An Exploratory Study of the Use of Complementary and Alternative Medicine for Osteoarthritis

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Abstract

Background & Aim: Osteoarthritis (OA) sufferers frequently turn to complementary and alternative medicine (CAM), of which the most common are acupuncture and homeopathy, to improve manageability of their condition. However, there is little extant evidence of effectiveness for these treatments for OA, particularly for homeopathy. One criticism of homeopathic studies is that treatment protocols do not reflect true homeopathy. The nature of true homeopathy is not documented in extant literature. In the current study a mixed methods approach was used to investigate the use of homeopathy for osteoarthritis using a survey, conducted with a parallel acupuncture survey for comparison, follow up interviews with homeopaths and a patient-centred study in a homeopathic department offering treatment on the NHS, in order to inform future studies.

Method: The current study involved three phases; **(1)** A descriptive survey conducted on n=362 medical and non-medical homeopaths and acupuncturists, was used to investigate practice of the therapies. **(2)** Follow up interviews of n=28 of the homeopathic practitioners. **(3)** A patient-centred study of n=11 patients with OA receiving homeopathy in the primary care setting.

Results: (1) Most commonly encountered conditions were chronic diseases. Medical and non-medical acupuncturists practised very different forms of acupuncture particularly in terms of diagnostic techniques used and theoretical underpinning. Homeopathic practitioners used individualised treatments, abiding by classical homeopathy. Differences between medical and non-medical homeopaths included time spent in the consultation ($p= 0.01$), strength of confidence in homeopathy for asthma ($p=0.01$), musculo-skeletal ($p=0.046$) and acute conditions ($p=0.01$), and confidence in conventional medicine ($p=0.01$). There was a belief amongst acupuncturists and homeopaths that the treatments may work on electrodynamic fields in the body.

(2) A similar approach was taken by participants during a detailed initial consultation. However, irrespective of medical status, varied approaches were used to identify the remedy, potency, and remedy form, and the source of remedy also varied. Main themes regarding the modus operandi of homeopathy included stimulation of self-healing mechanisms and identifying in detail events at the point where the initial

health imbalance occurred. Identification of this point together with the patient was considered a potential trigger for the healing process to begin, adding a particular importance to the role of the consultation.

(3) OA patients in the primary care setting identified pain or stiffness as the most common primary complaint. with an emotional factor such as anxiety and limitations caused by their condition as a secondary complaint. A desire to reduce their medication or to improve the manageability of their condition was a common theme for interest in receiving homeopathy, with access to NHS homeopathic treatment and perceived safety of receiving treatment from medical doctors being important factors. Following 6 months of homeopathic treatment, most participants reported an improvement in the manageability of their condition. This, however was not supported by results from VAS pain, VAS stiffness, MYCAW scores or SF36 sub-score, or salivary concentration of substance P results which were not found to be significant. Few correlations were found between outcome measures. Substance P level was strongly correlated with the functional limitations sub-score of the SF36 ($p=0.01$), indicating a potential role for this biochemical measure in future studies.

Conclusion: Findings from the current study can inform future studies on how to enhance the evidence base for homeopathic and acupuncture treatment, and inform the integration debate. Future advances in the understanding of subtle processes in the body, the placebo response, and the nature of cure may add to our understanding of CAM treatments. However, it is likely that in order to advance the evidence base on the effectiveness of homeopathy for OA, more effective tools that are sensitive to changes in biopsychosocial dimensions of health will be necessary. Future research on combination therapies is also warranted.

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Chapter 1

General Review

1. 0 Osteoarthritis Epidemiology, Mechanisms & Management

Osteoarthritis (OA) is a chronic condition which is characterised by defective integrity of articular cartilage with related changes to the bone in the joint regions (Altman, 1986). The exact causes are largely unknown but OA is generally associated with constitutional factors such as aging, obesity, metabolic and genetic factors and also mechanical factors such as trauma, recreational usage and mal-alignment (Cooper et al, 2000). It is the leading cause of joint pain in middle ages and elderly persons (McAlindon & Dieppe, 1990; Scott & Hochberg, 1984) with approximately 4 million people in the UK alone suffering from this condition. It is a global problem, in America more than 13% of the population aged 55 to 64 and approximately one third of Americans aged 65 and over suffer from the pain and limitations of osteoarthritis of the knee (Maurer 1999). In the western world, between 3% and 11% of the population over 35 suffer from hip OA alone (Zhang et al, 2005), and in Europe 10% of those over 55 suffer from osteoarthritis of the knee, one quarter of whom are severely disabled (Peat et al, 2001). A report by the World Health Organisation predicted that OA is likely to become the fourth major health concern for women and the eighth major health concern for men in subsequent years (Murry and Lopez, 1997).

1.1 Pathophysiology of OA

The progression of OA includes cartilage destruction, subchondrial bone thickening and new bone formation. This can be divided into three stages, 1) the proteolytic breakdown of the cartilage matrix, 2) fibrillation and erosion of cartilage surface, accompanied by release of breakdown products into the synovial fluid, 3) synovial inflammation occurs

as a result of synovial cells ingesting breakdown products through phagocytosis producing proteases and pro-inflammatory cytokines (Pellier et al, 2000). The point of onset of OA, that is the initial cartilage breakdown, has been extensively investigated (Martel-Pelletier, 2004). Exact processes are still uncertain but it is likely that the metalloprotease (MMP) family have a major role (Martel-Pelletier, 1999). The MMPs include collagenase which is responsible for the breakdown of collagen, and stromelysin which is responsible for proteoglycan degranulation and these two factors play primary roles in the degranulation of the extracellular matrix. An irreversible step in OA onset is the degredation of collagen and it is suggested that collogenase-1 and collogenase-3 (also known as MMP1 and MMP13) specifically are responsible for this (Reboul et al , 1996) Aggracanase, consisting of disintegrin and MMP domains, is also thought to be responsible for the proteoglycan fragmentation seen in OA synovial fluid (Lark, 1997). Other factors also play key roles but these may work as activators of MMP.

It is acknowledged that the synovial membrane also plays a role with synovial inflammation occurring with other morphological changes at the clinical stage of the disease. The synovial inflammation in turn produces inflammatory mediators including IL-1β and TNF-α, pro-inflammatory cytokines thought to be the principal mediators of joint destruction (Martel-Pelletier, 1999). IL-1β is synthesised as an active precursor that is activated by an enzyme called IL-1β converting enzyme (ICE). ICE is produced in both cartilage and the synovial membrane and concentrations are significantly elevated in OA (Saha et al, 1999). Animal studies have lead to the belief that IL-1β is of pivotal importance to cartilage destruction due to its involvement in the shifting the enzyme system, TNF-α, drives the inflammatory process (Van de Loo, 1995). Pro-inflammatory cytokines such as IL-1β and TNF-α are thought to increase enzyme synthesis, inhibit synthesis of the inhibitors to these enzymes and inhibit synthesis of matrix constituents such as collagen and proteoglycans. The integrity of the joint is largely dependant on the balance between cytokine-driven anabolic and catabolic processes and it is likely that other cytokines, IL-6, LIF, IL-17, IL-8 are also involved (Martel-Pelletier, 2004).

1.11 Diagnosis and Treatment of OA

Radiographic evidence is often taken for diagnosis of OA due to the characteristic features such as joint space narrowing, subchondrial sclerosis and osteophyte formation that can be seen on an x-ray. It has, however become recognised that one third of women over 55 show x-ray evidence of OA but only 50% of these actually experience pain associated with this (Odding, 1998). In addition it should be noted that many who do experience joint pain do not have the characteristic damage when x-rayed (McAlindon, 1992).

Osteoarthritis has far reaching consequences for those sufferers and main symptoms include pain, stiffness and swelling, with doctors and patients both reporting that the most crippling factor is pain (Hawley & Wolfe, 1991). Current guidelines on OA management include both pharmacological and non-pharmacological treatments depending on a range of factors (Zhang et al, 2005). Many OA sufferers also turn to complementary and alternative medicine (CAM) (Rao et al, 1999).

1.2 Pharmaceutical Treatment

In the most severe cases of OA patients can be offered joint replacement. In most cases, however, with very few disease modifying medications available, conventional treatments for OA tend to be focused on symptomatic relief of the condition, in the form of Non-steroidal anti-inflammatory drugs (NSAIDS). Commonly prescribed NSAIDs include Ibuprofen, Fenoprofen, Piroxicam and Naproxen. The use of NSAIDs for analgesia and inflammatory pain dates back decades. Evidence suggested that the conversion of arachadonic acid to the pro-inflammatory prostaglandins that mediate the classic inflammatory response to pain, oedema, pyrexia and erythema could be inhibited by blockage of the COZ enzyme (Vane, 1981). There is little definitive evidence of effectiveness of NSAIDS for OA and these drugs produce multiple side effects (Shealy et al, 1998). Side effects include compromise to liver and kidney function, though milder gastrointestinal side effects are one of the most common (BNF, 2008) with NSAID-associated dyspepsia occurring in up to 50% of users (Singh, 2000). Side effects are reported as a particular issue for patients (Fraenkel et al, 2004). The Fraenkel

study examined patient treatment preferences in 100 patients with OA of the knee using a face to face delivered questionnaire. Results showed that 32% had experience gastrointestinal side effects, with patients prepared to sacrifice any improvements in function or analgesic effects of the medications in order to avoid the side effects brought about by them.

In addition steroidal creams are sometimes still prescribed. Inflammation is not always characteristic to OA and these treatments are therefore seen as futile for this condition by many sufferers. Symptoms are also managed with multiple pain killers including codrydamol and paracetamol.

There are several non-pharmacological approaches to aid OA management. These can be classified as either conventional approaches or complementary and alternative medicine approaches.

1.2.1 Conventional non-pharmacological approaches

A full list of conventional non-pharmacological approaches to improve manageability of OA are shown in figure 1.

Figure 1

Conventional Non-pharmacological Interventions for Osteoarthritis

Patient education:

Self-management programs (e.g., Arthritis Foundation Self-Management Program)

Physical therapy and exercise Programmes:

Aerobic exercises

Stretching exercises

Nutrition:

Weight loss

Nutritional Supplements

Assistive devices for activities of daily living:

Assistive devices for ambulation

Patellar taping

Appropriate footwear

1.2.2 Patient Education & Exercise

This approach is centred on the notion that a more optimistic outlook on the Osteoarthritis condition is beneficial to the patient. There is some evidence that pain levels do not correlate with severity of cartilage loss (Davis, 1992; Salaffi, 1991) and that a correlation is seen between low educational attainment and lack of time in education, and pain levels from OA (Hannan, 1992). These programmes take a biopsychosocial approach and include cognitive behaviour therapy, psychological support and arthritis self management programmes. The Biopsychosocial model developed from a reaction to the limitations of the biomedical model and advocates a view of illness that is not just based on molecular, cellular and organisamistic interaction but also incorporates interpersonal and environmental factors (Engel, 1977). For a biopsychosocial approach it is important to consider the individual and their surroundings as a part of the disease. Evidence of helpfulness of these projects is so far encouraging but independent review is necessary to draw firm conclusions (Perrot & Menkes, 1996).

Table 1 A Summary of the major trials and systematic reviews on non-pharmacological approaches to CAM

Treatment	Author	Study Design	Population / n	Intervention & Control	Outcome Measures	*Findings*
Exercise Therapy	**Roddy et al (2004):**	Systematic Review based on 2 studies	419	Aerobic Exercise only	Reduction in pain	*Inconclusive*
	Downs (1998)	Systematic review based on 2 RCTs	306	Strengthening Exercises v GP follow up	Pain reduction	*There is some evidence of benefit of strengthening exercises on Hip OA. Point estimate of effect size 0.22 and 0.73*
	Fransen et al , 2003	Systematic Review including 2 studies on OA of the Hip	100	Exercise v control group follow up	Self-reported scores of function, pain reduction	*Inconclusive due to lack of studies. Unable to make recommendations on exercise routine*
Nutritional supplements (Glucosamine Sulphate)	**Rozendaal et al (2008)**	Randomised double blind placebo controlled RCT on patients with OA of the knee	222 Patients with OA	Glucosamine sulphate v placebo given over 2 year treatment period	WOMAC Pain and joint function	*No between group differences*
	Herrero-Beaumont et al (2007)	Randonmised trial on patients with OA of the hip	318 patients with hip OA	Glucosamine sulphate v paracetamol v placebo over 6 month treatment period	Pain and joint function including WOMAC and Lequesne index	*Glucosamine sulphate found to be significantly better than placebo and paracetamol in pain reduction and improved function.*
(Omega 3)	**Stammers et al, 1992**	Patient blinded RCT. Patient were to continue taking routine NSAID treatment throughout study	86	Fish oil (cod liver oil) v placebo (olive oil)	VAS pain & inflammation	*No significant reduction in pain or disability*

Table 1 Cont.

Treatment	Author	Study Design	Population / n	Intervention & Control	Outcome Measures	*Findings*
Acupuncture	**Kwon et al 2006:** Fink et al (2001)	Double-blind RCT, parallel groups	67	Acupuncture (Intervention) v sham acupuncture (Sham)	VAS pain, functional impairment	*No inter-group difference*
	Stener-Victorin et al (2004)	Three parallel groups	45	10 acupuncture sessions plus education (intervention), Hydrotherapy plus intervention (control), education only (control)	VAS pain (daytime and night time), Disability rating index	*Significant increase in post intervention function in both groups compared with education alone, improvement in electroacupuncture group for longer tiem perid post intervention ($p<0.05$)*
	Christensen et al, (1992)	Two parallel groups, assessor-blind	32	Acupunture 2 sessions a week from 3 weeks (Intevention, Waiting list (Control)	VAS, time to walk 50m, Time to climb 20 steps, HSS Knee function scale, WOMAC	*Significant differences for all outcome measures listed to the left at p=0 01*
	Arichi et al (1983)	100 patients with osteoarthritis of one knee, 100 patients with rheumatoid arthritis of one knee, and 100 disorders of motility of one knee after cerebral haemorrhage or thrombosis.	200 Including 100 with OA and 100 with Rheumatoid Arthritis (RA)	Participants received acupuncture at ST34, ST35, ST36, SP10, LV8 and SP9 and/or a combination of flections-extension exercises in either the affected knee or the healthy knee. Treated 1-4 times per week for 10 weeks	Knee flexibility angle $>10^{\circ}$	*Acupuncture plus flection-extension exercises effective in 30% of patients with RA.*

Table 1 Cont.

