncturist with a belief and conviction that acupuncture 'worked', drawn from both first hand personal experience and practical knowledge. I was also undertaking a role of practitioner on the trial in which my own qualitative study was nested. This duality of roles was not initially seen as a problem, however it could be argued to have implications for the authenticity and trustworthiness of the qualitative research due to the potential inherent biases arising from this situation (e.g. that the findings are not based on my prior assumptions and beliefs). This is a weakness of the study. These circumstances required adaptation of both my input as part of the trial research team, and those participants sampled for interview (see chapter four).

The trial itself was also based on the hypothesis that empathic therapeutic intent could enhance outcome. This combined with my novice status as a qualitative researcher meant that in the early stages of this PhD it could again be argued that my objectivity was compromised. For example initial qualitative findings appeared to mirror those issues bound up with the trial design, however this seemed to be due to my need to follow a coding procedure rather than a reflective interpretation of the data gleaned from the interview participants. In order to address these limitations I was required to take a step back and become a

more reflective researcher and observer. From a personal perspective I significantly limited my practice of TCM acupuncture during the study and even stopped practicing acupuncture privately until recently. In terms of the hip/knee trial I also withdrew from my initial role in the team. Whereas previously I had recruited prospective participants into the trial and therefore met some individuals prior to interview, this had the potential to emphasise my role as research team member and therefore impact significantly on the interview process. It was not possible to minimize this potential bias completely however and therefore I have documented my interactions with each interview participant (see section 5.3)

With this new 'role' in practice, I reanalyzed my interviews to date (ten at the time) in order to overcome any potential bias that may have occurred in my initial analysis. My first attempts at analysis failed to see beyond the obvious. Setting aside the hypotheses of the trial, issues emerged that related to active participation, where participants spoke of their motivations, commitment and being valued. There also appeared to be elements of uncertainty and notions of differentiating the experience. This reanalysis is a strength of the study and formed the first stage in my development of a substantive theory, and although this theory and the ideas that underpin it did not emerge until much later in the research process, they all appeared to be there from the beginning of the study. Had I continued to concern myself with the aims of the trial, the findings of this thesis may not have emerged, which raises the issues of competing research paradigms.

10.4.2 The issue of paradigms

The issue of inconsistency of outcome in acupuncture research and other investigations of complex interventions has seen the encouragement of mixed method approaches with the aim of exploring and understanding this phenomenon further. However this approach raises challenges to researchers in a number of ways which will now be discussed.

As previously mentioned the qualitative study presented in this thesis was nested with in a trial on which I was working. The challenges of conducting a

qualitative study in these circumstances arose throughout the research and I was not entirely aware of the full implications at the outset. Essentially tensions resulted from my involvement in research that stemmed from both positivist and interpretivist paradigms. These opposing stances on inquiry were due to the underlying epistemological and ontological assumptions of the competing paradigms, which inform methodology. Paradigmatic views differ with regard the acquisition of knowledge of reality (epistemology) and the form of the reality under investigation (ontology).The positivist position underlying the hip/knee trial was hypothesis testing, deductive inquiry, based on a view of single reality in which the researcher and participants are independent of each other. By contrast the interpretivist paradigm underpinning the qualitative study was predominantly that of a hypothesis generating, inductive inquiry in which multiple realities are possible, and the researcher and participants are inseparable. As a researcher I was caught between the two paradigms, which in terms of my qualitative work potentially challenged the authenticity of my research. Yet by being aware of this and addressing it, the subsequent process has appeared to have served to support the findings of this study.

The findings of this qualitative study in the context of an acupuncture trial have produced a theory of active participation, in which many of the concepts underpinning research participation that inform it appear representative of recruitment and retention issues for research participation in a wide variety of contexts. By working within two paradigms I should be able to triangulate my qualitative findings with those from the hip/knee RCT itself. The quantitative study has been completed and the results are being analyzed in preparation for publication. Despite being at an early stage, they appear to support the findings that ‘active participation’ in which participants forge convictions which affect the three stages of participation in the study (making a commitment; maintaining a commitment & producing an outcome) is a social process that occurs across all conditions of the trial e.g. intervention, consultation types, locations and possibly all types of clinical research. However, only future research will be able to explore whether or not the theory of active participation will be applicable to other specific situations and research participation in randomized controlled trials generally.

It has been essential throughout this study that the research is perceived as credible, and as discussed previously in chapter three, there is an array of assessment criteria for qualitative research (Le Compte & Goetz 1982; Lincoln & Guba 1985; Miles & Huberman 1994). For example Lincoln & Guba (1985), argue that rather than using conventional methods of evaluating research such as rigor, reliability and validity for qualitative research, alternative criteria of credibility, transferability, dependability and confirmability should be sought to assess the quality. The values they describe are inextricably linked with the notion of authenticity and trustworthiness. An assessment is made to evaluate the faithfulness of the work e.g. are the researcher's findings compatible with those of the participants. The fit and meaningfulness to other contexts of the work, being known as transferability are essential components of this process.

Throughout this thesis it was my aim to present a transparent and open account of how the study was carried out in the hope of demonstrating its dependability and confirmability for the phenomena under exploration. This document offers a clear audit trial (see chapter 4) emphasizing the connections between all aspects of the research process, allowing the reader to see the wider context and establish the value of the research (Lincoln & Guba 1985: Koch 1994). I have also included continual reflexivity within the thesis, acknowledging my own experiences, beliefs and skills in order that the data emerging from the interviews was not subject to influence such as my own preconceived ideas or assumptions, either due to the way I collected it or analyzed it.

In summary working within two paradigms has the potential for conflict and may even challenge the findings of both studies. Yet I suggest that this can be overcome if the possible biases and undermining issues are acknowledged, acted upon and the research team value the findings of both data sets. The differing methods have the potential to enhance each other, providing a broader more in-depth explanation of a topic under enquiry that ultimately may help to explain statistics and authenticate a generated theory, and is another strength of the research.

10.4.3 Conflicting information at interview

At times during the participant interviews, I was struck by the revelation that the information shared with me conflicted with that recorded in the trial outcome measures. Previous qualitative research among osteoarthritis patients partaking in a clinical trial has shown that the level of concordance between the outcome questionnaire and interview data was less than 50% (Campbell, Quilty & Dieppe 2003). A lack of concordance between data sets may undermine the outcomes of a trial, in that RCTs require validated patient based outcomes in order to determine if a particular intervention is effective. Campbell et al (2003) acknowledge that such discrepancies are 'disquieting'. However Campbell et al offer no suggestions for addressing the issues further, rather an explanation that the situation was likely to be due to the context in which the data was collected. This suggests that quantitative data collected in the clinical trial in the presence of a doctor may produce a different interpretation of individual outcome when compared to qualitative accounts at the patient's home with an independent researcher (Campbell et al 2003).

These differing methods of data collection appear similar to the hip/knee trial and my qualitative study. However my research had an added complication in that as a researcher I was not independent of the study process and had knowledge of the interview participant's trial documentation in order to share their randomization if desired. This again means that the qualitative interviews had the potential for social desirably as participants may have felt the need to justify their outcomes in order to save face should they have responded to a placebo intervention. It is unknown at this stage if the discrepancies highlighted in the qualitative study will challenge the results of the RCT, however the possibility that it might is further evidence that such discordance concerning individual clinical outcome requires future consideration.

10.4.4 The issue of un-blinding

In chapter nine I discussed issues related to un-blinding, and included a vignette of Peter who expressed a negative reaction to being informed he was a placebo responder. This had a profound impact upon me not only as a practitioner but also as a health professional who is used to being the patient's advocate.

Much has been written with regard to the ethics of informed consent and use of placebos in clinical trials but there is scarce research on the ethics of disclosure, unmasking or un-blinding (Di Blasi, Crawford, Bradley & Kleijnen 2005). As a researcher one of the key responsibilities as detailed by the department of Health's research Governance Framework for Health and Social Care (2005) is to feed back results of research to participants. The problem is that it appears that this can be interpreted as the overall findings of the study they participated in, and or disclosure that encompasses their individual results. Previous research found that less than half of trial investigators surveyed, informed participants of placebo controlled trials about their treatment allocation at the end of the study (Di Blasi, Kaptchuk, Weinman, & Kleijnen 2002).