Treatment	Author	Study Design	Population / n	Intervention & Control	Outcome Measures	*Findings*
Acupuncture (Cont.)	**Berman et al (2004)**	Three parallel groups, assessor and patient blind	570 patients with OA of the knee	Chinese acupuncture targeting 9 points, with electrical acupuncture to 1 point. 23 sessions over 26 weeks V sham insertion acupuncture V sham non-insertion acupuncture	WOMAC Pain, WOMAC Function, Patient Global Assessment	*Sig diff in function at 8 weeks with true acupuncture against control. Significant difference between WOMAC pain between intervention and sham week 14-26 (P=0.02). No intergroup difference in patient global assessment.*
	Sangdee et al (2002)	4 parallel groups	186 patients with OA of the knee	Electroacupuncture (EA) + diclofenac vs electropucture + placebo tablet V diclofenac + Placebo EA	WOMAC pain, stiffness and disability, Pan VAS, Lequesne's functional index, 50ft walk time	*Significantly more improvement in VAS Pain between EA and placebo and EA and diclofenac ($p<0.05$) Lequesne index significantly improvement in EA vs placebo group ($p<0.05$). No significant differences seen in WOMAC stiffness, disability or Walk time.*
	Witt et al (2005)	3 parallel groups, Blinded	300 patients with OA of the knee	Acupuncture (intervention) V minimal acupuncture (sham) V Waiting list	WOMAC Pain, stiffness, function	*Significantly differences in WOMAC score, more favourable with acupuncture group ($p<0.01$) at 8 weeks but no difference sustained to 52 weeks.*
	Scharf et al (2006)	Three parallel groups. No blinding between conservative and acupuncture groups.	1007 patients with OA of the knee	Acupuncture to 4 Ashi points(2 standard and 2 chosen) V Sham acupuncture V conservative treatment (physician visits) all consisted of 10 sessions over 6 weeks, in addition to physiotherapy (6 sessions) and NSAIDs as required	WOMAC Pain Index, SF12	*Significont difference in global assessment with acupuncture or Sham acupuncture compared with conservative treatment ($p=0.001$). No difference between True acupuncture and sham acupuncture*

Table 1 Cont.

Treatment	Author	Study Design	Population / n	Intervention & Control	Outcome Measures	*Findings*
Homeopathy	**Van Haselen & Fisher (2000)**	Randomised Double Blind	184 patients with OA of the knee	Homeopathic gel v NSAID gel. Topical application tds	VAS pain, single joint Ritchie Index	*Homeopathy significantly greater reported reduction in pain p=0.01. No difference between groups in single joint Ritchie Index*
	Shealy et al (1998)	Double-blind RCT, Standardised preparation (no individualisation)	65 patients with OA of the knee	Homeopathy versus placebo +/- paracetamol. 10 drops qds for 1 month	VAS Pain	*No significant difference between groups. Homeopathy at least as effective as paracetamol*
	Shipley and Berry (1983)	Double-blind cross over study, over a 2-week period)	36 suffering from either knee or hip OA or both	Fenoprofen (NSAID) 300mg & placebo Rhus toxicodendron v placebo fenoprofen and Rhux toxicodendron v placebo fenoprofen & placebo Rhus Toxodendron, 2 weeks per regime	VAS Pain at rest, on movement and night pain	*NSAID significantly more successful in pain relief than placebo and Rhus Tox, irrespective of setting.*
	Nahler et al (1998)	Single blind equivalence study	121 patients with OA of the knee	Combined (non-individualised) homeopathic preparation versus hyalduronic acid, 10 injections over 5 weeks	VAS Pain, VAS Tolerance	*Improvements to both treatment groups with no significant difference*
Herbal **(Avocado-soyabean unsaponifiables)**	**Little et al (2008)**	Two primary studies (Blotman 1997, Maheu, 1998), RCT	327 patients with OA in various joints	Avocado-soybean unsaponifiables (ASU) v placebo alongside NSAID treatment	VAS pain, Functional Index, NSAID usage	*With ASU a significant reduction in VAS pain ($p<0.05$) , greater difference seen in OA of than Hip compared to knee, significantly improved functional ability($p<0.05$), significantly reduced intake od NSAIDs ($P<0.05$)*
Magnetic Therapy	**Harlow et al (2004)**	1 Primary study, double blind RCT	194 Male and female patients with OA of the Knee	Magnetic bracelet (test) v Dummy bracelet (control)	WOMAC Tool (VAS pain, VAS Stiffness)	*Bracelets Significantly reduced pain, at $p<0.05$, but unable to firmly demonstrate that this was more than a placebo response*

1.2.3 Exercise programmes

Due to restricted joint mobility that occurs with OA, and the resultant impact on muscle strength, it is beneficial to keep the joints mobile. Reduced muscle capacity can occur when patients have limited function, and mobility in everyday life is reduced compounded by little or no deliberate attempts to exercise. Patients may become overweight and this together with muscle weakness makes it even harder to exercise. Studies have been conducted on both aerobic exercise and muscle strengthening exercise for patients with OA but these have been inconclusive to date (Moe et al, 2007). A summary of the studies are displayed in Table 1.

1.2.4 Dietary Management and Nutritional Supplements

This is an area of therapy that falls somewhere between conventional medicine and CAM. It is considered conventional in the terms that advice is provided by registered dietitians within the NHS (British Dietetic Association, 2009), yet other patients seek dietary advice from nutritionists or naturopaths in settings that is considered to fall under CAM. A number of different supplements and dietary interventions are used for OA, associated either with conventional treatment of CAM nutritional therapy, though of course there is also some overlap.

Weight loss can improve function for the many OA sufferers that are overweight. This is very hard to achieve, however, since patients may not lead active lives (Arthritis Research Campaign, 2008).

1.2.4(i) Glucosamine Sulphate

Glucosamine Sulphate is a naturally occurring compound in the body that has an important role in the synthesis of factors that are integral biochemical components in joint structures. These factors are glycosaminoglycans and glycoproteins and are essential to the structure of ligaments, tendons cartilage and synovial fluid. Glucosamine is given either as glucosamine sulphate or glucoamine hydrochloride and it is thought that glucosamine supplementation may delay the degradation of cartilage associated with OA and may even repair it . Two recent trials of glucosamine sulphate have been conducted but produced contradictory results on effectiveness. Rozendaal et al (2008) looked at pain and joint function on n=222 patients with OA of the knee in a double blind RCT where participants received either glucosamine sulphate or a placebo over a two year period and found no significant between group difference. Herrero-Beaumont et al (2007) compared glucosamine sulphate with a placebo plus paracetamol on a sample of n=318 patients with OA of the hip, and found that the test group had significantly greater improvements in pain and joint function, but this was only measured over a 6- month period (Willemsen et al, 2008). These results are displayed in Table 1.

1.2.4(ii) Omega 3

Omega 3 fatty acids have been documented to have a number of health benefits including cholesterol lowering and heart disease prevention (Wang, 2004). They are also recommended for control of OA and other joint disease. Omega 3 fatty acids exist in large quantities in the body oil of fish such as salmon, mackerel, sardines and pilchards. They have anti-inflammatory properties, breaking down inflammatory elements in white blood cells but also are components in prostaglandins, which are hormone like substances that fight infection and inflammation in the joint. There is very little extant literature on the use of fish oils for OA. One RCT comparing cod liver oil with placebo olive oil preparation found fish oils to be ineffective as an adjunct to NSAIDs, though this was attributed by the authors to be due to the NSAIDS blocking the COX enzyme in Inflammation (See section 1.2) also blocking the omega 3 pathway

to inflammation (Stammers, 1992), see Table 1 for details. Current guidelines for this patient group are in line with the general population that are based on cardiovascular disease prevention, to take 1 to 2 portions of oily fish per week as part of a healthy balanced diet, for example taking approximately 120g of Salmon, mackerel or sardines biweekly (European Society of Cardiology, 2007), however recommendations of up to twice per week plus for high strength omega 3 capsules a day for a three month period have also been made for OA patients (Rayman & Patterson, 2008).

1.2.4(iii) Other vitamins and supplements

There are many other nutritional supplements including flaxseed oil, ACE vitamin supplements plus Selenium, and vitamins B, C and D individually but these have not been thoroughly explored and research to date in inconclusive (Ameye & Chee, 2006). Many of these nutrients can be acquired in the diet naturally by following a healthy balanced diet. For example, following the national guideline of 5 fruit and vegetable portions a day (Gillman, 1996) provides the recommended daily intake of vitamins A, B, C & E. Sufficient Selenium (Se) levels can be achieved by dietary means, with brazil nuts providing the highest source of Se per 100g.

1.2.5 Assistive techniques and devices for everyday living

Physiotherapy and occupational therapy also offer some support to OA patients including the prevision of devices that make everyday life easier. This includes special footwear, ambulatory techniques and muscle strengthening exercises.

1.2.6 Limitations of conventional non-pharmacological treatments for OA

Such approaches however are limited in the degree that they can improve the quality of life for those who suffer from OA as they can only assist management of a functionally limited joint rather than bring about an improvement in function. For this reason, complementary and alternative medicine (CAM) approaches, offering new philosophies

and a holistic treatment are being sought by OA patients keen to increase the manageability of their condition.

1.3 Complementary and Alternative Medicine

Increasing numbers of such patients are seeking CAM. Results of a 1998 survey of use and expenditure on complementary medicine in England suggested that 28% of respondents had either visited a complementary therapist or had purchased an over the counter herbal or homeopathic remedy in the past year (Thomas et al 2001). At present only 0.8% of NHS grant money is allocated to CAM treatments. The 6th Report of the House of Lords Select Committee on Science and Technology (2000) entitled 'Complementary and Alternative Medicine,' recommended the need for methodologically rigorous research to investigate the effectiveness, efficacy and safety of CAM. In the report CAM treatments were identified and categorised in terms of their history, philosophy and the stage which their research has so far reached. The treatments were also prioritised according to which most urgently needed further research. Class 1 contained those which were considered to be professionally organised alternative therapies. Homeopathy and Acupuncture were, along with herbal medicine, among those placed as class one treatments. Among the OA population, 60% of sufferers in the UK try some form of CAM treatment to manage the condition (Bishop et al, 2007). The range of CAM therapies used for OA includes herbal remedies, special diets, acupuncture, mind-body interventions, manual healing, electromagnetic therapy and homeopathy (Rao, 1999). Amongst these, homeopathy and acupuncture are two of the most popular treatments (Thomas et al, 2001).

1.3.1 Homeopathy

Despite the popularity of homeopathic treatment, evidence for the use of homeopathy for OA has been inconclusive to date, though homeopathy has been found to be at least as effective as allopathic treatment. Nahler et al (1998) performed a multi-centre randomised single-blind clinical equivalence study to compare the efficacy of a combination homeopathic preparation composed of *Rhus toxicodendron, Arnica montana, Soalanum dulcamara, Sanguinara canadensis* and *Sulphur* with a brand of hyaluronic acid on n=121 patients with primary knee OA. Symptomatic improvements were observed for both treatments though no significant differences were observed between groups on the outcome measures used in the study. This study did not use individualised remedies and used multiple prescribing, which may not be typical to homeopathic treatment. It also raises the issue of what are the active ingredients of homeopathy, and whether it can be guaranteed that these were all absent in the placebo group.

Shealy et al (1998) carried out a double blind placebo controlled RCT in which 69 patients with knee OA were randomly assigned to receive either a liquid homeopathic preparation (consisting of equal parts of *Rhus toxicodendron, Cauticum* and *Lac Vaccinum*) and placebo capsules or a liquid placebo and paracetamol capsules. Patients were asked to take 10 drops of a solution sublingually four times daily along with a capsule four times a day for one month. Assessment was by means of a daily diary where patients recorded their average pain using a VAS for each day. Improvements in VAS ratings were observed for both treatment groups. There was, however, no statistically significant differences between groups. The homeopathic treatment was reported to be as least as effective as paracetamol with the advantage of having fewer adverse effects. This is another example of a study that did not use individualised homeopathic remedies and so is not representative to homeopathic treatment.

Shipley and Berry (1983) carried out a double-blind placebo-controlled crossover study on a mixed population of 36 patients suffering from either knee or hip OA or both.

Patients were allocated to either a homeopathic advice group in homeopathic hospitals or to a rheumatology department. Patients were then randomly assigned to one of three treatment regimes consisting of placebo capsules and placebo drops, fenoprofen capsules and placebo drops or placebo capsules and *Rhus toxicodendron* drops. All patients received each regime over a 2 week period per regime with no washout period between. No significant differences were observed between the homeopathic drops and placebo treatment phases. The NSAID treatment produced significant pain relief compared with both the homeopathic treatment and placebo. This effect was irrespective of setting (homeopathic hospital or rheumatology department). However the small sample size and methodological limitations, including lack of individualised treatments, of the study make it difficult to draw definitive conclusions.

Van Haselen and Fisher (2000) performed a randomized double-blind controlled trial to compare the efficacy of a topically applied homeopathic gel with a NSAID gel (0.5% piroxicam) in the treatment of OA of the knee in n=184 patients. A difference between the 2 groups for pain (VAS) favouring homeopathic treatment was found. No significant difference between groups was found for joint tenderness using the single joint Ritchie index.

A systematic review by Long and Ernst (2001) of the 4 primary studies mentioned above concluded that results between trials were inconsistent. Due to methodological problems in all trials, firm conclusions could not be drawn. They did, however, conclude that more research was warranted and that there was little potential risk of harm from homeopathic treatment.

A major criticism of the trials conducted is that they are not representative of homeopathic practice where at least 4 basic types of homeopathy are differentiated: classical homeopathy, clinical homeopathy, isopathy and complex homeopathy. For

chronic diseases such as OA, the 'classical' homeopathic approach is probably most widespread whereas the interventions investigated in the above trials (with the exception of Shipley & Berry, 1983) deal with the administration of fixed combinations of several homeopathic remedies ('complex homeopathy'). The standardized treatments in these trials are hence unlikely to represent 'classical' homeopathic practice where individual remedy selection and the possibility of changing the medicine during the treatment are an integral part of the treatment regime. Further the outcome measures used in the trials do not reflect patients' perceptions, expectations and experience of the homeopathic consultation and treatment which may affect qualitative dimensions of their condition and hence overall quality of life. The RCT studies on homeopathy and OA date back to 2000 and it is possible that the reasons discussed in this section may have resulted in no further trials into the effectiveness of homeopathy for OA being conducted in the past 10 years. It is therefore important to identify the issues that have contributed to the inconclusive findings of these previous studies and the areas that need to be developed in order for an enhanced evidence base on homeopathy for this condition. This is something that was addressed throughout the current study and in particular in Chapter 5.

1.3.2 Acupuncture

Of all the CAM therapies, acupuncture has come the furthest in terms of achieving an evidence base for effectiveness for OA. It has well documented approval for pain management (Ernst, 2006) and is widely used by the OA patient group (Chandola et al, 1999). One Systematic review by Ezzo et al in 2001 on acupuncture for OA of the knee included seven RCTs that comprised 393 participants with OA, comparing acupuncture treatment to sham acupuncture. This study concluded that acupuncture was more effective than sham acupuncture at reducing pain in OA. There was also some evidence, though less convincing, that suggested acupuncture was also associated with improved function. A more recent systematic review found 13 suitable RCTs, eight of which were considered to use sufficient acupuncture and used the WOMAC outcome score and so could be grouped together in a meta-analysis (White et al, 2007). Some of the individual studies showed favourable results for acupuncture versus sham and no treatment

(Berman, 2004; Sangdee, 2002; Witt, 2006) with some outcome tools at certain time points (see Table 1). The meta-analysis conducted by White et al (2007) included 5 studies comprising 1334 patients and concluded that acupuncture was superior to sham and to no intervention at post intervention and long-term follow-up. The different studies, however, were too heterogeneous in nature to draw firm conclusions, in particular, the type of acupuncture used varied. Some studies used electro-acupuncture while others used manual (see section 1.5.9) and studies were conducted in different locations world-wide on varying patient populations. In addition the intensity of acupuncture used varied. One study that was included in the review consisted of 570 patients with x-ray evidence of OA of the knee (Berman et al, 2004) used an intense acupuncture treatment of twice weekly sessions for 8 weeks and then decreasing the frequency down to once a month from week 14 to week 26. At 8 weeks the acupuncture group showed improved function but not pain compared to the Sham group, but both pain and function had improved by week 26, compared to the sham group. The study did, however, have a high drop-out rate and had lost 25% of participants prior to week 26, casting some uncertainty over the results at that stage. It is not possible to tell from this study whether a less intense treatment plan would have achieved similar results and there is no indication on the effectiveness of acupuncture compared with other therapies for OA of the knee. Details of some of the large RCTs of acupuncture for OA can be found in Table 1.

Some Individual RCTs for acupuncture, however, have found that improvements were seen in both the intervention and the sham acupuncture groups (Christensen et al, 1992; Kwon et al, 2004; Scharf et al, 2006). This is reflected in another meta-analysis (Manheimer et al, 2007) that looked at acupuncture RCTs of osteoarthritis of the knee and found clinically relevant differences between acupuncture groups and waiting list groups but that differences between acupuncture and sham acupuncture groups were clinically irrelevant. The sham protocols used in the included studies, however, varied considerably. The results of the individual studies were perhaps too heterogeneous, due to differences in treatments and protocols, to be grouped together in this manner, but they raise concerns regarding how well sham techniques actually mimic without simulating active acupuncture treatment.

The popularity of acupuncture treatment is still increasing. A retrospective survey conducted on participants who had received acupuncture treatment (n=110) found that over 90 per cent of respondents who had received acupuncture had said they were very satisfied with their treatment and over 50 per cent said it had allowed them to make significant changes to their lifestyle (Xing & Long, 2006). Most of the current literature shows strong evidence that acupuncture is very effective in treatment for chronic lower back pain, dental pain, nausea and vomiting following chemotherapy or surgery and migraine. In the case of OA, as well as neck pain and angina, there is evidence to suggest the effectiveness of acupuncture but criticism of the research methodology has decreased the impact of these findings.

1.3.3 Other CAM for OA

(i) Herbal Medicine

A Cochraine review on herbal treatments for OA was conducted in 2008, including data from all published placebo controlled RCT of herbal treatments for OA patients where herbal treatment was used alone, not in conjunction with other treatments. They found five studies that met their inclusion and exclusion criteria, covering four different herbal treatments. They concluded that there was sufficiently convincing evidence to support avocado-soybean unsaponifiables, but that for Tipi, Capsaicin and Reumalex studies were few in number and proved inconclusive (Linde et al, 2008). See Table 1 for details of the study.

(ii) Magnetic Therapy

A study on 194 men and women aged 45-80 with OA of the knee was conducted on magnetic bracelet therapy (Harlow et al, 2004). This was conducted as a double blind randomised control trial (RCT) where participants were given a magnetic bracelet (treatment group) or a dummy bracelet (control group). Pain outcomes were measured using the WOMAC tool, containing visual analogue scores relating to pain and stiffness felt from osteoarthritis of the knee. The study concluded that the magnetic bracelets

significantly reduced pain, but the group were unable to satisfactorily demonstrate that this was more than a placebo response.

(iii) Additional CAM treatments of OA

Other CAM methods for OA include Reflexology, therapeutic touch, yoga and imagery. Encouraging results have been seen with these therapies but they are in need of independent replication to draw firm conclusions (Ernst, 2006).

1.3.4 Impact of the Evidence gap on Patient Care

With the popularity of CAM therapies, in particular homeopathy and acupuncture and high level of usage of these treatments by OA patients it is clearly not ideal that studies to date on the efficacy of these treatments are largely inconclusive. This is also a frustration for patients actively trying to improve the manageability of their condition but confused by the lack of clear guidance on available treatments. In addition GPs and other health professionals are often consulted for advice on the suitability of homeopathy and acupuncture for their condition and the lack of substantiated evidence on the treatments means that the health professionals are not suitably equipped to respond helpfully to such inquiries. It is therefore clear that further exploration into acupuncture and homeopathy treatment for OA is necessary to enhance the evidence base concerning the therapies.

1.4 A Detailed Exploration into Homeopathy and Acupuncture

Homeopathy and acupuncture are the two most popularly used CAM treatments for OA (Chandola, 1999). They are both treatments highlighted as in need for further research

(House of Lords, 2000), in particular homeopathy which is a therapy surrounded by controversy and as discussed in 1.13 many previous studies have been inconclusive. These two therapies are addressed in this study and it is first necessary to look at the treatments in more detail.

1.4.1 Introducing Homeopathy

Homeopathy is a treatment that grows in popularity every year. Increasing numbers of such patients are seeking CAM and homeopathy is one of the most popular to the OA patient group (Chandola et al 1999). Ernst and White (2000) found in a telephone survey that 20% of 1204 randomly selected British adults had used CAM in the year preceding the study and homeopathy was among the top three CAM therapies used.

As a "Class 1" CAM treatment, homeopathy was highlighted in the House of Lords Report in science and technology (2000) as high priority for further research and will be the main focus of this study.

1.4.2 History of Homeopathy

Homeopathy was founded by the German physician Samuel Hahnemann in the 18th Century. Hahnemann was dissatisfied with the medical practices used at the time, which included blood letting and leeching. Following Cullen's discovery of quinine (Peruvian bark) as a treatment for malaria (1789), Hahnemann noticed that quinine produced the same symptoms in a healthy person as in those suffering from the disease. He could not accept Cullen's views that it was the astringent nature of the bark that was responsible for the effects. He then began to conduct a series of experiments on himself, diluting the substance so that it would be harmless; a process now termed a "proving" in homeopathy. He noticed that these minute doses of something that cause symptoms similar to a disease in their original form could treat the diseases they mimicked. The word Homeopathy comes from "homo" meaning same and "pathy" meaning suffering.

This "Law of Similars", as it came to be known, had previously been conceptualised as a treatment in the past by Paracelsus and Hippocrates who were both unconventional physicians in their time. The minute doses involved meant that it was possible to include metals and other substances that would be toxic at higher concentrations among potential remedies. Hahnemann's work developed and its popularity grew and soon an extensive *material medica*, a list of all remedies and their uses in difference circumstances, was created.

Provings such as the experiments that Hahnemann originally performed on himself (described above in this section) are still conducted, with new remedies being identified as an on-going process. Famous provings include those by Jeremy Sheer, whose work is well known in homeopathic circles. The provings are conducted on a group of volunteers who take a small amount of the undiluted form. The volunteers are then required to record any symptoms, sensations, emotions or dreams that they notice. These findings are all compiled to form new repertories. The most significant finding can be a seemingly incidental report from just one of the volunteers (Sheer, 1994).

Homeopathy was first introduced to the UK by Quinn who then founded the Royal London Homeopathic Hospital in 10th October 1849. The popularity of homeopathy peaked during the cholera outbreaks as homeopathic hospitals reportedly had much lower death rates. The practitioners did face serious opposition from the mainstream physicians of the time who were beginning to use the first synthesised drugs as treatments. Many physicians who practiced homeopathy were banned. Homeopaths were treated in a similar manor in other countries including the USA where the American Medical Association (AMA) was formed in a deliberate attempt to stamp out homeopathy (Ullman, 1992). The main reason for this was that mainstream physicians felt threatened by homeopathy, but the treatment itself involved the acceptance of some very controversial ideas.

The simillium principle of treating like with like came across to many as a foreign idea, since most conventional treatments of the time and also in present times work by

suppressing the symptoms. That is conventional treatments oppose the symptoms, and so is termed "Allopathy" by homeopaths (Allos meaning other). The other focus of controversy is the minute doses used in homeopathy. Most of the homeopathic preparations used are diluted so much and are beyond the Avogadro number. The Avogadro number, the number of molecules of a substance needed to weigh 1 gram mole (M) of pure substance, can be used to calculate the number of molecules in a particular solution of a pure substance. That means that they are unlikely to contain even a single molecule of the original substance. Further, homeopathy takes the belief that the more dilute the remedy, the more times it has gone through the succusion or shaking process that is considered to be crucial in the preparation of remedies, and so the more potent it is.

In spite of the opposition, homeopathy continued as a treatment and by 1948 when the NHS was founded, several homeopathic hospitals were up and running in the UK. These hospitals were therefore incorporated into the NHS from the start and so to some degree the treatment was already integrated into the UK health system. Homeopathy is now more popular than ever with an estimated 3.4% of the UK population having used it during 1999 alone (Ernst & White, 2000).

1.4.3 Homeopathic Theory

A major factor in the distrust of homeopathic treatment amongst the medical profession is a lack or knowledge of how the remedies could work. To those who have studied pharmaceutical medicine in the UK and its focus on drug-receptor reactions on a molecular level, the idea of a remedy that is so dilute that it is unlikely to contain even a single molecule of the original substance having any biological effect sounds highly implausible. Different theories have been put forward regarding the physical and biological science of homeopathy (see section 1.4.5) but the homeopathic community is often seen as being indifferent to the mechanism of action, as Hahnemann himself

stated that there is no reason to ask how it works (Hahnemann, 1982). Below are some areas that have been presented that are relevant to how homeopathy works. There are three areas involved here, the controversy of the plane of the body that homeopathic medicines are said to affect, the extremely controversial process of the preparation of remedies and biological effects of homeopathic remedies in the body.

1.4.4 Preparation of remedies

Homeopathic remedies involve a very particular preparation procedure. Hahnemann originally included the succussion process into the preparation of his remedies in order to utilise insoluble materials as remedies. The substances would be combined with sugar and shaken to form a suspension in the water or alcohol. A sample would then be taken from this preparation and further diluted and succussed. Most of the theories on the mechanism of homeopathic remedy preparation suggest that the original substance leaves an imprint in the water and that this imprint is passed through the succusion process, even in the absence of molecules of the original substance. The exact nature of the imprint is unknown but is described as being some kind of an energy field. The factors that makes these theories sound both more plausible and yet more difficult to fathom is the complexity and gaps in knowledge with regard to the properties of water itself. Water is a unique substance that has the ability to form crystals in its liquid phase (Shui-Yin-Lo et al, 1996). It is suggested that the formation of these water crystals allow for the information transfer from the original substance to the ultra-diluted remedies (Widakowich, 2000).

In the case of homeopathy, one theory is that during the succusion process in the preparation of remedies, the essence or energy of the original substance is transferred and upon subsequent succusions this energy becomes increasingly strong (Widakowich, 1991).

1.4.5 How do homeopathic remedies work?

Homeopathy as a treatment has stood the test of time in spite of strong opposition; however the mechanism that could be responsible for the reported effects remains one of the biggest mysteries of modern science. Some suggest that any observed clinical improvements following homeopathic treatment are solely due to the placebo effect (Vandenbrouke, 1997) .The placebo effect is described as the health benefits a patient feels due to the fact that they are being cared for and the trust they have in their therapy. Studies comparing homeopathic treatment with placebo are discussed below under "Effectiveness of Homeopathic Treatment".

1.4.6 Biological effects following HP administration

This is an area that is very under- researched. Several studies have been carried out and produced some astonishing and yet highly disputed results. An immediate example of this was the much publicised horizon study (Horizon, 2002) where the work of Jacques Benveniste's group was replicated in a laboratory by scientists who had been selected by the editor of Nature. Benveniste's group carried out research involving using homeopathic concentrations of allergens and measuring their effects on human Basophil cells (Davenas et al, 1988). Basophils are a type of white blood cell with immunoglobulin E (IgE) antibodies on the surface that release histamine in the presence of anti IgE antibodies. The study conducted a series of experiments on the activation of basophils to release histamine with dilute concentrations of IgE antibodies, from 1×10^{2} down to 2.2×10^{-120} M. The study found that in this range of concentrations a 40-60% degranulation of basophils was achieved.

The Avogadro number, as mentioned previously, is the number of molecules of a substance needed to weigh 1 gram mole (M) of pure substance, can be used to calculate the number of molecules in a particular solution of a pure substance. Solutions of under 1×10^{-100} M are unlikely to contain a single molecule of original substance. Therefore all concentrations below this were unlikely to contain a single molecule of IgE antibody,

in a similar way that many homeopathic preparations are unlikely to contain a single molecule of original substance. The serial dilutions were shaken in a similar manner to the method of succussing homeopathic remedies. The group concluded that the results were suggestive towards a "memory of water" brought about by a molecular organisation of H_20 in its liquid phase. The results therefore seemed quite profound in light of current scientific thought.

The team from Nature consisted of hand-picked scientists, the editor of Nature and an American magician called Randi, a millionaire famous for his tricks and dedicated to disproving homeopathy. The Nature team carried out an inspection of Benveniste's laboratory and concluded that there were methodological flaws in his study. One fundamental limitation was that Benveniste's research group who were conducting the study were not blinded to the different cell groups and so were aware when collecting results which were the test and the control groups. This could have been a likely source of bias. When the study was replicated, with blinding carried out by the nature team, the findings were not concurrent with Benveniste's and he was portrayed as a fraud (Maddox et al, 1988). Criticism of the Nature team's study include the unorthodox approach of the conduction of the study, in an unscientific environment with the magician Randi present in the laboratory, and also the potential for bias as the intentions of the group were clear. Benveniste then replicated the study with enhanced scientific rigor and produced positive, though less pronounced results (Benveniste et al, 1991). The repeated studies, however, are not well-known and were published in less renowned Journals. Horizon put a team of scientists together to repeat the experiments, again with Randi and the other sceptics present, and could not demonstrate the replicability of Benveniste's findings (Horizon, 2002). Additional criticism of this study was that the succussion process on the remedy was carried out unsatisfactorily, since they used a machine rather than shaking by hand.

Scientists have continued to carry out biochemical studies with ultra dilutions and the evidence base is slowly growing (Bellavite et al, 2006). Notable studies amongst these include one by carried out by Madeline Bastide which involved investigating the effects of homeopathic doses of bursin, an immunomodulatory tripeptide, in chickens showing

that these produced the same effects on the immune system as the tripeptide itself (Bastide, 1997). Funding issues and controversy may have kept these studies from appearing as scientific breakthroughs.

One group carried out a series of studies of homeopathic dilutions on oxidative metabolism of neutrophils activated by formulated peptides (Bellevant et al, 1993), finding that phosphorus and magnesium phosphoricum both had significant inhibitory effects on the neutrophil oxidative metabolism at dilute concentrations but that they did not always appear at the same concentrations, making statistical analysis difficult. However, when the results were pooled it was possible to identify a statistically significant inhibition of 10% to 15% of oxidative activity.