The process of debriefing is important ethically as it is believed to show respect and appreciation of the trial participants, yet the process can also be potentially harmful when debriefing placebo responders. Miller, Giaconi, Ahern, Robert & de Laat (2008) suggest that this ethical issue is compounded by therapeutic misconception. This can be two fold, occurring when participants believe that their own therapeutic needs may be met through a research protocol, and when researchers misidentify their role and believe that their actions towards participants are in the individual's clinical best interest. A recent survey of prescribing 'placebo treatment' practices among internists and rheumatologists in the US (Tilburt, Emanuel, Kaptchuk, Curlin & Miller 2008) raises the question of whether therapeutic misconception is also occurring in clinical practice. The survey suggests that recommending treatments to promote patient's expectations (placebos in the form of vitamins; over the counter analgesia and antibiotics) are common place, yet physicians appear to be not fully transparent with their patients about their motivation and prescription (Tilbert et al 2008).

As a novice researcher such intricacies of research are often overlooked. I certainly felt unprepared for the challenge. Admittedly the majority of interview participants un-blinded as placebo responders appeared to 'take it well'. It is unknown though as to whether that reaction was genuine or for the sake of the interview. It is also impossible to know if in cases where participants did respond positively to a placebo, the perceived healing response from the intervention on

the trial diminished following un-blinding, and if that were the case are we as researchers doing them unintentional harm? Di Blasi et al (2005) offer advice to researchers, asserting that the process of sharing information is of vital importance for those participants who desire it. They recommend that individual treatment allocation be shared sensitively in the context of placebo effects and the study's results. At the time of my debriefings the study results were unavailable, and on reflection I agree that this additional information would have been useful. Such challenges will continue for as long as there are placebo controlled trials, and this highlights a need for further research.

10.4.5 Translating research into clinical practice

One final consideration I have reflected upon is whether or not the theory of active participation is relevant to the clinic practice of acupuncture. It may be argued that results from pragmatic trials are more easily transferred to clinical practice, given the constraints of a protocol that a randomised controlled trial demands (Sherman, Linde and White 2008). However the use of mixed methods offers an additional participant - centered view which may well be transferable from this study to other clinical trials particularly those involving chronic pain.

The findings of this qualitative study have highlighted a basic psychological process of 'forging a conviction' that may also explain an individual with chronic pain's CAM use in the world outside trials. Apart from the issue of altruism, the emergent influences on participation in the trial and commitment to it may also be rationales for choosing to seek and continue with treatment from acupuncture or other CAM therapist. Is the process of 'forging a conviction' in conjunction with a theory of active participation the 'extra ingredient' that acupuncture offers over conventional medicine for pain? This appears to be an area for future research, given that previous nested qualitative research by MacPherson et al (2006a) in a pragmatic trial for low back pain suggests that acupuncture practice in association with explanations based on acupuncture theory may be what helps patients make sense of their condition and facilitate their 'active involvement' in making changes to their lifestyle. I will now end this chapter with my overall conclusion and recommendations for future research.

10.6 Conclusion

The findings of this qualitative study substantively challenge the 'static' model of non-specific effects, which seek to separate participant's beliefs and expectations from contextual factors associated with the trial. The findings correlate with a 'fluid' model of active participation in which participants forge convictions which appear to be modified during the study and affect their commitment to the trial. Such convictions in turn appear to influence reported outcomes, which may have implications for all aspects of the study (i.e. quantitative outcome measures used for data analysis and interpreting the results). These findings appear to transcend the variable conditions and factors involved and evaluated in the hip/knee trial. These included a priori assumptions about the effects of the therapist, location; three treatment interventions and two consultation types (empathic and non empathic).

The factors that were most significant in the context of the hip/knee trial were that the participants appear to be 'active', with existing convictions about acupuncture and research that made them open to the study, curious, hopeful and altruistic. Once enrolled they continued to be actively committed to the research process, forging new convictions based on contextual issues such as environment, staff, professionalism and flexibility that aided their continued participation and influenced their convictions during the study. Lastly, these existing convictions, and the continued forging of new opinions throughout the trial, appear to have impacted upon their production of an outcome, both qualitative and quantitative.

This theory of active participation and the emergence of the core category 'forging a conviction' offer some insight into the non specific effects of acupuncture in a trial setting and goes some way in offering an answer to the original research questions of what causes recipients of the treatment to report benefits even if no significant specific therapeutic effect is demonstrated over a control intervention; if outcome is linked to the efficacy of the treatment itself or is outcome the delivery system used and finally the implications of receiving acupuncture within a clinical trial setting from a participant's perspective.

A ‘Theory of active participation’ has highlighted that within the context of a specific randomized controlled trial, participation is an ongoing, fluid process, influenced not only by contextual factors but a participant’s own behaviour in response to these. Outcomes within such a setting are produced in response to a wide variety of factors and the notion of convictions or beliefs impacting on behaviour and outcome may explain why individuals who receive acupuncture report benefits even if no significant specific therapeutic effect is demonstrated over a placebo control. The findings of this study concur with and support the existing literature for example Paterson et al’s (2008) TCM for migraine research in which participants and practitioners are ‘playing their parts’ resulting in both their expectations and behaviour adapting to the scientific requirements of the trial in which they are involved. Similarly outside the field of acupuncture, or even previous CAM research, the literature suggests that participant beliefs about the design of a trial may affect internal and external validity (Featherstone and Donovan 2002) and that an RCT context can affect both participant experience and outcome due to behaviour modification (Heaven et al 2006). The findings presented in this thesis also highlighted discrepancies in reporting and difficulty with quantitative outcome measures which may impact on the quantitive outcomes. This too supports previous research that quantitative outcomes do not always capture participant centered outcomes (Moffat et al 2006).

Acknowledgement of such phenomena is important if researchers are exploring complex interventions. It appears that it is not possible to replicate a complex intervention such as acupuncture within a trial setting, as those participants taking part choose to adapt to the constraints of a study, whereas in real life they may have not. Therefore the outcomes from such trials may not be transferable to clinical practice. What is also not known however is to what extent these findings (theory of active participation in an acupuncture trial) are transferable to other types of trials and studies within medicine therefore my recommendations for future research are outlined below.

10.6.1 Recommendations for future research

A first step would be to investigate if these findings are transferable. Future research could explore whether this model of trial participation is transferable to trials in other CAM areas and conventional medical interventions. The use of a number of nested qualitative studies with in a randomized controlled trial could also offer researchers greater insight into the research process from the participant's perspective. This may aid recruitment and retention issues and also provide explanation of quantitative results. This would be beneficial for both qualitative and quantitative methods with regard to triangulation of findings. The findings of this study have at this point drawn upon existing research, however once the quantitative findings of the hip/knee trial are available these too will be used within the triangulation process as a means of exploring the data further.

Undertaking this study has also raised the issue of un-blinding within clinical trials. Recent research has shown (e.g.Tilbert et al 2008), that the challenge of working with 'placebos' are relevant to both research and clinical practice. As health professionals we are ethically bound to inform our participants/patients as to the interventions they have received. This process however is not without conflict and I feel is deserving of further research. Areas to be considered include the practicalities of un-blinding participants in a placebo controlled trials. Qualitative research could explore both researcher and participant perspective. Plus whether or not there are differences between drug trials and practical 'hands on' interventions such as acupuncture and physiotherapy.

To conclude the use of qualitative research is fundamentally important in the evaluation of complex interventions. Such methodology has the potential to generate new theories which may shed light on previously unexplained phenomena. Timing of qualitative assessments should be considered for example early in a study as a means of possibly improving recruitment and retention in clinical trials, in addition to the end when exploring outcomes. In the context of understanding complex interventions and the impact of research participation, the nesting of a number of qualitative studies offers the potential for further knowledge and possible solutions to problems that challenge researchers involved in these types of enquiry.

Appendix 1 Hip/knee trial protocol

The process of acupuncture treatment. A randomised controlled trial and qualitative study to evaluate the relative contributions of specific and non-specific effects.