An interesting phenomenon found in these in vitro studies is that results at different concentrations followed a biphasic response curve, whereby lower concentrations, for example between 0.1-10 µg/ml produced the same response but concentrations of over 100 µg/ml caused an inhibitory response. It is possible that these concentrations interact with the cells micro component signalling pathways, and may indicate the presence of cellular messengers that operate at concentrations similar to homeopathic preparations.

1.4.6 The Vital Force and Energy in the Body

In order to consider possible mediatory mechanisms it is first necessary to consider the theories of health and disease behind homeopathy. Hahnemann wrote the following on this in his original homeopathic text, The Organon: -

"In the state of health the spirit-like vital force (dynamis) animating the material human organism reigns in supreme sovereignty. It maintains the sensations or activities and all the parts of the living organism..." Organon 9

"Every power that acts on life, every medicine, alters the vital force more or less and brings about in human health certain modifications" Organon 63

In these quotations from The Organon, Hahnemann is saying that biological effects of homeopathy are said to occur due to the remedies' actions on the vital force of the body. That the vital force is a life force that orchestrates a coordinated healing response throughout the body, as opposed to local actions on specific receptors by drugs on the physical body. The body translates the vital force to make local changes to restore a balance and hence cure acute and chronic conditions. These theories date back to when homeopathy was established and is comparable to Qi of Traditional Chinese Medicine, Prana of Ayurvedic medicine and Ki of Japanese medicine. Dr Rupert Sheldrake wrote that he believed that certain "morphogenic fields" are involved in operation and replication of DNA and similar ideas had been articulated by Plato and Socrates (Sheldrake, 1995). Certain research biologists, e.g. Paul Weiss have similar ideas to this (Weiss, 1958). These "Morphogenic Fields" are said to be intangible but can be inferred from their effects on tangible things, in the same way as magnetism and gravity. Dr Harold Burr (1972) explains in his book "Fields of life" his studies using delicate electrodes to meticulously study electrical potential of plants, people and animals. He came to the conclusion that every organism is established by electrodynamic fields that in some ways are determined by the physiochemical properties and in some ways shape these physiochemical properties and regulate and control living things. A colleague of his, Dr Ravitz, researched emotional and mental behaviour and found that particularly in schizophrenia and hypnosis that a voltmeter showed an excess of energy and a voltage drop would follow from an improved condition (Kashalikar, 2009).

A recent study conducted on fibromyalgia patients prior to treatment with classical homeopathy, n=62, specifically set out to investigate the associations between classical homeopathic construct of the vital force and clinician and patient ratings on aspects of their health, pain, mood, well-being and spirituality (Bell et al, 2004). This included use

of multiple self-completion tools on matters such as spirituality, social desirability, mood and positive states of mind, in order to test the strength of vital force. The study concluded that the vital force better reflects perceived mental function, energy and positive dimensions of the individual, beyond absence of disease, rather than pain, age or illness duration.

Homeopathy is often referred to as energy medicine. Acupuncture and radionics also fit into the category. Some suggest that all these therapies work on the subtle energies, or vital force, in the body but that they manipulate these in different ways (Gerber, 2001). For example, manipulating qi by needling specific acupuncture points, allowing it to flow to the areas where it's needed may in someway be comparable to the actions of homeopathic remedies on the vital force, or Ayurvedic herbs on prana.

1.4.7 Biomedical science limitations

Modern biomedical science has been criticised for not incorporating the advances in physics of the 20th Century. Biological science sees matter in terms of Newtonian models but Einstein's work on quantum mechanics and energy physics is not involved in the models applied to the human body. Homeopathic researchers have commented that it can only be when modern biomedical science is updated with new advances in physics that homeopathy will be understood. It is therefore regarded by many as a therapy that has come about ahead of its time. The biopsychosocial model of health allows for a global view of health and the impact of socioeconomic, asperational, cultural factors and values and degree of contentment upon this. Understanding the mechanisms by which biopsychosocial factors impact on health together with advancement in the physical science of the body may lead to an enhanced understanding and expansion of the two models of health in a way that means that the biomedical model is able to incorporate biopsychosocial factors.

As many aspects of homeopathy, such as the processes by which it may mediate a response, remain largely unclear and patchy it would be useful to know what views the experts, the homeopaths themselves, hold on homeopathic theory and also their views on the priority of future research. This will provide information on an area very much lacking in research and investigate whether there is any foundation for the general view that homeopaths themselves are uninterested in the actual mechanisms of the therapy that they provide.

1.5 Introduction to Acupuncture

1.5.1 History of acupuncture

Another popular Class 1 CAM therapy (House of Lords, 2000) acupuncture has been practised in China for at least 2000 years and possibly dates back as far as 300 BC. The earliest record retrieved of acupuncture discussion is in the ancient Chinese medical text "Huang Di Nei Jing", the Yellow Emperor's classic work of Internal Medicine, originating around 300 BC (Veith, 1949). Westernised style medicine spread across China at a similar time to its emergence throughout the world and began to replace acupuncture treatment. In rural areas, however, acupuncture remained extremely popular. A resurgence of Traditional Chinese Medicine, including acupuncture, began in 1949, with the formation of the People's Republic of China. This formed part of Chairman Mao Zedong's policy of isolation from the West and focusing on Chinese traditions.

1.5.2 Acupuncture Practice Worldwide

Acupuncture has been practised in Japan for around 1500 years and Europe over 300 years transferring to North America around 150 years ago (Lu and Needlam, 1980). According to the Work Health Organisation it is now practised in over 100 countries worldwide. Acupuncture first reached Britain via Europe where many Chinese,

Japanese, and Vietnamese acupuncture masters has moved. Direct contact with teachers and schools in countries including Korea and Taiwan then followed. Study of acupuncture practice was not seriously conducted in the UK until the late 1950's. The use of acupuncture in the UK is rising rapidly and is becoming increasingly popular (Ernst & White, 2000). In the 1970's the UK had only a handful of acupuncture practitioners but there are now over 2,800 acupuncturists registered with the British Acupuncture Council (BAcC), one of the leading affiliations for acupuncturists, alone (British Acupuncture Council, 2007).

1.5.3 What is Acupuncture?

The practice of acupuncture was a combination of "Zhen" meaning needle therapy and "jiu" meaning moxa or cupping (the burning of dried mugwort herb), originating from the TCM method of treatment, the origin of which is described above. Traditionally the practice needling acupuncture and moxabustion was taught together. Derived from the Latin "acus" (needle) and "punctura" (to puncture) the term is now more synonymous with needle therapy as opposed to moxa therapy, although a proportion of practitioners do still employ adjunctive techniques including moxa therapy as part of their treatment of patients (Birch & Kaptchuk, 1999). In addition, other variations including electro-acupuncture and laser acupuncture, or "zhenjiu" are occasionally used. The needles used in acupuncture are very fine and solid, as opposed to the hyperdemic hollow needles frequently used in Western medicine. Needles are inserted into specific energy points, the angle of insertion ranging from 15 to 90 degrees and the depth is variable dependant on specific treatment methods. For the purposes of this thesis acupuncture is defined as:

"Acupuncture refers to the insertion of a solid needle into any part of the human body for disease prevention, therapy or maintenance of health. There are various other techniques often used with acupuncture, which may or may not be invasive." (Acupuncture Regulatory Working Group, 2003, p12)

1.5.4 Acupuncture Theories

In Traditional Chinese Medicine (TCM) acupuncture is used to stimulate flow of "Qi" in the body. Meridians and collateral channels, which are non- physiologically observable entities run throughout the body Qi runs through these (Kaptchuk, 1989). Any ill health due to a disturbance in the balance of the flow of Qi and it is this blockage that must be removed by acupuncture. The balance of Yin (The more gentle, creative "female" force) and Yang (the more strong, energetic "Male" force) and the 5 elements (metal, wood, water, fire, earth), and influences that the different organ systems have on each other are all fundamental concepts to TCM and expressions such as "Yin deficiency in the spleen causes the stagnation of liver qi" are frequently used descriptions of diagnostics.

1.5.5 Medical acupuncture

Other theories exist that seek to explain effects seen in acupuncture. Western or medical acupuncture takes the view that traditional acupuncture pathways were documented following observations of effects and in the absence of knowledge of the physiology and biomedical structure of the body these effects were explained by abstract means, and seen as making them inaccurate descriptions of phenomena that can be more precisely explained in light of modern advancement of science (Filshie & Cummings, 1999). Medical acupuncture proposes that acupuncture needling works on the nervous system and the endocrine system, causing release of endorphins and hence producing effects such as pain relief. Current evidence suggests that this in fact involves a complex network of pathways with several centres in the central nervous system processing inputs from numerous modulators and nerve reflexes, with no set physiological response to acupuncture needling. It suggests that physiological response is variable, dependant on a number of factors including site stimulated, type of stimulation, the recipient's current health state and any medication or treatment they may be taking (Filshie & White 1998; Pomeranz, 2001). These numerous response pathways appear to be elicited via the stimulation of afferent neurones, as a result of

needling, that then conduct impulses to the central nervous system. The nerve impulses typically produce one of three effects, 1) an increase in neurotransmitters within the CNS, 2) mediators being released into the circulatory system via the pituitary gland, 3) an effect (muscle or gland) being stimulated by an efferent neurone. Evidence to reinforce the theory that acupuncture causes the stimulation of afferent neurones includes inhibition of acupuncture effects by injection of local anaesthetic into acupuncture points prior to treatment on analgesia (Sims, 1997), on the cardiovascular system (Filshie & White, 1998) and antiemetic effects (Pomeranz 1998). In addition animal studies show that severing the end of the nerve that is still attached to the CNS can abolish the effects of needling (Pomeranz, 2001). Also damage to peripheral nerves and neurones has also been demonstrated to impede the effects of acupuncture (Sims, 1997).

The medical acupuncture system uses a smaller number of acupuncture points than traditional acupuncture but a fairly extensive network of points have now been mapped out for a range of treatments.

1.5.6 Trigger point acupuncture

Trigger point acupuncture works directly on the muscles, to alleviate tightness and loosen knots. Needling the trigger points is considered to deactivate them causing pain relief. This method is founded in the Western medical tradition but is similar to the Ah Shi school approach dating back to the 7th century (Mann, 1987)

1.5.7 Five-element Acupuncture

This form of acupuncture is believed to have ancient roots dating back as far as 200 BC. It uses many of the traditional diagnostics and theories of TCM acupuncture but places

greater emphasis on the five elements, identifying which of these elements first went out of balance.

1.5.8 Japanese Acupuncture

Many areas of ancient Japanese culture and medicine are not well understood, largely due to lack of documentation. Acupuncture is thought to have arrived from China to Japan in 6th Century AD. The first recorded Medical Law of Japan was established in 701 and explains acupuncture in detail, demonstrating that is was used under government authorisation. For the next 1200 years acupuncture continued to be important in Japanese medicine (Kobayashi et al, 2007) and those who studied in China brought back new styles of practise that they transferred on in acupuncture schools in Japan. In 1635, The Edo government that was in place at the time, decided to cut off Japan from the rest of the world and this national isolation caused Japan to undergo some unique development. Popularity of acupuncture increased with ordinary people being able to practise it themselves. Japanese acupuncture therefore evolved and became distinct from other forms of acupuncture. The only country that Japan maintained contact with at this time was Holland. Western medicine therefore flowed in from Holland and was a major influence on medicine practised in Japan. At the same time Japanese style of acupuncture was brought to Europe via Holland at this time. The first book on Japanese Acupuncture to be published in English was by Hermann Bushoff in 1676 (Kobayashi et al, 2007). Japanese acupuncture remains a distinct form of therapy that is practised worldwide.

1.5.9 Electro-acupuncture

Electro-acupuncture was developed in 1958 in China when people began to experiment with pain management for surgery. It does not have a distinct theoretical background but involves passing a small electrical current through needles that have been inserted into acupuncture points, in order to enhance treatment. It is a technique that can be used

in both medical and TCM acupuncture. There is a growing level of evidence for electro-acupuncture and many of these studies originate from Asia.

In summary, there are several different types of acupuncture treatment. Various theories to suggest a mechanism of action for homeopathy and acupuncture have been proposed. This has occurred to a much greater extent for acupuncture than homeopathy and acupuncture has two divergent theories of action, biomedical and the Traditional Chinese Medicine theory, based on the flow of Qi, described by some as energy medicine. For homeopathy on the other hand, there is no proposed theory relating it to current frameworks that fit in with the current biomedical model. The science of homeopathy is still extremely controversial and it is a therapy thought to work on "energy" rather than "substance". It is possible that with developments both in biological and physical science that the two frameworks will be more compatible in the future.

1.6 CAM and the UK Health System

With Complementary and Alternative Medicine (CAM) becoming increasingly popular, the issue of integrating the therapies into the health system of the UK is a heavily debated topic. At present, the vast majority of CAM treatment in the UK occurs in private practice, with the average CAM user being female, aged 30-50 years old and from a middleclass background (McDonough et al, 2007; Thomas & Coleman, 2004) and this is consistent with findings from other countries, for example Australia (Zochling, 2004) and the USA (Eisenberg et al, 1998). A likely factor is that the treatments are reserved for those of middle class and above due to the inaccessibility of CAM to certain groups of society for financial reasons. This is an argument for integration to tackle inequalities in health, if these therapies prove to be effective yet inaccessible to many. Another argument for integration is in order to enable application

of the same regulatory bodies and codes of practice to CAM therapists as are applied to mainstream health professionals in order to ensure standards of treatment and patient safety. The definition of the term Integrative health care is itself controversial but usually refers to a situation where a medically qualified doctor takes some additional training in a CAM therapy such as acupuncture or homeopathy or where a medical practice employs a CAM therapist so that some CAM is on offer from the practice.

1.6.1 Practitioner attitudes regarding CAM and the NHS

In spite of this documentation of a positive move towards integration, the problem remains that a large proportion of the medical profession still have little regard for CAM treatments. This seems to have an obstructive influence to their integration into the system. A cross-sectional postal survey concerning views on integration was carried out on 120 CAM practitioners and 413 MD's in Canada (Mortiz, 2004). The participants were presented with four different integration models for six CAM therapies, one of which was homeopathy. The results found that both conventional and CAM practitioners favoured a collaborative model and least favoured the CAM therapies being administered by the MDs. Similar results were found from a qualitative study on primary care staff and chiropractors (n=16) that concluded that both groups favoured collaboration rather than integration under the same structure as it allowed the CAM practitioners more autonomy (Boon, 2004). This reflects another potential obstacle to integration of CAM in the UK, that CAM therapists may be reluctant to be fully integrated into the NHS as some see it as an institution with extensive hierarchy and regulations and feel some resistance towards regulation of their treatment (Welsh et al, 2004).

The above study by Moritz (2004) suggested that in order for integration to work MD's need to begin fostering more respect for CAM practitioners. One factor that has been presented as influencing medics' opinion of CAM is their exposure to it. An

international multi-centred survey carried out on medical students' views, n=648, on integrative medicine showed that these depended on exposure and or personal positive experiences of the treatments (Schmidt, 2004).

These studies raise some interesting questions regarding integrative medicine but they are mostly small studies and were carried out in different countries where different state health systems are in place.

1.6.2 Primary care provision of CAM

An increasing number of GPs in the UK are now also offering CAM therapies within their practice. Therefore most NHS provision of CAM is in the primary care setting as it tends to be used for chronic conditions most prominently (Colin, 2000). In the majority of cases the GP themselves has completed training and offers to treat the patient directly. A survey on n=870 randomly selected GP practice respondents across England showed that 29.6% of GP practices offered some form of CAM via a member of the primary health care team, up 8% since 1995 (Thomas et al, 2003). The most common CAM therapies to be offered by doctors and other health professionals are homeopathy, offered with the primary health care team by 8% of practices and acupuncture, offered within the team by 20.5% (Thomas, 2003). Large professional bodies exist for health professionals practising CAM, including the Faculty of Homeopathy, which has 4,987 medically trained members (FOH, 2004), The British Medical Acupuncture Council who have 6000 members (BMAS, 2006) and the Acupuncture Association of Chartered Physiotherapists (AACP). A large proportion of the CAM practised by these affiliation members does occur in private practice. For example, a questionnaire survey on the use of acupuncture in Ireland found that private practitioners accounted for 92% of respondents who used acupuncture, of those who had managed two years part-time post-graduate training in acupuncture (McNeil et al, 2003). However, in the UK significant numbers of practitioners in these affiliations also working in the NHS, many of these would have completed shorter courses than those in the McNeil study and some health practitioners offer CAM within the remit of their orthodox practice. This demonstrates a form of integrated practise and in 1995, around 21% of general practices offered access to CAM via members of the primary care team (Thomas et al, 2001).

Another group of CAM practitioners are un-medically qualified individuals who have undergone full training, often in the form of a degree programme. Although these practitioners are most likely to work privately, there are incidences of integrated practice amongst these practitioners. In 1995, 6% of general practices employed independent CAM therapist (Thomas et al, 2001) and this had increased to 12% in 2001 (Thomas et al, 2003). The Thomas study also showed that an estimated 24% of NHS practises made CAM referrals and homeopathy accounted for 50% of these. Patients seeking CAM had the suggestion from their GP. Some NHS trusts, however, keep a list of registered non-medical CAM therapists, including homeopaths, who they will refer patients to. In some areas this is covered by the trusts NHS provision, reported in the 2001 survey as 26.8% of trusts making some kind of NHS CAM referral, including 14.9% to homeopathy treatment and 14.1% to acupuncture treatment (Thomas et al 2003) however, the study did not clarify how many of these referrals were to other practice members offering CAM service provision. In other practices the CAM referral is merely a recommendation to the patient, who will be required to cover the costs themselves.

A recent study carried out at the Bristol Homeopathic Hospital showed that 58% of patients who attended the homeopathy clinics were encouraged to go there by their GP (Thompson, 2004). Acupuncture is also often practised by GPs and physiotherapists and is therefore sometimes offered to patients within the NHS package of care. Based on figures from 1995, each year 220 million patient consultations were conducted in the primary care setting, and the figure had increased to 289 million per year in 2006 (Hippisley-Cox et al 2007): for 90% of people this is their only contact with the health service (Royal College of general practitioners Information Sheet no 3 July 1995). With growing numbers of GPs bringing homeopathy and acupuncture and other therapies such as herbalism and nutritional therapy into their practise, even though this a small minority of practices, the proportion of NHS provision of homeopathy is by no means insignificant.

1.6.3 History of NHS Homeopathic provision

The history of homeopathic provision by the NHS dates back to the founding of the NHS itself in 1948, when the 5 existing homeopathic hospitals were naturally incorporated into the new health system alongside more conventional hospitals. This five were the Royal London Homeopathic Hospital, the Tumbridge Wells homeopathic Hospital in Kent, The Bristol Homeopathic Hospital, The Glasgow Homeopathic Hospital and the Liverpool Homeopathic Hospital, this last mentioned hospital being the predecessor to the Department of Homeopathy at the Old Swan medical centre in Liverpool, where phase III of this study is based.

A lot of recent difficulties have faced the UK homeopathic hospitals mentioned above, and all of them have faced the prospect of closure during the past few years due to pressures such as decreased funding from Primary Care Trusts (PCTs) (Campbell & Fitzgerald, 8 August 2007). The Tunbridge wells Homeopathic Hospital was diminished in 2006 and services have mostly ceased. The Royal London Homeopathic Hospital has been under a lot of pressure in particular and has struggled to stay open, the fate of it is still under question.

1.6.4 Financial Implications of Integration

An obvious incentive for the health system to be integrative, in addition to the possible therapeutic benefits, is the cost effectiveness of many CAM treatments compared to conventional drugs. Homeopathy is particularly inexpensive due to the minute doses it uses. A case control study carried out at one integrative GP practice, n = 97, involving self-assessment questionnaires that were completed by the patients at the initial consultation and 6 months later, showed that 57% of patients who had GP-led practice based homeopathic treatment stopped or reduced their conventional drug intake, causing a saving of £2,807.30 per year and the rate that they needed to see a GP in a six month period reduced by 1.18 consultations per patient (Slade, 2004). A systematic review that contrasted the findings from the Slade study to two other local studies found similar results with 39% or more patients reducing medications, and GP visits dropping

by up to two thirds compared to those not taking CAM (Wye, 2009), with one centre reporting a potential savings of £8,944 per year (Christie & Ward, 1996). In a survey that compared the use of diagnostic tools by 27 homeopaths over a 1 year period to the results of a national ambulatory medical care survey, results suggested that homeopathic physicians used considerably less diagnostic tools for the same chronic conditions suggesting the possibility of additional cost savings through homeopathic treatment (Jacobs et al, 1998). One larger scale study followed n=493 patients with chronic diseases receiving either conventional or homeopathic treatment over a 12 month period recording treatments, contact time with clinicians and severity of symptoms from patient and practitioner reports (Witt, 2005). The study concluded that although treatment costs were approximately equal, the patients who sought homeopathic treatment had better outcomes overall, indicating a decline in future costs due to the disease. The findings of this study were supported by the Smallwood report, an enquiry focused on the role of CAM in the NHS, which concluded that homeopathic treatment was a less costly means to bring about improvement in patient satisfaction compared to the cost of conventional medicine to bring about the same degree of improvement (Smallwood et al, 2005).

1.6.5 The Evolving NHS and CAM

The cost savings suggested above indicate that financial incentives exist to provide CAM treatments for budget holders within the NHS. However in order to perceive financial implications in context it is necessary to consider structures that surround funding within the NHS

In order to understand the pressures on the main UK homeopathic centres mentioned above and to appreciate the standing of homeopathy within the healthcare system, it is necessary to put this into the context of the NHS itself. The NHS has been constantly evolving and in recent years has been subjected to a serious of almost continuous reforms. The management structures, regional divisions as well as categories of service provision and divisions of power and budget holding has been constantly reviewed and

revised within a healthcare service where funds remain strained and demands are continually increasing. The NHS trust budgets often have a deficit of funds and both primary care trusts (PCTs) and hospital NHS trusts constantly have to tighten their budgets, resulting in recruitment bans on vacant posts, the abolition of posts and ultimately cuts to services. The future of the NHS itself remains questionable and private funding initiatives (PFI) where partial funding comes from private sources is increasing. Trusts increasingly have to run like businesses and some services are now treated like social enterprises, whereby they become self dependant in generating their own income to continue to provide services.

As has been mentioned, homeopathy practice within the NHS is mostly contained within primary care. Primary care trusts have been subject to enormous reform during the last 2 decades and "Super surgeries" with several GPs often held within one practice are cropping up all over the country as separate practices merge. With PCTs now acting as fund holders for their own budgets, a process that began in 1991 and continued under the white paper "A service with ambition (Department of Health, 1996), and with increasing incentives for practices to go this way, they must now be very business minded, keeping a tight hold on the budget and concentrating on generating income. This change in budget management is believed to have made an impact on service provision by the trusts, with decisions on medical investigations and referrals to other services now having to take into account the direct impact of this on the trusts funds whereas previously this cost would be met centrally (Gosden & Torgerson, 1997). Unsurprisingly, GPs who are characteristically sceptic of CAM therapies in general are now less willing to refer patients to CAM services which they would be commissioning for themselves. Since most referrals to services at the Department of Homeopathy in Liverpool, for example, come from GP referrals the number of these referrals have dropped sporadically due to financial pressures (Campbell D & Fitzgerald M (The Guardian, Sunday 8 August 2007) therefore resulting in a reduced income at the hospital, which is struggling to find the means to stay open. Political pressure and the opposition to CAM treatment by a large component of the medical profession is adding

to this burden. Primary care trusts have put in place measures to stop new referrals being accepted by NHS homeopathic services, first subjecting them to a review panel to assess whether they should be funded (Barnet Primary Care Trust, 2007). It is clear that further evidence is required on clinical outcomes of CAM and cost effectiveness of homeopathy and acupuncture treatment.

1.6.6 Empowerment of patients

From a different view point, a priority of recent public health agenda focuses on empowering patients to take responsibility and be actively involved in the issues around their own health, as is reflected in recent white papers such as Choosing Health (Department of Health, 2004). Providing patients with the tools to do this as well as allowing choice in terms of which hospital they go for treatment is at the forefront of this (Department of Health 2009b). As previously discussed CAM is immensely popular with the general public. Patient choice may therefore ensure that treatments such as Homeopathy are not expelled from the service.

The aims of the current study will address the issues of the inclusion of CAM in mainstream healthcare and the research agenda for CAM. The aims are discussed in Chapter 2.

Chapter 2

Overview

2.0 Aims of the study

The future of CAM therapies including homeopathy and acupuncture therefore to some degree rests on reforms of the UK health system and with so many variables, policy changes and conflicting opinions the direction that this will take is by no means certain. It is for this reason that it is important to have information available on the practice of CAM practitioners, not only to inform clinical judgement on suitable treatments for individuals with conditions such as osteoarthritis, but also to inform the integration debate and on which to base different models of integrated systems.

Of the two most widely used CAM treatments for Osteoarthritis, there is a much larger evidence base on the practice of acupuncture than on homeopathy. The key purpose of this study is to build on the evidence base of homeopathic practise in the UK. The focus of the study is homeopathic treatment of osteoarthritis, a poorly managed condition within the contexts of conventional medicines and a condition that is commonly encountered by homeopathic practitioners (Colin, 2000) and acupuncture practitioners (Dale, 1997). Many of the issues concerning homeopathy and OA treatment are also pertinent to acupuncture and other CAM therapies. Phase 1 of the study seeks to gain much needed information on UK homeopathic practice through a practitioner survey, alongside a survey of acupuncturists to allow direct comparison between the two groups and expand findings relevant to CAM use in general. In Phase 2 areas identified in phase 1 that are relevant to homeopathic treatment of OA are further explored using qualitative interviews. The third phase of the study focuses on patients treated for OA in an integrated NHS department of homeopathy. The patient's treatment outcomes in addition to overall experiences of treatment are measured and observations on the operation of an integrated CAM practice are made. The results of this study will fill the

gap of knowledge on UK homeopathic practice, add to the evidence base of homeopathy for OA and provide insight to areas of focus for future studies on homeopathy for OA, and for other conditions. The results will therefore inform the integration debate and future homeopathy research.

The specific aims and objectives of each phase of the study is described in subsequent chapters, and the overall aims of the thesis are summarized below:

2.1 Overall Aims:

1) To identify and describe homeopathic and acupuncture practice in the UK and the extent of generalisability that applies to each therapy

2) To compare modes of practice and views of medically qualified and non-medically qualified homeopathic and acupuncture practitioners

3) To further explore homeopathic practitioners' experiences and opinions of their practice and in treating patients with osteoarthritis.

4) To obtain data from patients receiving homeopathy in the primary care setting on the functional and psychosocial aspects of homeopathic treatment.

2.2 Methodological Approach

This study takes a mixed methods approach, addressing the aims and objectives through a series of three phases.

The purposes of Phase one, as outline in section 2.1 of the following chapter, was to attain background information on homeopathy and acupuncture practice in the UK. This was an exploratory study addressing many areas where there is very little extant literature to date. Therefore, in order to access a wide and diverse sample and get a large quantity of data on a range of topics on acupuncture and homeopathy, a quantitative survey was used. This contained 9 topic areas with a total of 56 questions in the homeopathy questionnaire and 54 for the acupuncture questionnaire on areas including demographics, modes of practice, style of practice and opinions on theory. These were broad questions but covered some more specific areas relating to treatment of OA. Generalisations and comparisons were made between different groups of practitioners.

The aim of phase two was to further explore areas of interest highlighted by the phase one study using in depth interviews to gain an understanding of the processes of homeopathic treatment, focusing on consultations for osteoarthritis to gain an insight into the key dependable factors for potential health benefits of homeopathy. This allowed further exploration into the homeopathic consultation and other aspects of treatment.

In addition, this part of the study allowed information to be gathered that would be useful in phase three of the study, in terms of ensuring that the treatment under study in phase three utilised a representative treatment protocol, and to gain an understanding of the experiences and perspectives of homeopathic practitioners.

Phase Three was a clinical feasibility study and aimed to gain an insight into the perspectives of OA patients being treated with homeopathy, identify appropriate outcome measures that could be used in future trials and observe homeopathic treatment in an integrated NHS setting. Therefore, a sample of patients were recruited to be followed up at different time points over the first 6 months of treatment. They were asked open questions to allow freedom of expression on their experiences of

homeopathic treatment and also completed various outcome measures together with the researcher, to assess dimensions of pain, function and psychological aspects associated with OA. This included obtaining a saliva sample from the patient in order to perform a novel biomedical assessment of substance P as a biological marker of pain.

Chapter 3

Phase 1

3.1 Introduction

3.1.1 Medical Status of Practitioners

Homeopathy and acupuncture are both CAM treatments where practitioners are frequently medically qualified. However, a significant number of practitioners may be non-medically qualified. This study will look at both medically qualified and non-medically qualified practitioners, and whether their status has an influence on their mode of practice and beliefs. Professionalisation within CAM has increased over the past 2 decades, with smaller organisations merging to form larger umbrella organisations (Saks, 1999). The two largest homeopathy affiliations are the Faculty of Homeopathy and the Society of Homeopathy. The Faculty of Homeopathy is an association of medically qualified homeopaths. Members of the Faculty of Homeopathy may offer homeopathic treatment in the NHS but many also hold private consultations (Faculty of Homeopathy, 2004). The Society of Homeopaths is a well-recognised association of non-medical homeopaths. A small proportion of non-medical or independent homeopaths that belong to organisations such as the Society of Homeopaths are employed by primary care trusts (Thomas, 2001) but most members of the organisation work in private practice (SOH, 2002). Following pressure from the House of Lords (2000) the two societies came together to create a National Code of Standards in Homeopathic Treatment that stated matters like the degree of training that a homeopath must have. It was noted, however, that members of the Faculty of Homeopathy were not required to meet this. Medical doctors are required to undergo training at one of the courses accredited by the Faculty. This training consists of 3 to 4 years of study, involving 5 study days spread out through each year. This training can be seen to be less extensive than the courses required by the Society of Homeopaths and is a possible source of hostility between Society homeopaths and their medically trained colleagues. . Differing degrees of training can be perceived as having an effect on level of skills and knowledge for practice,

causing hostility from Society homeopaths to Faculty homeopaths. This scepticism over ability to be fit for practice may be reciprocated by medical homeopaths who may feel that non-medically trained homeopaths have inadequate medical knowledgeable for homeopathic practice.