Summary: The efficacy of any treatment is inherently bound up with the delivery system employed to provide that treatment and its associated non-specific effects. We propose to investigate the patient/ practitioner interaction and context of acupuncture treatment within a randomised controlled trial (RCT). This will involve 2 practitioners, treating patients with osteoarthritic pain, specifically investigating the clinical effects, on pain, of real acupuncture and different currently available acupuncture placebo controls. The results of this study may have broad implications for other physical treatments employed in painful conditions.

Aims: 1) To investigate the relative effects of different currently used acupuncture placebo controls, 2) To evaluate the specific effects of acupuncture on pain, in a population of patients with severe OA knee or hip, awaiting joint replacement. 3) To evaluate the effects of patient/ practitioner interaction on outcome.

Hypotheses: Primary. A) Needles cause an enhanced placebo effect in acupuncture treatment which will affect clinical outcome. B) Acupuncture is more effective than placebo in the treatment of O.A. hip/ knee. Secondary: Empathic consultations are more effective than non-empathic consultations

Background: Complementary and Alternative Medicine (CAM) is widely used, Thomas et al indicate that 10% of the U.K. population use CAM annually and 47% are lifetime users[1], whilst Ernst and White [2]suggests a U.K annual expenditure of £1.6 billion. Acupuncture is one of the most widely used CAM therapies and 0.6 million individuals received this treatment in 1998[1]. This popularity is not sustained by a strong evidence base, as indicated by the recent House of Lords report.

The systematic reviews of acupuncture imply that it may be of value in neck and low back pain[3;4], but White et al have demonstrated that the evidence for a specific therapeutic effect is weaker than might be believed because of poor research, small studies and inadequate systematic reviews[5-7]. The specific analgesic effects of acupuncture in O.A. knee[8] may be greater than for spinal pain, but this conclusion is based on limited primary research. Our study population will be awaiting joint replacement and there is limited evidence to suggest any specific efficacy for acupuncture for patients with either hip/ knee pain and systematic reviews suggest more thorough clinical research. Our recent large study on chronic neck pain[9] (n=135), with a 1 year follow up, suggests that acupuncture is effective over a prolonged period, but that its effect may be non-specific rather than depending on a particular point prescription, acupuncture methodology or even the insertion of needles. It also suggests that contextual considerations such as empathy, empowerment, the consultation and the nature,

rather than the efficacy, of the intervention , appears to have profound influences on the outcome for pain and analgesic intake.

Therapeutic interventions achieve their results through a combination of mechanisms. The specific or therapeutic effect of intervention and non-specific effects which include the natural history of illness, the therapeutic interaction between the patient and therapist, the process and rituals involved in treatment administration, patient expectation, suggestibility and conditioning [5;10;11]. Little is understood about the complexities of the interaction between acupuncture placebo interventions, the patient and practitioner. We believe that further research into the nature of the 'placebo' or non-specific effects is vital to understanding both the nature of the clinical benefits of acupuncture and also as a possible means to enhance other currently available physical treatments. The question, 'what is it about the treatment process which has such a profound effect on pain?' forms the basis of our planned research and could have very important implications for many forms of manual therapy in the management of pain.

If acupuncture has specific effects, then these should be maximised, if however benefits are due to non-specific or placebo effects then these to need to be investigated and applied in order to increase overall benefit to patients[12]. The magnitude of the non-specific effect will also affect the results of any clinical trial[13], because if the placebo or non-specific contribution is large, it could mask the effectiveness displayed in a verum group. Similarly, the nature of the placebo is also important as different interventions may have different placebo effects. It has been suggested that acupuncture possesses an enhanced placebo effect because of the use of needles, as do 'high tech' medical devices [13-15]. The main acupuncture placebo/controls currently used are 1) Placebo needling, 2) Sham electrical unit, the latter having been used for many years and so has been well validated as an inert intervention.

Plan of investigation: This 3 year investigation involves a multi-centre, RCT of patients awaiting hip/ knee joint replacement. It will be a factorial design with patients allocated to one of two acupuncturists, to receive one of three treatments (1 real acupuncture and 2 placebo controls). The non-specific factors that will be evaluated are: primarily the empathic nature of the consultation. The study will form an essential stand-alone element of a series of investigations to evaluate the contextual effects and processes of acupuncture treatment. Pursuant to this, we have, and are continuing to re-evaluate the credibility of the placebo needle[16] among patients awaiting joint replacement, with local orthopaedic surgeons. This ongoing validation is important, as the placebo needle is the only true acupuncture placebo currently available. This study is part of a larger planned programme of research, which will involve functional PET imaging and may allow clear differentiation between real and placebo controlled treatments (pilot work is funded in cooperation with Prof. Frackowiac).

Method: Subjects will be aged between 18 and 80 with chronic/ stable pain, predominantly from a single joint (hip/ knee) of known mechanical aetiology i.e. O.A. Patients should: score an average of 30 or more on the 100mm visual analogue scale (VAS) in the pre-randomisation phase of the study; not be on any active treatment (e.g. physiotherapy, homeopathy); be literate in English and able to attend clinic twice a week for duration of treatment. They would be

excluded if pregnant, suffering serious co-morbidity (including severe back pain), prolonged or current steroid use waiting for hip/knee revision. Also if having needle phobia or allergy to sticking plaster.

This is to be a single blind multi-parallel arm factorial trial involving both quantitative and qualitative approaches. The qualitative element will explore common hopes, expectations, beliefs and experiences of participants following treatment. Subjects will be randomly allocated to 1 of 2 practitioners. Stratification for gender, joint type, baseline pain and time on wait list will be undertaken. Randomisation will be secure and distant via a party not connected to the trial. All subjects will undergo 7 days of baseline pain recording prior to treatment randomisation. They would then be randomly allocated to either 1) real acupuncture, 2) Placebo needling, or 3) Decommissioned electrical unit. This will enable us to evaluate the contribution of the use of needles as a non-specific factor. Whilst undergoing intervention, each subject will be treated twice a week for 4 weeks, each session lasting 30 minutes. This is a pragmatic approach to acupuncture treatment and utilises a 'western', style approach as practised in many UK hospitals. A range of acupoints will be specified from which the practitioner may choose the most appropriate for their patient. After 4 weeks of treatment, subjects will continue to record their pain on a daily basis for one week, prior to attending clinic for the last time. Subjects will continue with their normal medication.

In order to provide an estimate of the effect of the interaction between and practitioner and patient, patients will also be randomly allocated to either empathic consultations or a much more 'purely clinical' approach involving as little interaction as possible although the actual treatment regime will be unchanged. For those involved in the non-empathic approach, physical contact will be minimised, the practitioner will not engage in any conversation other than to ascertain the progress of the treatment, practitioners will not react sympathetically or in an encouraging way to improvement or exacerbations in symptoms. Changes will simply be noted without comment. Wherever possible, the patient will be left alone during the treatment process. In contrast, whilst giving an empathic consultation, practitioners will make every effort to be sympathetic, encouraging, put the patient at ease and engage in friendly conversation in an enthusiastic manner. Structured sheets will be drawn up for both types of consultation. A selection of the consultations will be audiotaped and an independent assessor will monitor these to ensure that consultations are truly empathic or non empathic, this approach has been used in other studies[17]
[18]

For the qualitative investigation, a purposive sample of 20 participants will be interviewed in their own homes 6 to 8 weeks following treatment. In order to gain a mix of perspectives, the sample will include responders and non-responders to each intervention of different ages and genders. Participants will initially be asked to reflect on and talk about their condition with particular reference to their experience of receiving the intervention. In order to reduce interviewer bias, specific questions to explore what each individual believed to have happened during the intervention will be included towards the end of the interview. The interviews will be audiotaped, transcribed and analysed using a

phenomenological approach to extract common themes. The practical part of the study will be undertaken by Dr. J. Walker, who has appropriate expertise and experience.

A flow chart of the trial protocol is shown in Figure 1.

Outcomes:

A) Prime. Change in mean pain from baseline to the 1 week post treatment will be calculated as measured on a 100mm VAS in a self-completed patient diary. The prime outcome will therefore be differences between groups in percentage change in pain. Differences of 20% or more will be considered clinically important. Pain will also be measured throughout the trial.