The largest acupuncture affiliations in the UK are the non-medical British Acupuncture Council (BAcC), the British Medical Acupuncture Society (BMAS), and the Acupuncture Association of Chartered Physiotherapists (AACP). Training for membership to these affiliations follows a similar pattern to that required by the homeopathy affiliations. The BAcC requires acupuncturists to have 1200 hours of acupuncture education in order to be registered, compared with 100 hours for the BMAS. The AACP was previously 20 hours of education (Acupuncture Regulatory Working Group, 2003) but has increased to 80 hours since 2007

As stated by the House of Lords 6th Report on Science and Technology (2000), further research into homeopathy is required. This has been echoed in the conclusions of many of the studies into homeopathy, and it is important that these further investigations focus on the right areas, investigating a representative treatment model and commonly encountered conditions.

It will therefore be interesting to see any differences in modes of practice and views that arise in this study. Regarding homeopathy, these matters have not been previously investigated, though some documentation already exists for acupuncture. The current study will also provide some information regarding the validity of the medical world's views regarding integrative medicine. Equally, in this study, participants' views on other medical systems such as Ayurveda and conventional Western medicine will be covered as their opinions also would influence the structure of a successful model of integration.

3.1.2 Views and Practices of Homeopaths and Acupuncturists

Most research into homeopathy has focused on effectiveness, and little emphasis has been placed on the practice itself, including what methods are used by practitioners under

the umbrella of homeopathy. Equally, little serious consideration has been placed on the mechanism by which these treatments may work, or even the theories that the homeopaths themselves hold regarding this. Some areas of acupuncture practice have been studied more thoroughly in comparison to homeopathy but in other areas there is a lack of current evidence, for example the opinions of the practitioners. The current study focuses on these aspects and in sections 3.2-3.4 topics on acupuncture and homeopathy practice and the degree of availability of literature concerning them are reviewed in turn. Included in this study are aspects of how the therapies are practised in terms of conditions treated, consultation times, methods of practice, additional therapies practised, and views on matters relating to homeopathy and acupuncture.

3.1.3 Other Therapies Practised

An issue that is particularly relevant to integrative health care is the proportion of overlap that already exists. This can be conventional practitioners who also practise CAM within the context of their healthcare provision, or CAM practitioners who may have come from a healthcare background and continue to offer some conventional treatments.

In the case of homeopathy, treatment can be offered by conventional doctors who have trained in homeopathy, in addition to other conventional health professionals. Acupuncture can also be practised by medical doctors and other health professionals, in particular physiotherapists. It would be useful to see how many of these practitioners from different backgrounds actually practise other types of conventional or CAM therapy. The different therapies that all practitioners offer, their motivations for training in these areas and the setting in which they practise and the number of patients seen are all examined in this chapter.

Homeopathy and acupuncture have both been decreed therapies in need of further research (House of Lords, 2000), and both therapies have struggled to find suitable methodologies through which to conduct quality studies. A lot more literature exists on the practice of acupuncture in the UK, compared with UK homeopathic practice. The lack of knowledge about practice makes it impossible to design studies that are certain to be representative of UK treatment. Section 2.1 focuses on the literature

available on the practice of the two treatments and identifies where there is a knowledge gap.

3.1.4 Studies on effectiveness of homeopathy and acupuncture

Studies on the effectiveness of homeopathy for OA are discussed in section 1.3.1. Some interesting studies have been conducted of homeopathy for other conditions. Given that homeopathy remains a very controversial treatment, a brief summary on evidence for effectiveness for other conditions is provided in this section, to give an overview of the research base for the treatment as a whole. Acupuncture studies have predominantly focused on pain relief, though some studies on allergy and smoking cessation have also been conducted with favourable results. The evidence base for acupuncture and low back pain has now become strong enough to allow its inclusion in the recent NICE guidelines for management of low back pain (Savigny, 2009). Effectiveness of acupuncture for OA is discussed in section 1.3.2. Evidence on effectiveness for other conditions is beyond the scope of this study and is therefore not covered here. Perceived effectiveness for different conditions was investigated in a survey conducted on AACP members (n=112) in the UK (Altree, 1993). Participants were asked which pain conditions and non-pain conditions, of those they had experience of treating, they believed acupuncture to be most and least effective for. For the non-pain category, gynaecological, stress and allergy scored highest with neurology, tinnitis and inflammatory conditions scoring lowest. For pain conditions low back pain, neck pain, headache and non-specific musculo-skeletal scored highest and neuropathic pain, tennis elbow and foot and ankle pain scored lowest. The results were dependent on which conditions the participants had actually used acupuncture for, however, and since all were physiotherapists, the numbers who had treated the non-pain conditions in particular, were very low. The study was also conducted over 15 years ago, and up to date information in perceived effectiveness from AACP members and other acupuncture affiliations would be useful.

3.1.4(i)Trials on Effectiveness of Homeopathy

A large number of trials on the effectiveness of homeopathy have led to several reviews of the research to date. A meta-analysis carried out by Linde et al (1997) looked at all trials of homeopathy to date in all languages, which were either placebo

controlled or compared two types of treatment. The study included all forms of homeopathy and n=89 trials. The results showed an indication that homeopathic treatment was more effective than the placebo, but there was a lack of individually replicated models, and the study included all forms of homeopathy, many of which used the one size fits all approach. One of the main principles of homeopathy is that the remedies are individualised to the patient (Hahnemann, 1982; Vithoulkas, 1980).

Due to criticism received on the study, the Linde group went on to complete another review that this time focused solely on individualised homeopathy trials (1998). In this second study 32 trials fitted the inclusion criteria with an average of n-44 participants per trial. The results suggested that homeopathy had an effect over the placebo, however heterogeneity of the trials made it difficult to reach definite conclusions. It was also suggested that study designs that included replicability and quality control would be very beneficial in future.

One review covering 6 different trials all of which compared homeopathy to another form of treatment, found mixed results (Ernst, 1999). Two of the trials included showed homeopathy to be more effective than the conventional treatment and two of the studies suggested that conventional treatment was more effective than the homeopathic treatment. The review concluded that due to methodological error no conclusion could be made about treatment. This is a criticism often stated of trials of homeopathy (Shang, 2005).

In spite of the methodological constraints faced in conducting RCTs on homeopathy, new research continues to be produced. The Department of Health now produces an Annual Evidence Update on homeopathy which highlights this (Department of Health, 2009c). The current study will therefore investigate the degree to which homeopaths themselves feel that their treatment is effective for different types of conditions. This will provide information on whether the conditions that are frequently presented to homeopaths are ones that they feel confident in treating. It will also provide information which will allow future trials of homeopathy to focus on the most relevant conditions.

To date there is no available literature on perceived effectiveness of homeopathy by those who practise it.

3.2 Homeopathy in Practice

3.2.1 Commonly Treated Conditions

Little documentation has been produced on commonly treated conditions for homeopathy. Trials however have been criticised for not reflecting the treatments for conditions that homeopaths are most commonly presented with (NHS Centre for Reviews and Dissemination, 2002). Most conditions treated by homeopathy are chronic (Becker-Witt, 2004). An epidemiological study carried out in one homeopathic practice in France on n=2148 patients showed that rheumatological, mental and infectious diseases were the most common in homeopathic practice (Colin, 2000).

A recent observational cohort study investigating treatment of the patients attending the clinics of 103 homeopathic physicians in Germany and Switzerland (n=3,981 patients), where physicians documented aspects of the treatment for each case over a 2 year period, showed that the most common condition in adult males was allergic rhinitus, headaches in adult females and dermatological conditions in children (Becker-Witt, 2004). No widespread studies of this nature have been conducted so far in the UK.

One audit that was carried out in the UK, on 116 patients at the Bristol Homeopathic Hospital showed asthma / eczema especially in children was most common, plus IBS and hormonal problems (Thompson, 2004). A survey carried out in Norway on 1097 patients visiting 80 Norwegian homeopaths showed that the trend in commonly encountered conditions has changed in the past 15 years (Steinsbekk & Forrebo, 2003). The study compared the conditions that homeopathic treatment was sought for in 1985 with those in 1998. The results of the study showed that the proportion of patients that were children aged 9 and under had increased from 10% to 25% over the period. The most common conditions treated in 1998 were respiratory and skin complaints, compared with digestive and musculo-skeletal in 1985. The study also mentioned that in 1998 the 5 most commonly encountered conditions by homeopaths were the same 5 as those encountered by GPs.

The current survey provides an up to date overview of the conditions that homeopaths across the UK encounter most commonly. Also included are the homeopaths' own views on the effectiveness of homeopathy for particular treatments. This information will be useful to researchers when arranging the focus of trials and research in the area.

3.2.2 Initial Consultation Times

Recent studies into CAM have commented that the consultation period itself has a role in the effectiveness (Brian, 2004). Homeopathic treatment involves taking a detailed case history of the patient and therefore, traditionally, the initial consultation would be of some length, greatly exceeding that of a routine GP consultation. The Becker-Witt observational cohort study mentioned earlier found that the average initial consultation length for 2,851 adult consultations would last 117 minutes plus or minus 43 minutes, and the average length of initial consultation for 1, 130 children was 83 minutes plus or minus 36 minutes (Becker- Witt, 2004). The current study will look at the consultation length at UK homeopathic practices and investigate whether there is a difference between those of medical and non-medical practitioners.

3.2.3 Follow up appointments

The frequency with which homeopaths tend to see patients following the initial treatment is another area that is of interest with regard to possible integration and costing of homeopathic treatment. It is also an area where there is very little extant literature available. Another issue of importance is how frequent visits to a homeopath tend to be. The Becker-Witt study mentioned previously found that the average homeopathy patient in Germany and Switzerland had 8.6 appointments (plus or minus 9.3) per 2 years (Becker-Witt, 2004).

3.2.4 Assessment tools used

In clinical trials of homeopathy, the outcome measures chosen for the study are a determining factor on the success of the trial. Most trials of homeopathy have solely used the clinical assessments used in routine medicine (Jonas, 2001). However, as

has been previously mentioned, homeopathy is also believed to work on the vital energy of the patient, and certain effects of the treatment would therefore not be registered by these standard clinical assessments. Several assessment tools have been designed to determine the overall health of a patient. One such tool is the MYCAW (Measure Yourself Concerns and Well-being) questionnaire which allows patients to identify the main concerns and the degree to which their lifestyle is affected by their illness. The SF36 (Short Form 36) questionnaire contains a series of short questions designed to assess the patients' physical and mental health, including vitality and overall health. Another is the GHHOS (Glasgow Homeopathic Hospital Outcome Score), a score that the practitioner attributes to the overall health and condition of the patient. Some practitioners design their own questionnaires to make case history taking easier. This study will examine whether these tools actually reflect measurements taken in homeopathic practice in the UK to inform their suitability as outcome measures for homeopathic trials.

3.3 Homeopathic Prescribing

3.3.1Classical Homeopathy

Classical homeopathy is a term which often emerges in homeopathic literature. In spite of this there seems to be some controversy over what it actually means. In some cases it is simply used to describe individualised treatment (Relton, 2004). There does seem to be a little disagreement among homeopathic circles regarding whether classical homeopathy is a reflection of Hahnemann's early writings or those that he worked on in his later years, which are in some ways contradictory. For example there is the issue of single versus multiple remedies.

To some, classical homeopathy means prescribing single remedies (Drosdovech et al, 2002). The argument for this, presented in a debate on the issue at the London Homeopathic Hospital, is that when people prescribe multiple remedies they are delving into the unknown. Other symptoms may develop and it is impossible to tell which remedy is working and could cause problems with repeat prescription etc. Others however feel that in order to get the precise remedy a combination of homeopathic remedies must be used. They talk of the different aspects of the disease

and may incorporate knowledge from physiology or biochemistry with how the body is working with the simillium principles. In his earlier work Hahnemann stated that remedies must be used individually. However, in a 6th edition of the Organon, which did not get published until 1921, years after his death, he spoke of multiple remedies. The controversy over the validity of the 6th edition has not helped the dispute. It will be interesting to discover what proportion of homeopaths use this, and whether those with medical knowledge are more likely to use multiple remedies.

A similar issue of controversy in homeopathic prescribing is whether the correct method is to start with a remedy at a low potency and work upwards if necessary, or to start with a high potency and work downwards. This is another issue where Hahnemann's earlier writings are contradicted by some of his later methods.

It is the view of some homeopaths that such issues are futile and that being a true classical homeopath means having a clear understanding of the materia medica and maintaining the flexible approach necessary for successful treatment (Shah & Shah, 1994). In any case it will be interesting to observe which methods modern UK homeopaths put into practice.

3.3.2 Length of Treatment

Some homeopaths believe that homeopathic remedies must be given for the shortest possible time and in minimal potencies, due to the possibility of causing aggravational side effects. Aggravation is defined as a worsening of symptoms occurring close to the time of taking the remedy and is considered to often be followed by an improvement of symptoms. A recent audit carried out in Bristol Homeopathic Hospital on outpatients attending the clinic, n=116, showed that after 6 to 10 weeks of treatment 27% of patients experienced new symptoms and 18% experienced a return of old symptoms (Thompson, 2004). Some of these symptoms were experienced as adverse effects. The recurrence of old symptoms was considered to be due to the effects of Hering's Law. Hering's Law describes how illnesses effect the outermost areas of the body first where least damage can be done, and as they become more serious they move inwards the major organs and eventually to the mental plane. It would therefore make sense that, in the same way, as the body is

recovering from disease, the disease is then being pushed outwards to more external areas of the body and so early symptoms of the disease may re-emerge.

It will be interesting to evaluate from the current study to what degree homeopaths take precautions against aggravations of remedies and if this is different for non-medical and medical homeopaths, who are likely to be used to the side effects of many conventional medicines, an area that previous studies have not covered.

3.3.3 Remedy scales

Homeopathic remedies are measured on 3 different potency scales. Each homeopath appears to have the freedom to choose which of these he or she will prescribe. From speaking to several homeopaths, it became apparent that they are extremely interested in which of the scales their fellow homeopathic practitioners use the most.

3.3.4 Continuing conventional medicine

When most patients start homeopathic treatment, they are taking it for a condition that they have been taking conventional medicine to treat for sometime. Whether it is a musculo-skeletal condition that GPs prescribe NSAIDS or painkillers for, would the homeopath encourage their patients to continue with the treatment? Hahnemann himself wrote the following on mixing of homeopathic and allopathic medicine: -

> *"There are two principal therapies, the homeopathic method....and the allopathic method. They are directly opposed to each other, and only someone who does not know either...could make himself so ridiculous as to treat homeopathically one moment and allopathically the next to please his patients."*
>
> Organon of Medicine, 52.

As has been described, allopathic medicine refers to conventional medicine which is viewed as allopathic because it works by opposing the symptoms rather than homeopathy where the remedy in its original form would cause those symptoms. Medical homeopaths would be used to prescribing conventional medicines so are they more willing for the patient to continue with these at the initial stages of

homeopathic treatment than their non-medical colleagues? This study will investigate this.

The current study will address the areas mentioned, obtaining a description of general homeopathic practice, methods of prescribing and the views homeopaths hold on the theory behind the treatment. This will provide information on what a patient could expect from a typical homeopath, and indeed if there is such a thing. In addition any differences from a treatment by a medical compared with a non-medical homeopath will be highlighted. This information will provide evidence which could inform the debate on integrative medicine and provide guidance for future trials on the areas that they should focus on, and how to ensure that the homeopaths involved in the studies are fully representative of homeopaths in the UK.

3.4 Acupuncture in practice

Unlike for homeopathy, it is a well established fact that different types of acupuncture are practised in the UK by medical and non-medical practitioners (Birch, 1997). On The British Acupuncture Council (BAcC) website it explicitly states:

> *"....it is important for patients and healthcare professionals to understand the difference between the two styles most commonly on offer. Acupuncture as practised by members of the British Acupuncture Council (BAcC) is an holistic approach to health based on over 2,000 years of development and refinement in the Far East. The tradition is as much about the maintenance of health as the management of disease. Western or medical acupuncture is a more recent development practised predominantly by doctors and physiotherapists which uses acupuncture techniques within their existing scope of practice on the basis of a western medical diagnosis."*

In order to assess the different approaches to acupuncture treatment it is useful to focus on a few aspects relevant to acupuncture practice.

3.4.1 Diagnosis

Traditional acupuncture texts describe a range of diagnostic techniques including pulse and tongue diagnostics. Pulse diagnosis was reportedly used regularly by 83% of acupuncture practitioners and tongue diagnoses used regularly by 61% of practitioners from the affiliations that made up the Council for Acupuncture, now incorporated into the BAcC (Dale, 1997). A study that looked solely at acupuncture in physiotherapy by surveying members of the AACP, n=112, found that 15% of respondents used pulse diagnosis often or always, 23% used tongue diagnosis always or often and that the use of pulse and tongue diagnosis were significantly more frequent in respondents who had taken a long course of over 10 days tuition than in those who had taken a shorter course less than 10 days in length (Altree, 1993). An extensive initial consultation was also taken, where aspects including the nature of the complaint and the patient's general health would be discussed. With Western Acupuncture taking a different approach and different philosophy, this also influences the diagnostic techniques seen as necessary precursors to treatment.

3.4.2 Needling time

The type of needles, types of stimulation, depths of insertion, and needling time are variable in acupuncture treatment (Birch, 1998) but there is little documented evidence on the variance of the actual needling time used for treatment amongst UK practitioners. It has been estimated that the needling time of non-medical acupuncturists is longer than that used by medical acupuncturists (British Medical Association, 2000).

3.4.3 Conditions treated by Acupuncture

A large proportion of acupuncture practice centers around musculo-skeletal problems and pain relief (Mann,1987), but due to the holistic nature of acupuncture, traditional acupuncture can be used for a whole range of conditions. For example acupuncturists also treat other problems and believe acupuncture to be successful for other conditions including emotional problems, stress and asthma (Dale, 1997, Wigram, 1989). The AACP, being a physiotherapists' affiliation of acupuncturists

would see a large proportion of musculo-skeletal patients in the routine course of their practice. A study conducted in Northern Ireland on physiotherapists' use of acupuncture used a retrospective approach using patient notes (n=599) and also included a survey of patients who were receiving acupuncture from physiotherapists (n=200) (Kerr et al, 2003). The Kerr study found that the three main conditions the physiotherapists has used acupuncture for were lower back pain (29.4%), spinal injury (23.2%) and soft tissue injuries of the joints (28.0%). The acupuncture practitioners who gave treatment to the survey patients were AACP trained. The retrospective study was conducted on the notes of a single acupuncturist and the survey was set in the outpatients' department of a single Hospital Trust and so were limited to conditions routinely treated in physiotherapy outpatients. However, both parts of the study came out with the same conditions and this provides useful information on conditions AACP acupuncturists may encounter.

3.4.4 Type of acupuncture practised

A survey of 1975 acupuncture practitioners from the main acupuncture affiliations found that 24% of acupuncturists reported practising wholly traditional and 14% reported practising wholly Western Acupuncture (Dale,1997). The study showed that when this was broken down into the different affiliations, 85% BAcC member reported practising mainly or wholly Traditional Acupuncture, 83% of BMAS members and 60% of AACP members stated their practice was mainly or wholly Western and 11% of AACP members reported to spend more than 25% of their clinical time delivering acupuncture treatment (Wigram, 1989)

From the results of the Dale study, it is clear that there is some ambiguity regarding the classification, and what is involved in treatments classed under one of the types of acupuncture. A small, yet informative follow up qualitative study of interviews conducted with acupuncturists (n=10) confirmed that the classifications meant different things to different practitioners, both medical and non-medical, and found that an interface between different theoretical approaches to acupuncture was enabled by medical acupuncturists allowing themselves to hold more than one explanation simultaneously (Dale, 1997b).

Essentially one question that this study will investigate is "Is there such a thing as a form of representative homeopathic treatment in this country?" Whether the status of

the practitioner influences the treatment, in a similar way as in acupuncture (Dale 1997, Hughes 2008), will be considered with this question. By identifying the views of homeopathic theory, providing an audit of general homeopathic practice, and determining popular prescribing methods among homeopaths, with comparison to acupuncture results, this study will enable future studies to use the most appropriate designs.

The documented evidence on acupuncture practice is clearly more extensive than that for homeopathy practice. There are however certain areas concerning practice and acupuncturists' opinions that has not been fully explored. By conducting a parallel study of homeopaths and acupuncturists, and exploring a broad range of their views and practices, a good overview of the practice of two of the main CAM therapies used in the UK for osteoarthritis will be gained, and areas in need of future research and reflections on CAM and the current medical scene can be highlighted.

3.5 Aims

- To determine the degree of cohesion or divergence between the treatments provided under the umbrella of homeopathy in the UK
- To explore opinion of homeopaths on the treatment they provide
- To conduct a parallel study to investigate practices and opinions of acupuncturists
- To compare and contrast findings of the above homeopathy and acupuncture study

Objectives

- To identify approaches used in homeopathic treatment
- To identify any differences that exist between the practice of medical and non-medical homeopaths
- To determine how closely the homeopathic and acupuncture methods used in previous studies of homeopathy and acupuncture reflect those used in practice
- To explore opinions of homeopaths on theories underpinning homeopathy
- To gauge opinions on effectiveness, research, and other medical systems
- To identify differences in the practice of medical and non-medical acupuncturists
- To explore opinions of acupuncturists on theories underpinning acupuncture and issues surrounding its practice and research.
- To compile and contrast findings on homeopathy practice and acupuncture practice and consider implications of CAM integration models.

3.6 Pilot study

3.6.1 Homeopathy Survey

As this study was explorative in nature, questions targeting the gaps in literature on homeopathic practice, focusing on the broader aims of the study (see section 2.1) were assembled to form the questionnaire. This was first checked for face validity, using the expertise of three homeopaths. Amendments were made and the final draft questionnaire was then piloted on the first 10 members on the sample list from the two homeopathic affiliations. As this was an exploratory study, focusing on topics

where there was very little extant literature, a factor analysis test of validity was not conducted on the questionnaire content and layout. However, review of the questionnaire and involvement of three homeopaths in the questionnaire design ensured that the focus remained relevant and pilot questionnaires and comments insured that it was easy to follow and addressed the areas necessary. The response rate from the pilot questionnaires was then used to calculate the number of questionnaires to be dispatched in order to obtain the required sample size for the study. A 70% response rate was received from the pilot study. It was assumed that pilot participants may feel more inclined to reply as they have an important role in shaping the questionnaire so it was likely that the main questionnaire response rate might be half this at 35%. Minor amendments were then made to the questionnaire layout due to the comments of the respondents of the pilot study. Amendments made included the addition of questions relating to the remedy scale used by practitioners and relating to aggravations from remedies and a refinement of the questions relating to homeopathic theory.

3.6.2 Acupuncture Survey

The acupuncture questionnaire was formulated in a similar way to the homeopathy questionnaire. Matters concerning acupuncture practice that had been identified by the literature as being in need of further attention, areas of interest that arose during discussions with acupuncturists, and areas that were covered by the homeopathic questionnaire where a comparison with acupuncturists would be useful were formulated into the questionnaire. This was first checked for content and face validity by one non-medical acupuncturist and then piloted on the first 10 members of each acupuncture affiliation. A 40% response rate was obtained from the pilot. It was anticipated that the response rate from the questionnaire was likely to be about 50% of that of the pilot, due to the lower importance attached to participating and so it was estimated that the response rate would be approximately 20%. Minor amendments were made to the questionnaire based on the feedback from the pilot. These amendments included addition of questions on needling times, removal of questions relating to follow up consultations and follow up tools.

3.6.3 Design

This is an exploratory study conducted in order to achieve collection of data on a wide range of topics relating to the practice of homeopathy and acupuncture. A survey was used in order to achieve a large sample size and address a broad range of relevant topics. Questions were mostly of a quantitative nature but the questionnaire contained some open questions and space for comment.

3.6.4 Participants

The sample of perspective participants included all listed members of the Society of Homeopathy (SOH) and the Faculty of Homeopathy (FOH), the British Acupuncture Council (BMAS), the British Medical Acupuncture Council and the Acupuncture Association of Chartered Physiotherapists (AACP) in the areas covered by the survey. In order obtain a representative sample of UK practitioners, regions that have a high prevalence of homeopaths and acupuncturists were identified from the register of members to the affiliations included in the study. A stratified sample was taken of 25% BAcC Members and 33% of AACP members in each area. Members of the affiliations mentioned above in these regions were then given a number and randomly selected using computer generated numbers. In the case of the FOH, SOH and BMAS, stratified sampling was not possible due to low membership numbers and the survey was therefore sent to all members in the selected areas. The setting for the study was London and surrounding areas, Northern England including Manchester, Merseyside, Yorkshire and Scotland including Lothian and Strathclyde. A small number of participants from Wales and Northern Island were also randomly selected, to represent the few existing practitioners in these areas. Full figures for the selected participants are displayed in Tables 3(i) and 3(ii). Due to low numbers of members of the Faculty of Homeopathy in the regions mentioned, this sample tended to be more spread out around the areas, for example practitioners in close proximity to London, but with postcodes belonging to surrounding counties. to insure an adequate sample was obtained. In total n =415 homeopaths. Only duplicated practitioners who had a practice in more than one region covered by the study were excluded. The total number of acupuncturists sampled was n=800.

Table 3(i)– Homeopathy sample: Table to show the breakdown of numbers included in the sample from each location and from the two affiliations.

	Location					
	London & Surroundings (% of sample from affiliation)	**Manchester & Surroundings** (% of sample from affiliation)	**Merseyside** (% of sample from affiliation)	**Yorkshire** (% of sample from affiliation)	**Lothian & Strathclyde** (% of sample from affiliation)	**Other areas of England, Wales & N. Ireland** (% of sample from affiliation)
Faculty	53 (46%)	8 (7%)	4 (4%)	7 (6%)	30 (26%)	12 (11%)
Society	163 (55%)	19 (6%)	9 (3%)	95 (32%)	8 (3%)	7 (2%)
Overall	216 (52%)	27 (7%)	13 (3%)	102 (25%)	38 (9%)	19 (5%)

Table 3(ii)Acupuncture Sample: Table to show the breakdown of numbers included in the sample from each location and from the two affiliations.

	Location of Sample				
	London (% of sample from affiliation)	Manchester (% of sample from affiliation)	Merseyside (% of sample from affiliation)	Yorkshire (% of sample from affiliation)	Other (% of sample from affiliation)
BAC	86 (29%)	35 (12%)	51 (17%)	100 (34%)	22 (7%)
BMAS	24(28%)	4(5%)	12 (14%)	25(29%)	20 (24%)
AACP	112 (29%)	50 (13%)	110 (29%)	105 (27%)	5 (1%)
Total	222(36%)	84(13%)	198 (10%)	210 (36%)	47 (5%)

3.6.5 Choice of Sample Size

The sample size mentioned in section 3.6.4 was based upon the numbers of homeopaths and use of homeopathy in different areas and based on an assumed 35% response rate. The sample size used was enough to tap into a number proportionate to the homeopaths in the areas and to obtain a representative sample of UK homeopaths. The sample taken from each affiliation, in each region was in part limited by the number of registered practitioners who were listed and the sample of

each was between 30 and 100% of those listed per affiliation per region. It was predicted that the response rate for the acupuncture survey would be much lower, due to the number of surveys carried out on these groups in recent years. Therefore a greater number of acupuncture practitioners were approached in order to get a similar number of responses.

3.6.6 Ethics

Ethical approval was sought and granted for the study from the Liverpool John Moores University Ethics Committee. Participants received a cover letter with the questionnaire explaining the purpose of the study and assuring confidentiality and anonymity (see Appendix 1).

3.6.7 Data Collection Methods

The questionnaires were specifically designed for the study. Most quantitative data were gathered in the form of frequency counts and median values. The use of prescribing methods etc. was measured on ordinal rating scales, and attitude data gathered by means of five point Likert items (Oppenheim 1992).

Principal categories of information were based upon areas identified in the literature review and also on discussions with medical and non-medical homeopaths and acupuncturists.

Therefore the principal categories of information sought in the questionnaire were:

- Demographics – including affiliation and length of time practised
- Details of Practice – including other forms of medicine practised, number and duration length of consultations held and commonly encountered conditions
- Views on effectiveness of homeopathy / acupuncture on commonly encountered conditions
- Prescribing –to identify the frequency with which practitioners used certain methods of homeopathic prescribing
- Theory – designed to gauge the opinions of homeopaths / acupuncturists on matters of the underlying theory of homeopathy and acupuncture

- Research, attitudes and beliefs concerning homeopathy and acupuncture, including opinions on priorities for future research and views on other medical systems

The questionnaires can be found in Appendix 5 and 7.