B) Secondary. Questionnaires i.e.quality of life (NHP), a condition specific measure (WOMAC), the credibility rating, the Holistic Health questionnaire (HHQ), will be administered both pre and post the course of intervention. Validated Empathy and Empowerment questionnaires will be administered after the fourth and last treatment session. All subjects will also complete the needle sensation questionnaire although for those undergoing mock TENS treatment, references to 'needling' will be omitted. Subjects will also record their daily analgesic intake

Sample size: Our recent neck pain trial showed improvements in pain of 58% and 42% (SD=38%) from real and placebo acupuncture treatment (a difference of 16%). We have calculated for an equivalence trial, using a 2x3 multifactorial approach. Limits of equivalence= +/-20% change in VAS pain. Therefore: $2x38^2/20^2x$ multiplier (11.7). Allowing for a 13% drop out rate (dropout rate was 8% in our acupuncture/ neck pain trial), therefore 96 subjects will be required per arm to give 80% power at 1% significance. Thus a total of 288 patients will be required to include each of the controls and an active arm

Recruitment: Patients will be recruited from the Hip and Knee joint replacement waiting lists at Southampton, Salisbury, Winchester and Bournemouth hospitals although the same 2 practitioners will provide all of the treatments.

Data analysis: The analysis would be on an intention to treat basis and would involve an ANCOVA for a factorial study, controlling for stratifiers (and confounders as appropriate) for change in pain (VAS). We will assess interaction between factors and if interactions are not found, we will present the main effects. Confidence intervals will be reported. Data on empathy will be reported only if it is shown that there is a difference between empathic and non-empathic consultations. Analysis of wait-list time as a covariate, will enable an estimation to be made of the influence of regression to the mean.

Timescale (months): Preparation/ printing of paperwork, diaries, CRF's etc, recruitment of PhD student, liasing with Consultant Orthopaedic surgeons, ethics(1-4); patient recruitment, treatment, data collection (5-29); data analysis, write up dissemination (30-36).

Collaborators: Dr G Lewith (Complementary Medicine Research, Southampton); Prof A Kendrick (Community Clinical Sciences); Prof P Prescott (Dept of Mathematics, Southampton); Prof P Little (MRC Research Fellow, Southampton); Dr J Walker (Dept of Nursing, Southampton)

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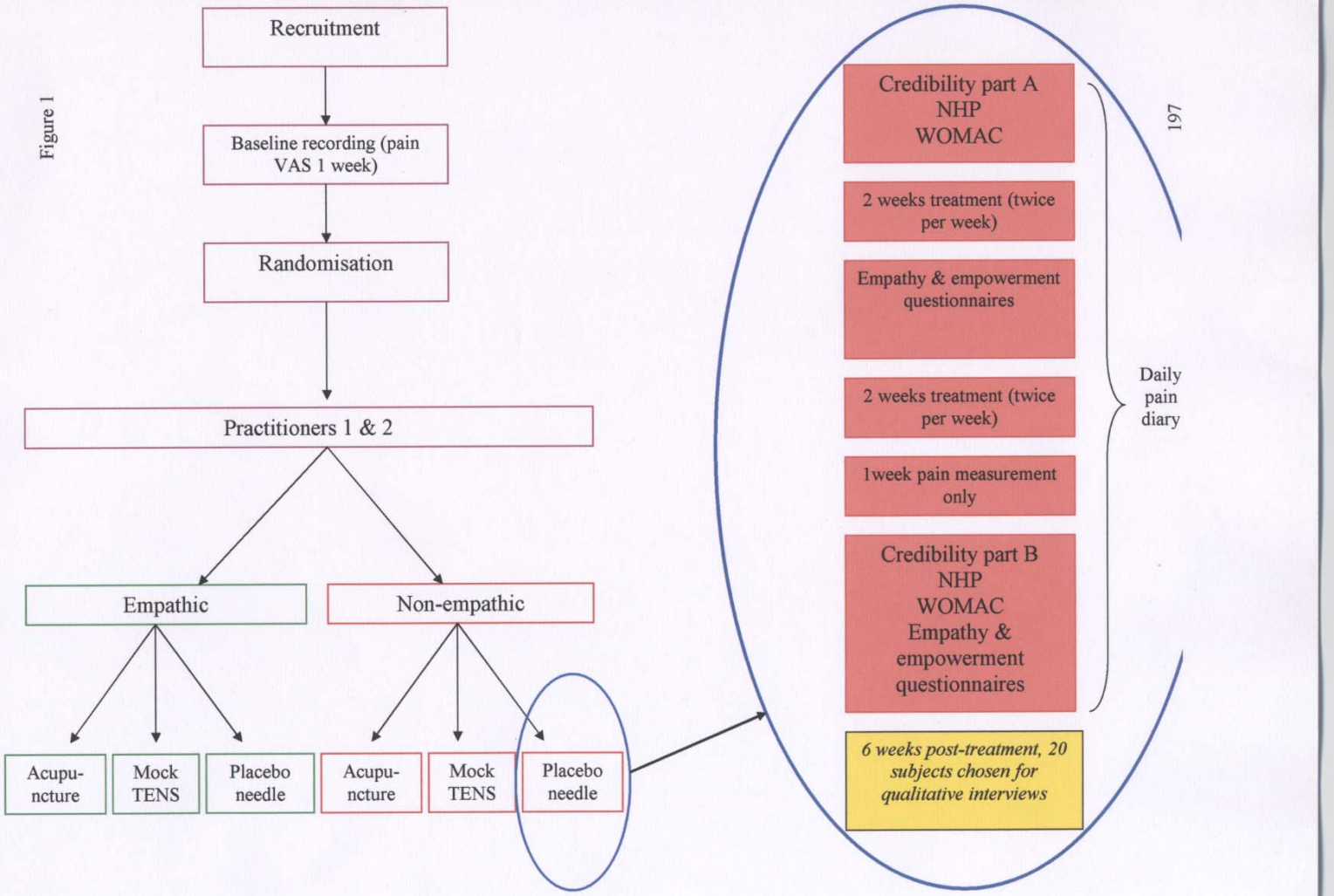
Figure 1


Recruitment
Baseline recording (pain VAS 1 week)
Randomisation
Practitioners 1 & 2
Empathic
Non-empathic
Acupu-ncture
Mock TENS
Placebo needle
Acupu-ncture
Mock TENS
Placebo needle
Credibility part A
NHP
WOMAC
2 weeks treatment (twice per week)
Empathy & empowerment questionnaires
2 weeks treatment (twice per week)
1week pain measurement only
Credibility part B
NHP
WOMAC
Empathy & empowerment questionnaires
6 weeks post-treatment, 20 subjects chosen for qualitative interviews
Daily pain diary

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Appendix 2 Patient information sheet

23/05/05 version 3

A study to assess the effects of acupuncture treatment

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being carried out and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Why are we doing this study?

Acupuncture is an ancient form of treatment, which involves the insertion of needles at various places in order to treat many different problems. It is used by many people throughout the UK and it is becoming increasingly popular, yet despite its popularity, we still know very little about how it actually works or how effective it is. This is where our study should help, as we are particularly interested in finding out not only how well it works but also whether the type of consultation you receive makes a difference to how well you do.

We will be comparing different acupuncture interventions: 1) Needling to acupuncture points using acupuncture needles, and 2) a modified electro-acupuncture treatment using a machine which has been specially modified for use in this type of treatment and uses small electrodes placed over the acupuncture points. We will be particularly interested in how your pain reacts (or not) to the treatment and this information may help us to provide more effective treatment in the future for those suffering with similar pain, it will also help us to understand more about how acupuncture works

Placebo/ dummy treatment.

A proportion of patients will receive placebo (dummy) treatment and so the acupuncture points will not be stimulated. i.e. the needle will not penetrate your skin or the machine will not deliver any current. This will be allocated on a random basis. You will probably not be able to tell and you will not be told if your treatment is placebo or not. After the trial, if you would like to know, we will tell you if your treatment was placebo.

What happens?

If you are eligible and agree to take part in the study, you will not receive any treatment on the first visit but we will give you some questionnaires to answer, which will cover several different areas. We will also ask you some questions

about your pain and your medical history, these help us to understand how much of a problem your hip/knee pain is for you.

This sounds like a lot of work but the questionnaires are all quite short and shouldn't take more than a few minutes to fill in. (some of the questionnaires are also repeated at the end). Then for one week you will be asked to keep a daily diary of how much pain you have (we will provide the diary and show you how to fill it in). You will also be asked to keep a note of how many painkilling tablets you need to take. After the first week, you will be assigned to one of the treatment groups (you might be assigned to a placebo group), this will be done randomly using a computer and treatment will then commence. You may find that the treatment will help to reduce your pain or you may find it has no effect at all on you. So that we can test the effect of patient/ practitioner interaction, some patients will receive consultations that will have to stick to a pre-determined and very structured formal approach (rather like using a checklist) and this will impose limitations on the practitioner in terms of what he/ she is able to talk about. Other consultations will be much more 'free flowing' and informal. This will also be decided on a random basis but it won't affect the overall standard of care or the actual content of your treatment.

The treatment.

If you are allocated to either of the 'needle' groups this will involve inserting very thin needles into specific points around your hip/ knee area. Some needles may also be used in your foot. These will be left in position for up to 20 minutes and stimulated manually from time to time. The needles usually cause some sensation but this is not painful. Often patients feel nothing at all. There are very few side effects associated with acupuncture but some patients feel a little tired afterwards and often sleep very well that night. Occasionally a small bruise may appear, but this rarely happens. If you do experience any adverse reaction to the treatment, this will be noted and treatment may be modified accordingly. If you do find that the treatment causes you excessive discomfort we would withdraw you from the trial (or equally you are free to pull out at any time).

The surface electro acupuncture treatment consists of using small adhesive pads, which are stuck over acupuncture points and then connected to a small electrical unit which has been specially modified for use in this type of treatment. The position of the pads may be altered from time to time depending on how your symptoms react to the treatment. These will again be left in position for up to 20 minutes. When the machine is switched on you should feel no discomfort or sensations at all. There are no side effects associated with this treatment although, as with needle acupuncture, some people report feeling a little tired after treatment, but again if you experience any adverse reaction this will be noted and your treatment may be modified to cater for this or you can withdraw at any time.

Audio taping

A small proportion of the treatment/ consultations will be audio-taped, this will then be reviewed by an independent assessor. The reason for this is to ensure that we are conducting the trial in the proper way. Tapes will need to be kept for up to 18 years after the trial as recommended by national guidelines after which they

will be destroyed. Similarly, you might be asked to share your thoughts on how you felt about your experience of the whole treatment process and this would normally be done as an informal interview at your own home (if you are agreeable).

Am I eligible?

We need volunteers aged between 18-80 to help us with our research and you have been asked because you have osteo-arthritis pain in your hip or knee and are awaiting a joint replacement operation. There are also other conditions which need to be fulfilled if you are interested in taking part. You must not have any other major or serious illness (if you are not sure about this part, I can discuss it with you). You must not be pregnant or trying to become pregnant. You would need to be able to attend a clinic twice a week for four weeks. You must not be allergic to ordinary sticking plasters or have a needle phobia.

What if I don't want to be involved or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and after you have had time to think about it you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive either currently or in the future.

Do I need to ask my Doctor?

We would normally want to let your GP know that you are helping us with a trial but we will ask your permission before we write to your doctor.

What happens to the information you collect?

All data that we collect will be handled and kept by the investigators at Southampton University (prime investigator: Dr Peter White). All personal details will be considered private and confidential and will at no point be released into the public domain. All data will be anonymously coded and held on computer at Southampton. Any data that is subsequently published, will be in statistical form only and will not include any identifiable personal details.

Who pays for this?

The study is funded by the Department of Health and all treatment is free to you at the point of contact.

If you need any more information please feel free to contact Peter White at the University of Southampton, School of Medicine 023 8024 1072

Many thanks for taking the time to read this information sheet.

Appendix 3 Treatment and points guidelines

Treatment

This will be twice a week for four weeks. These will be as evenly spaced during the week as possible i.e. not on consecutive days, as patient time and clinics allow.

Points

An average of five or six points will be chosen as follows according to the location of pain described by the patient.

Local points (2 or 3 from the list below)

Hip
- GB30
- GB31
- UB 34
- ST31

Knee
- ST35
- Xiyan (eye of the knee)
- GB34
- SP9
- UB40
- UB39
- ST36
- LIV 8
- Heding

Distal points (1 or 2 from the list below)

- GB34
- GB41
- UB60

One or two ahshi points may also be used if appropriate

Appendix 4 Non empathic consultation guidelines

Prior to randomisation all contacts and consultations with the potential participants will be as the practitioner ***usually interacts*.**
For the purpose of this study this usual behaviour will be deemed ***Empathic.***
All scripted interactions will be deemed ***Non Empathic.***

General advice

Try not to smile too much, be professional, efficient, not ignoring the patient but trying to maintain an air of detachment. Do not engage the patient in conversation unless prompted by the script. If in answering your clinical questions, the patient deviates from the information you require, remind the patient that you are unable to discuss anything other than their complaint and the treatment you are giving them. If however the patient mentions something that might have a serious impact on their health and which to ignore it would cause or prolong a health problem, we must act upon it.

Treatment session 1

Hello Mr/Mrs…….
Please sit down. My name is …….., and I will be your practitioner whilst you are involved in the study. I will provide you with my contact details at the end of this session, so that you may contact me should there be any difficulty attending an appointment etc.

You have been randomized to receive ……..treatment and I will be working from a conversational script during our sessions together. I will not be able to deviate from this script. However if you have any urgent questions related to your treatment, or you forgot to mention when asked if there is anything I need to know that may affect your health by proceeding with the treatment please make me aware of it.

You will be receiving your first treatment today. However first of all I would like you to complete these questionnaires (page 6-15 inclusive of CRF).
Answer related questions as required.

Thank you. We will now begin the treatment. Please remove your lower, outer clothing and make yourself comfortable on the couch. I will use towels to keep you covered and may request you to alter your position, assisting if required so that I can access the areas I need to treat.

Are you ready to begin?

Today I will be placing needles/applying electrodes to …….. (*state location*).
Insert needles as quickly as possible and with minimum conversation /interaction.

Do you feel any sensation on the needles? (*repeat as necessary*)
Obtain de qi as necessary.

I am going to leave you know to relax and will check on you again in about 5-10 minutes.
Leave the patient, returning to re-stimulate the needles every 5 minutes in this case. After 20 minutes return to the patient and end the treatment.

I am going to remove the needles/electrodes now (*remove in silence*)

The treatment is now finished Mr/Mrs……..
In order that I can ensure you are safe to leave, please sit/stand up slowly in your own time and inform me if you have any feelings of light-headedness and /or pain in any of the needle/electrode sites.
Address these issues if necessary.

Please can I remind you to keep your diary this week and if we can arrange your next appointment for ……
Thank you, and here is my card. Goodbye.

Follow up treatments

Hello Mr/Mrs……..
Please sit down. May I have your diary – thank you.

Here is your new one *(if a week later*).

Before your treatment today I need to ask you some specific questions about your hip/knee pain and the last treatment you had.
Did you notice any effects from the last treatment?

Is your pain better or worse?

Is the pain in the same?

Have you noticed any changes in the pattern of your pain?

Have you noticed any ill effects from the treatment?

Any tiredness?

Any bruising?

Any post treatment pain?

Is there anything else directly related to your hip/knee or to the treatment that you think I should know about?

We will begin now……. (*script as treatment 1*)
If you decide to change the point prescription inform the patient of the changes and ask their permission to do so. Do not offer an explanation for this, but if asked…..
"Acupuncture is regarded as a balancing treatment and should be flexible taking into account changes in the condition of the patient. So in light of the reaction to the last treatment, it is standard practice to adjust the points used in order to maximize the benefit of today's treatment."
Continue and close the session as treatment 1. If a weekly session provide the patient with a new diary.

Appendix 5 Ethics approval letters

NHS
Salisbury Health Care NHS Trust
South Wiltshire Primary Care Trust

R&D Management Committee
South Wiltshire R&D Consortium
Room 9, Level 4
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ

Telephone: (01722) 425027
Fax: (01722 425037
email: stef.scott@salisbury.nhs.uk
or myra.stevens@salisbury.nhs.uk

11 October 2005

Dr Peter White
Post-doctoral Research Fellow
School of Health Professions
University of Southampton
Highfield
Southampton SO17 1BJ

Dear Dr White

RDMC17/05/06: The process of acupuncture treatment. A randomized controlled trial and qualitative study to evaluate the relative contribution

Thank you for clarifying the mechanism of recruitment for the above study. The Consortium RDMC reviewed the additional information under Chairman's Actions.

The study was approved on the understanding that the consultants will give clear guidance to the orthopaedic secretaries regarding which patients can be invited to participate in the study. The secretaries will send out the patient information sheet on your behalf, with a covering letter of introduction.

Approval is also subject to the standard conditions appended to this letter. The project has been allocated a Local Start Date 1/11/05 and Local End Date 31/10/06.

If you do not intend to proceed with this project then please let the Consortium RDMC know so that we can amend our records.

If you have any questions about this letter, then please do not hesitate to contact Stef Scott, R&D Manager for the R&D Consortium, on 01722 425027.

Yours sincerely

Ms Mo Neville
Acting Chair of the Consortium R&D Management Committee

W:\Letters RDMC 0506\RDMC17-05-06 Peter White OK.doc

SL38 Progress report reminder
Version 3, June 2005

STA/cb

20 September 2006

Dr Peter White
School of Health Professions and
Rehabilitation Sciences
University of Southampton
Building 45
Highfield
Southampton SO17 1BJ

**SOUTHAMPTON & SOUTH WEST HAMPSHIRE
RESEARCH ETHICS COMMITTEES (A)**
1ST Floor, Regents Park Surgery
Park Street, Shirley
Southampton
Hampshire
SO16 4RJ

Tel: 023 8036 2466
023 8036 3462
Fax: 023 8036 4110

Email: GM.E.hio-au.SWHRECA@nhs.net

Dear Dr White

Study title: **The process of acupuncture treatment. A randomised controlled trial and qualitative study to evaluate the relative contributions of specific and non-specific effects.**
REC reference: **170/03/t**

This study was given a favourable ethical opinion by the Committee on 21 August 2003.

It is a condition of approval by the Research Ethics Committee that the Chief Investigator should submit a progress report for the study 12 months after the date on which the favourable opinion was given, and then annually thereafter. To date, the Committee has not yet received the annual progress report for the study, which was due on 21 August 2006. It would be appreciated if you could complete and submit the report by no later than 20 October 2006.

Guidance on progress reports and a copy of the standard COREC progress report form is available at http://www.corec.org.uk/applicants/apply/progress.htm.

There is also guidance on declaring the end of the study at http://www.corec.org.uk/applicants/apply/endofproject.htm.

Failure to submit progress reports may lead to a suspension of the favourable ethical opinion for the study.

170/03/t	Please quote this number on all correspondence

Yours sincerely

pp

Mrs Sharon Atwill
Committee Co-ordinator

E-mail: GM.E.hio-au.SWHRECA@nhs.net

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Appendix 6 Reasons for withdrawal from the hip/knee trial

Reason for withdrawal	Number of participants
Called for surgery	3
Other time commitments	2
No improvement in pain after six treatments	1
Transport problems	2
Increased pain	2
Exacerbation of pain elsewhere (not related to treatment)	1

Appendix 7 Example of interview transcript

Participant 23 – 2/1 (even) 07/06/06 – Roy

Tell me what it was like to take part…

Well it was err… simple, very, very easy going. We made our way over twice a week by car and didn't park the car there. My wife went off up the road I popped in, half an hour later I popped out. It was a very simple procedure, just trousers off and sock off and the needles went in with a little prick here and a little prick there. He'd come back every few minutes and twirl the needles round. We'd have a chat about various bits and pieces and err…it was all very straight forward. Umm…not having had acupuncture before I half suspected that you had to be a bit of a believer or that there would be a particular dialogue you'd go through each time. Whether there would be certain things you'd talk about … but it was all very ordinary you know. I thought that … I anticipated that he might say something like if you try and believe in it, it will do something for you, but there was none of that. I could have been talking to the dust man, it was very simple. So we did our 4 weeks, did the questionnaires as best I could. But some of the questions err…I didn't think particularly applied umm....bust I just answered as subjectively as I could. And we did the months trial, went back for a close out meeting and that was that. During one of the sessions because I didn't seem to be getting any significantly… he said "well it should be doing something by now". And that was the only perhaps give away, if that's what he intended to suggest that I was actually receiving acupuncture. I always believed I was.

Uh huh.

Because I thought it would have been very difficult to mask the placebo by being there in front of me pushing pins in. I must admit I never watched more than the little knock. I never watched him manipulate the needles in because I asked him how far they do in, and he said "well they can go in up to an inch". Well I'd prefer not to know that so I looked in the other direction, but it always felt genuine to me. And I was always a little disappointed that it didn't give me more relief. But I can only tell it how it is. He was asking about my hips and I said

well lets get this straight when we started this I made it absolutely clear that the pain was knee pain and the hip pain was liveable with, and its not too bad.

Umm…

And obviously he redressed for the relief of knee pain and on that basis I went on the trial, and I believe I got some relief. When I say relief I can't say that I felt a step change reduction. I just recall that prior to the acupuncture I used to have a tendency of always locking the knee in anticipation of a jolt, you know every time I put my foot out and now I walk a little easier knowing that it's not going to be as bad. But it's certainly not gone away and the best I can say is perhaps its like 30-40% maximum reduction in pain. So overall… for me I wasn't too impressed. But then of course I could be on the placebo, so at that point I didn't worry about it any more. So one of the interesting points is that you'll tell me today whether it was or it wasn't. Because if I was on the placebo then there's obviously a placebo effect in my case but it also means that acupuncture might do me some good, which might bode well for the future. On the other hand if I'd had acupuncture at least I know that it's…at least in this situation not for me.

Would you like me to tell you now?

Yes whenever you like.

It was placebo.

It was placebo well I tell you what he did a bloody good job then, because he said to me it should be doing something by now. Well I suspect that's why I wanted to feel an improvement but as you've heard me say I didn't think it was for me, do enough for me. So in hindsight then I think I must have been reasonably objective because all the way through the trial you know, I think I'm on the real thing. He's spending all this time giving me this treatment and I'm disappointed for him really that's it's not given any more relief. "How do you feel this week, how do you feel ….no it's alright much the same" , and that's when you look at my trial chart you'll find they're absolutely consistent all the way through. My crosses on the thing for pain are exactly the same once it dropped or I thought it had dropped. It stayed there and it didn't go lower or go any higher. So yeah ok I had the placebo. That is very interesting because it

means that there is some opportunity that I may take acupuncture in the future. Because at the moment I've had this hip done (***points to right hip***), and the referred knee pain has reduced here. On the un-operated side the hip aches a bit and the knee is painful to some degree. It gets more painful over the day as you put more and more weight on, it goes on for longer periods. So when I have this hip done (***points to left hip)*** and I hopefully get reduced pain in this knee I intend to leave it a few months, let the whole situation settle down and stabilize. I expect I'll still be on a single Mobec (***analgesic***) if the pain is bearable, and I think it will be, and then in the long term I shall consider whether I try acupuncture in both knees. Because I … this one there ***(points to left knee)*** is some real, mild knee pain because when the operations done it reduced that (***points to right knee***) and there is some wear on this patella , and there is some wear on that patella. So I'm quite convinced that after all the dust has settled there will be some residual discomfort, and I'm not particularly keen on having any knee work done, because I've heard that it works for some people and not for others.

I doubt if I'll be able to go on any stronger drugs because A - I don't really want to and B- it might affect my INR. So if it's not too costly I might give acupuncture a go then.

At this point the interviewer discusses what it's like to give placebo interventions as a practitioner and describes for Roy how the placebo needle works. The various responses of participants with both real and placebo was brought up and how acupuncture is given in the 'real world'.

I was interested in what you said about having belief…

Yeah I'm sort of open minded and a little bit sceptic. I didn't think there was a lot of likelihood that it would do any good, but then the Chinese for 2000 years can't all be wrong. And I went into the trial because I'd already made up my mind that it might be worth trying. Then along comes a free trial so I grabbed it. As I say I didn't think it did an awful lot but I'm pleased in a way because it means potentially I might be a candidate (***laughs).***

At this point the interviewer explains that reaction to the placebo needle may actually be physiological not a placebo effect and that future research is intended to explore this.

If I had had the real thing, and based on my amount of pain reduction I wouldn't have followed it up at all. I wouldn't have continued, I'd have gone on a painkiller or an operation or whatever.

Yes you can't predict at the outset if a patient will respond or not. It appears to be like how people react differently to pain killers. ***Interviewer gives an example****.*

At this point Roy's wife asks about the trial and if the results are known yet.

Wife- I think the main criteria is that it affects everybody differently and it's either mind over matter or it's the other. Have you ever been to China?

Yes.

At this point Roy's wife raises the issue of NHS funding for acupuncture and this leads to a discussion on the two theories underpinning how acupuncture works. TV programmes are also mentioned. The interviewer returns to the subject of Roy's referred pain and how this may affect the trial documentation.

You said that you didn't think some of the questions were appropriate. Can I ask you which ones they were?

Well I can't recall now but its something like …Oh I'd have to see the questionnaire again. Err…I answered as best I could and for like 90% plus questions I think I was in a position to give an opinion, but there were one or two that seemed to be relating to… hospital conditions or something, I can't recall. I put the best I can because it said choose the one that in your opinion meets your condition today. So that's all you can do umm… if perhaps there was a not applicable box I might have ticked a few of those, in my view…but there wasn't so you're constrained by doing the yes or no. Anyway there you go.

At this point the interviewer discusses what others have said about wanting a 'sometimes'.

I felt most, well the great majority of questions were… it was just the minority that I thought it's not really appropriate for me but I've got to put something. Which ever way you tick it's not necessarily going to be right for your case because you want the N/A box (***laughs***).

Yes, so you're taking a tablet?
Yes I take one meloxicam. I've been taking that for a long time. That was for the hip/knee…because of the knee pain. I did ask the doctor if I could double it ***(medication).***Problem is he said was that "everything interacts and your INR could be changed if you change your medication". I said well if it's a choice between optimising the heart performance versus the knee pain I'll take the knee pain. That's the way it was you know, so I've just been getting on with it.
Is that why you said you'd made that decision to try something like acupuncture?
Absolutely because when this hip was done this knee pain (***right***)…80% of the knee pain was sort of referred pain and I just got 20 % there ***(left)***, which is viable with my expectation that it be the same on this side once everything's settled. But I do know from the x rays and I do know from this knee that there is going to be some residual knee pain, and I won't know what that level is until it's all settled. And if it's annoying I shall attempt to get some relief. I mean why shouldn't I? There's nothing more unpleasant than aches and pains and yet there are treatments available, yet you don't take them up. So I thought I might try acupuncture on what's left in the future.

Yes.
And what you said today is encouraging for me because it means I can at least try a session of acupuncture and see if it really does make any difference.
Wife – Also having been in Singapore for some time we were bombarded with the alternative medicine. You read a lot and hear a lot. It just seems quite an obvious thing.
So you were saying then that in this trial I took, the needle just touched the surface of the skin and whenever he came back and wiggled it …that's what he did wiggle it on the surface? There was no penetration at all?

At this point the interviewer explains again how the placebo needle works and Roy's wife mentions mind over matter again and cultural beliefs.

Is there anything else you want to ask?
No I don't think so. No I think that's covered it all. I honestly thought I was having the real thing.

How do you feel about the fact that I've told you it was placebo?
It doesn't bother me one little bit, in fact to some degree it's encouraging. Because as I say I didn't report any significant improvement so maybe … (***laughs***). Maybe if I'd had…
Wife – Well you know at least something's better than nothing and now he has a hope that it might be 90%.
Yes it just encourages me to think that…a worthwhile … that it does work. Maybe it does work and I shall find out next year, if I do decide to have a bit of acupuncture on the knees. But I shall only do it if they hurt a bit.
At this point the interviewer mentions how others have remained positive about acupuncture despite minimal results and have said they would consider having it again.
Wife – And it's not painful.
No it's not painful.
Wife – And after the first two they know what to expect.

Yes you can tell you're having it done?
Wife – It's certainly not like going to the dentist, so all in all it's wonderful. It's certainly worth a try.
At this point the interviewer raises the issue of being duped, as other shave mentioned this if they responded to placebo treatment, and enquires about this in relation to there not being an option to receive real treatment from the trial.

When you first got the letter did you think "I'll just take my chances" because there was a placebo aspect to the trial?

I jumped at it because I'd been contemplating it in the first place. Albeit a little premature but for me it was an opportunity to get free acupuncture and see if it worked for me. When I was told that it could be one of three treatments – the electrical, acupuncture or placebo I thought well just take a chance. Because we said didn't we as we came out to the car, this could be all to no avail, but unless you do it you don't know.

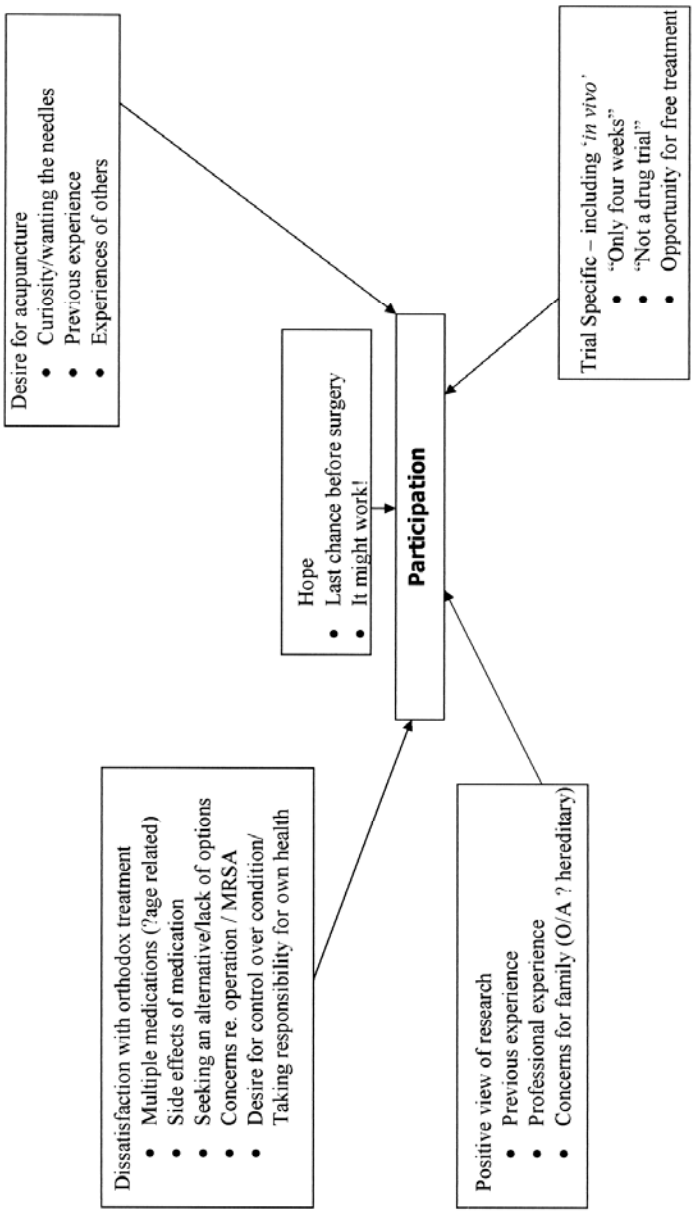
Wife - Especially as it was free! I mean I know how much these things can cost.

Not a lot of point being free if it's a placebo.

Wife – yes but unless you try, you might be lucky.

The interview is drawn to a close as Roy repeats about assessing any knee pain once the hips have settled down and that even before the trial he was on the web looking for an acupuncture practitioner. Roy's wife enquires as to whether the interviewer would like to speak to them again if Roy does have real acupuncture to compare accounts.

Appendix 8 **Open coding example of factors motivating participation**



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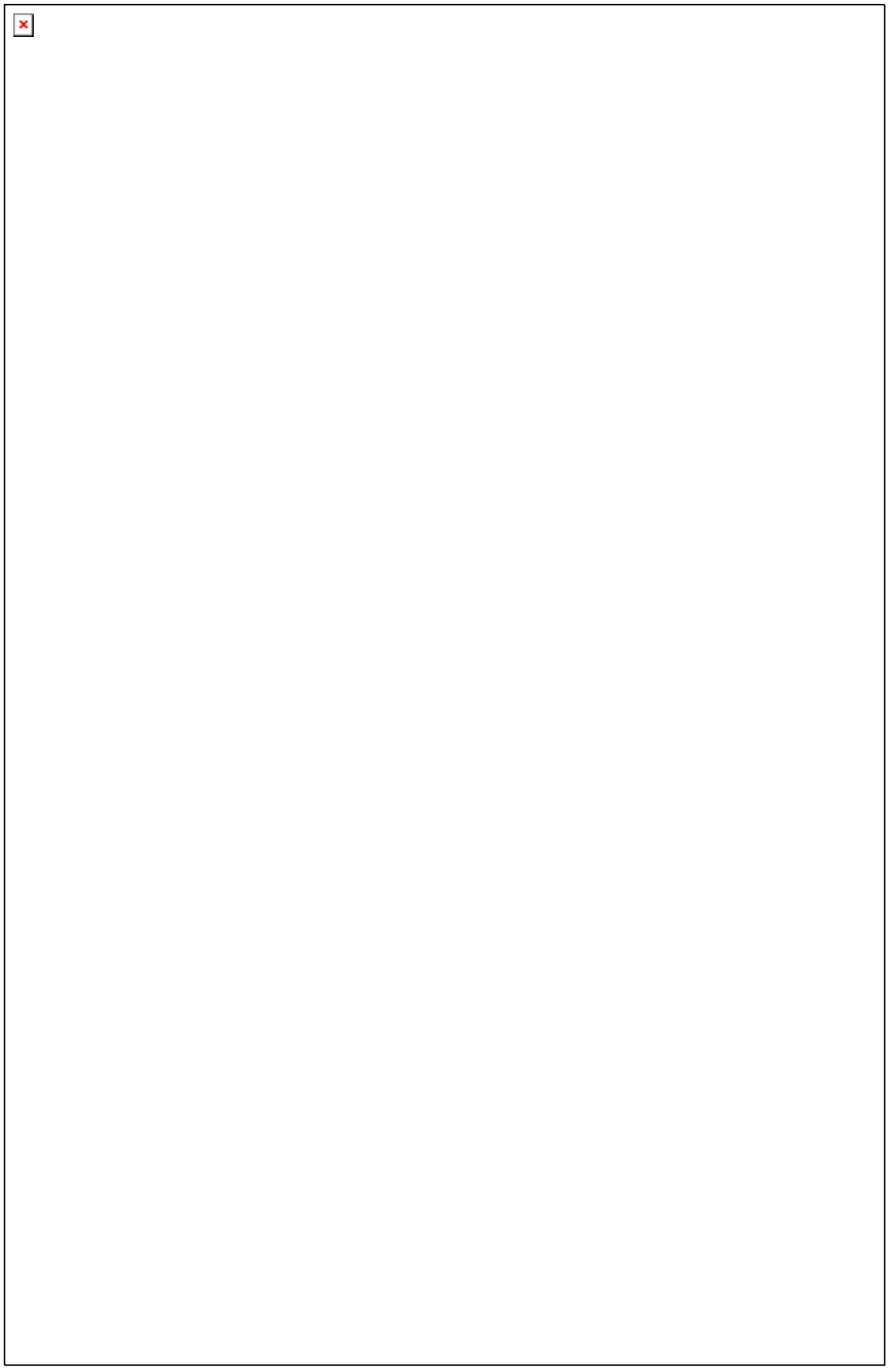
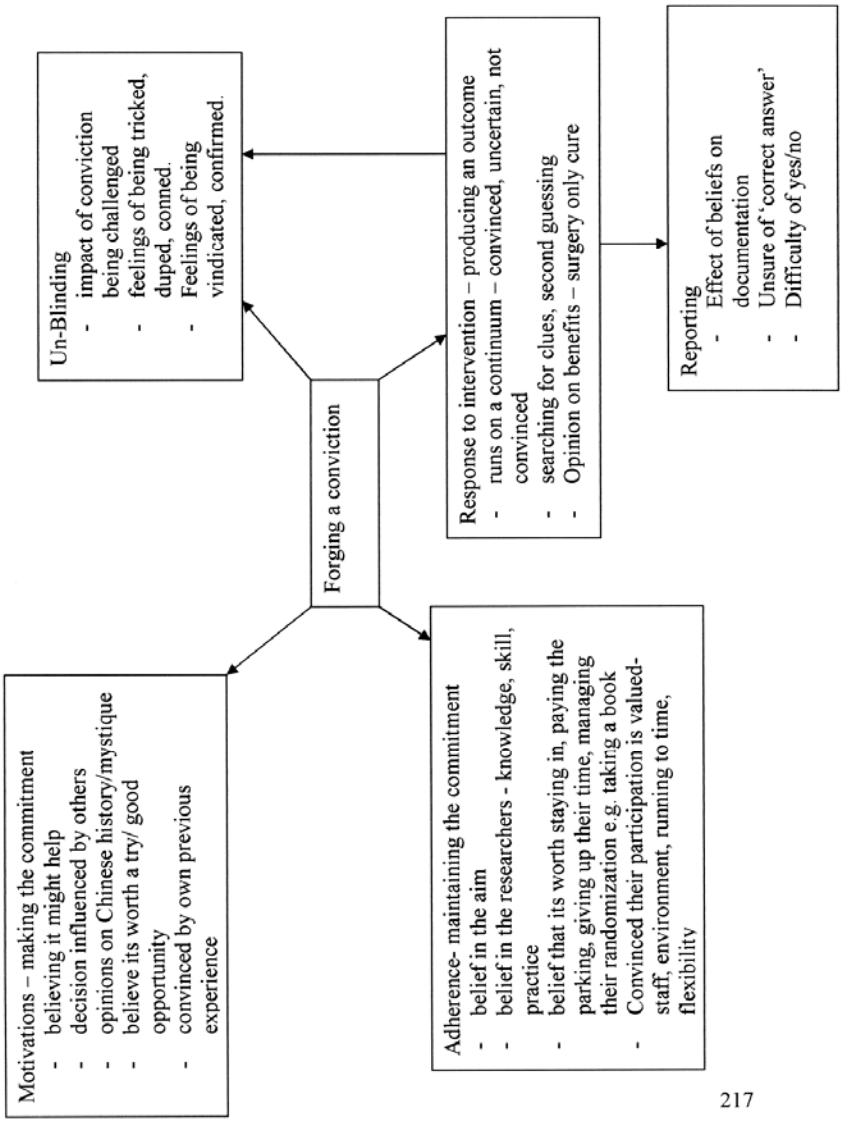


Appendix 10 **Exploring the core category**



Glossary of Abbreviations & Terms

CAM:	Complementary and Alternative Medicine.
OA:	Osteoarthritis
RCT:	Randomized Controlled Trial
TENS:	Transcutaneous electrical nerve stimulation
DoH:	Department of Health
NHS:	National Health Service
TR:	Therapeutic Relationship
TCM:	Traditional Chinese Medicine
***yin yang**:*	The logic underlying Chinese medical theory. Dialectical in nature it explains relationships, philosophical, patterns and changes based on the mythical concept of two polar complements- yin and yang. These dynamics are opposites, interdependent, inter-transforming and mutually consuming of each other e.g.

yin	*yang*
Female	Male
Night	Day
Water	Fire

Imbalances of *yin yang* and the *wu xing* are thought to result in ill health and disease.

wu xing:	The Five elements – in addition to yin yang this forms the basis of TCM theory. *Wu* means five, *Xing* means movement or process. It represents the five qualities of natural phenomena upon which a health & lifestyle can be balanced.
***qi**:*	One of the vital substances in TCM theory. Mostly referred to as vital energy it is the basis of all the substances and is something which is, at the same time, material& immaterial e.g. ice, water & steam.
Deqi:	Needle sensation e.g. localised heaviness, and distension
Ahshi:	Tender/trigger points

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