3.6.8 Data Collection Procedures

The homeopathy questionnaire was mailed to all those in the selected sample from the two homeopathic organisations and the acupuncture questionnaire was sent to those selected from the three included acupuncture societies. The practitioners from each of these affiliations received their questionnaires printed on different coloured paper to ensure that it was clear which group responses were from. A covering letter was enclosed with the questionnaire and participants were given a prepaid envelope in which to anonymously respond.

3.6.9 Validity

Content and face validity of the homeopathy questionnaire was established by 2 medical and 1 non-medical homeopaths, after the incorporation of their suggested amendments. For the acupuncture questionnaire content and face validity was also ensured by a review by 1 medical and 1 non-medical acupuncturist and minor amendments were made in light of their comments. Several regions of the country were included in the study to ensure that no geographical bias arose.

3.6.10 Reliability

Large sample sizes ensured the reliability of the data. All participants received the same questionnaire and data was therefore fully comparable.

3.6.11 Analysis

Completed questionnaires were analysed using appropriate descriptive and non-parametric inferential statistics using SPSS version 14. Mann-Whitney U tests were performed to test for differences in groups and statistical significance was set at $p \leq 0.05$ (two-tailed). Certain items of interval data were analysed using independent t-tests where again significance was counted as $p \leq 0.05$. Qualitative data obtained

from the open-ended aspects of the questionnaire underwent basic content analysis according to themes and categories.

Specifically, analyses were carried out to determine:

- Differences in proportion from each affiliation who also practised other forms of medicine in addition to homeopathy/acupuncture
- Differences between the length of a consultation and the patient assessment tools used by medical and non-medical practitioners
- Differences in opinions on medical systems, effectiveness of their treatment and on research, between medical and non-medical practitioners
- Differences in prescribing methods between medical and non-medical practitioners
- Whether length of time acting as a practitioner influenced practice methods.

3.7 Results 1

The results of the questions on general details regarding participants and their practice are shown in section 3.7.2 to 3.8.0. Sections 3.8.0 onwards show the results of some modes of practice, plus opinions on aspects of homeopathic and acupuncture practice and theory, most questions in these sections were structured as Likert scales.

Many homeopathic practitioners wrote a lot of comments addressing specific questions on the questionnaire paper, but in spite of this most practitioners managed to answer each question. The acupuncturists also managed to answer questions and far fewer comments were made on the questionnaire paper.

3.7. 1 General information of Participants - Homeopathic Sample

The total response rate from the questionnaires was 40%. Responses consisted of members of the Society of Homeopaths (SOH) n= 110 and members of the Faculty of Homeopaths) n=64. Total sample n=174.

3.7.2 Status of Homeopaths

Of the homeopathy respondents from the Faculty of Homeopaths 14% had FFHOM status and the remaining 86% had MFHOM status. These respondents are treated as Medical Homeopaths throughout this section

The respondents referred to as non-medical homeopaths were all registered members of the Society of Homeopaths. However, some respondents from the SOH had specified that they practised as conventional health professionals, either currently or previously. This included counsellors, some professions that involved a greater medical background (n=5) such as allied health professionals, nurses, and a doctor. The responses of these 5 participants were analysed with the "medical" responses.

Table 3.1 shows details of the respondents' affiliation and their current location

Table 3.1 - Table to show the location of respondents to the study

	Location (Respondents)					
	London	Manchester	Merseyside	Yorkshire	Strathclyde & Lothian	Other areas of England Wales & Northern Ireland
Faculty	25 (40%)	6 (10%)	7 (11%)	11 (18%)	12 (19%)	5 (8%)
Society	61 (55%)	11 (10%)	5 (5%)	26 (23%)	4 (4%)	4 (3%)

As can be seen from Table 3.1, a large proportion of the responses were from the London area. This coincides with the majority of homeopaths from these two organisations being located in London.

3.7.3 General Information on Participants – Acupuncture Sample

The response rate for the acupuncture sample was lower, at 25%, as predicted. The breakdown of responses from the different acupuncturist affiliations is shown in Table 3.2(i) below. The regional breakdown of participants is shown in Table 3.2(ii).

Status of Acupuncturists

The British Medical Acupuncture Council (BMAS) and the Acupuncture Association of Chartered Physiotherapists (AACP) were analysed together as "Medical Acupuncturists". The responses from "non-medical acupuncturists" were those from members of the British Acupuncture Council (BAC) that had not indicated that they currently or previously practised a form of conventional medical treatment. Any BAC respondents who had practised as conventional medical health professionals were to be included with the "medical acupuncturists" data, though it turned out that there were no such participants.

Table 3.2 (i) The spread of respondents from the different acupuncture affiliations

Affiliation	No. Respondents
BMAS	21
BAC	74
AACP	100
Other	3
Total	**195**

Table 3.2 (ii) The proportion of respondents from different geographical locations.

	Location					
	London (% of affiliation)	Manchester (% of affiliation)	Merseyside (% of affiliation)	Yorkshire (% of affiliation)	Other (% of affiliation)	
BAC	20 (27%)	8 (11%)	11 (15%)	32 (43%)	3 (4%)	
BMAS	6 (29%)	1 (5%)	3 (14%)	6 (29%)	5 (24%)	
AACP	42 (42%)	17 (17%)	11 (11%)	27 (27%)	2 (2%)	
Total	58 (30%)	18 (9%)	49 (25%)	60(31%)	9 (5%)	

Table 3.2 (ii) The right-hand column titles "Other" includes areas in Scotland, Wales and Northern Ireland.

3.7.4 Length of Time in Practice

3.7.4 (i) How long participants had Practised Homeopathy

Table 3.3(i) shows the length of time that the respondents had been practising homeopathy. As can be seen from the figures, most homeopaths (84%) had been practising for at least six years and 56% had practised for 11 years or more. Figures for medical and non-medical homeopaths were very similar.

Table 3.3(i)– Table to Show the Length of time Respondents had been Practising Homeopathy

	Length of time practicing homeopathy			
	Under 1 Year	1 to 5 Years	6 to 10 years	11 years or more
Faculty	0 (0%)	10 (15%)	17 (27%)	37 (58%)
Society	1 (1%)	15 (14%)	41 (37%)	53 (48%)

3.7.4 (ii) How Long Practised Acupuncture

Table 3.3(ii) Length of time respondents from each affiliation had practised as acupuncturists

	Length of time practising Acupuncture			
	Under 1 Year	1 to 5 Years	6 to 10 years	11 years or more
BMAS	0 (0%)	5 (24%)	1 (4%)	15 (71%)
BAC	3 (4%)	25 (35%)	12 (16%)	33 (45%)
AACP	10 (10%)	47 (48%)	27 (28%)	13 (14%)

As can be seen in Table 3.3(ii) the majority of BAC and BMAS members had practised acupuncture for at least 6 years, where as over half of AACP members had practised acupuncture for less than 5 years.

3.7.5 Other forms of medicine practised

The questionnaire inquired whether the practitioners currently practiced any additional forms of medicine. Homeopathy results of this are shown in Table 3.4 (i) and acupuncture results in 3.4(ii). Actual figures and valid percentages are displayed in the tables.

Table 3.4 (i) Table to show the percentage of respondents for each group that practise other forms of medicine in addition to homeopathy

Affiliation	Currently Practise Conventional (NHS)	Currently Practise Conventional (Private)	Currently Practise Other CAM
Society of Homeopaths	10 (9%)	7 (6%)	19 (17%)
Faculty of Homeopaths	44 (71%)	14 (23%)	31 (49%)

Table 3.4(ii) - Table to show the percentage of respondents for each group that practise other forms of medicine in addition to acupuncture and NHS provision of treatment

Affiliation	Currently Practise Conventional (NHS)	Currently Practise Conventional (Private)	Currently Practise Other CAM	Acupuncture Always on NHS	Some NHS Provision of Acupuncture
BMAS	14 (67%)	2 (10%)	2 (10%)	8 (40%)	7 (33%)
BAC	2 (3%)	3 (5%)	42 (57)%	3 (4%)	9 (12%)
AACP	55 (56%)	7 (8%)	27 (28%)	47 (52%)	19 (20%)

Table 3.4(i) shows that members of the Faculty of Homeopathy were much more likely to practice conventional medicine and this was most commonly within the NHS, than members of the Society of Homeopaths. The proportion of homeopathy offered within the NHS was not explicitly covered in the questionnaire; however 30% of Faculty of Homeopathy members indicated through comments that they provided some homeopathy on the NHS, compared with no Society of Homeopathy

members. As can be seen from Table 3.4(ii), over two thirds of medical acupuncturists also practised conventional medicine, usually within the NHS, and only a small proportion practised other CAM. Very few non-medical acupuncturists also practised conventional therapies (n=3), and these participants reported that it was forms of counselling and coaching that they practised additionally to acupuncture. However, approximately two thirds practised other CAM. This other CAM was most commonly reflexology, homeopathy or massage. Over 75% of the two medical acupuncture affiliations (AACP and BMAS) reported to offer all or some acupuncture treatment on the NHS, compared with 16% of non-medical (BAC) acupuncturists.

3.7.6 (i) Reasons for Initial Interest in Homeopathy

Reasons for initial interest are displayed in Table 3.5(i) below. The results show that for the respondents from the Society of Homeopathy, the main theme that emerged as initial interest in homeopathy was a positive experience with the treatment itself, either by a family member or by the physician themselves. Other reasons included dissatisfaction with conventional treatments, attracted by its holistic nature and minimal side effects or introduced to homeopathy by a talk, or by a friend or family member. For members of the Faculty of Homeopathy the main themes were the same but more had turned to homeopathy because of their dissatisfaction with conventional treatments. Positive experience of homeopathy by a family member, a patient, or of his or her own was also a main theme. As can be seen in Figure 5(ii) a very similar pattern can be seen in reasons for initial interest in acupuncture, with similar themes seen but proportions of medical and non-medical respondents in each differing.

Table 3.5(i) Table to show the percentage of respondents for each of the themes that emerged as reasons for initial interest in homeopathy.

	Dissatisfaction with conventional medicine	Interest in Holistic Approach	Positive experience with Homeopathy	Exposed by a presentation or similar	Other
Med	12 (19%)	4 (6%)	9 (13%)	7 (11%)	1 (2%)
Nonmed	5 (5%)	8 (7%)	17 (15%)	4 (4%)	1 (1%)
Total	18 (10%)	12 (7%)	27 (15%)	11 (6%)	2 (1%)

3.7.6(ii) Reasons for Initial Interest in Acupuncture

Table 3.5(ii): - Table to Show the Percentage of Respondents for Each of the Themes that Emerged as Reasons for Initial Interest in Acupuncture.

	Dissatisfaction with conventional medicine	Interest in Holistic Approach	Interest in TCM	Positive experience with Acupuncture	Exposed by a presentation or similar	Other
Med	38 (32%)	17 (14%)	14 (12%)	28 (24%)	13 (11%)	4 (3%)
Nonmed	9 (12%)	14 (18%)	11 (14%)	31 (40%)	7 (9%)	5 (7%)

3.8 Results 2: Details of Practice

3.8.1 Length of Initial Consultation

Practitioners were asked how many minutes their average initial consultations would last, when treating a chronic condition. The results are shown in Tables 3.6(i-ii).

As can be seen from Table 3.6(i) the initial consultation lengths varied within both homeopathic groups, the non-medical homeopaths respondents initial consultation length ranged form 60 to 150 minutes, whereas the length for medical homeopaths ranged from less than 20 to 120 minutes. The duration was significantly longer ($p = 0.01$) for non-medical than for medical homeopaths, with a mean length of 90 minutes for non-medical compared to 56 minutes for medical homeopaths. Some medical homeopaths mentioned that they had to have significantly shorter initial consultations for NHS patients and that they felt that this time was not really sufficient.

Table 3.6(i)- The Length of Initial Homeopathic Consultations and the Interval Between Initial and Follow- up Appointment.

	Medical Mean Time	Non-Medical Mean Time	T Value	*P Value –Medical trained verses Non-medical Acupuncturists*
Time (Min) for initial Consultation	65	96	**-4.986**	**<0.01**
Time (days) for follow-up appointment for Ear infection	12	13	-0.732	0.47
Time (days) for follow-up appointment for Eczema	33	27	**3.372**	**0.01**
Time (days) for follow-up appointment for Osteoarthritis	40	29	4.186	**<0.01**
Significance values from independent T-Tests between the two groups are displayed on the right hand column and significant values are shown in bold.				

Table 3.6(i) shows the time interval that the two groups of homeopaths left between the initial consultation and a follow up consultation for three different conditions. These follow-ups were face to face contacts between the practitioner and patient and it should be noted that some participants, from both affiliations but mainly non-medical, commented that they would first review their patients by telephone, most commonly after 7 days. As can be seen, the length of time between the two face to face appointments was significantly longer with medical homeopaths than non-medical homeopaths when treating eczema and osteoarthritis.

Table 3.6(ii) – Consultation Times and Needling Times of Acupuncturists

	Medical Mean Time	Non-Medical Mean Time	T Value	*P Value –Medical trained verses Non-medical Acupuncturists*
Time (Min) for initial Consultation	43	65	**-6.037**	**<0.01**
Time (days) for follow-up consultation	7	8	-.0832	0.41
Needling Time (mins) for an Ear infection patient	26	19	**1.974**	**0.01**
Needling Time for eczema treatment	20	22	0.824	0.82
Needling time for Osteoarthritis patient	20	23	**-2.409**	**0.02**
In addition average needling time for specified conditions is displayed. The results of an independent T-Test comparing the two groups is shown in the right hand column. Differences that were found to be significant at p= 0.05 in an independent t test are shown in bold.				

3.8.2 Number of Visits Likely to be Needed to Achieve 80% Improvement in Symptoms

3.8.2 (i) Homeopathy

Table 3.7(i) - Table to Show the Mean Reported Number of Visits to Achieve 80% Improvement in Symptoms.

	Median Treatment length for 80% Improvement in symptoms		Mean Rank		U Value	p Value
	Medical Median (IQR)	Non Medical Median (IQR)	Medical	Non Medical		
Ear Infection	4 (0)	4 (0.5)	83.6	75.5	2713.5	0.81
Eczema	3 (1)	3 (0)	85.9	71.7	2422.5	**0.03**
Osteoarthritis	3 (2.5)	3 (1)	78.8	64.3	1962.0	**0.03**
The results of a t-test comparing the values of the two groups is shown and significant values are asterisked. The questionnaire used a 4 point Likert Scale where 1= More than 12 Visits, 2= 8-12 Visits, 3= 4-7 Visits and 4=1-3 Visits						

Table 3.7 (i) shows that the number of visits the patients would actively visit the homeopath for treatment for Eczema and OA was significantly greater with non-medical practitioners than with medical ones. Ear infections were reported to need three or less visits by both medical and non-medical. The median number of visits ranged from 4 to 7 for Eczema treatment for both medical and non-medical practitioners, though non-medical reported significantly larger numbers of visits, as indicated by the mean rank (p=0.03). The mean number of visits for Osteoarthritis treatment was also 4-7, again with non-medical generally reporting greater numbers of visits than medical participants (p=0.027). For both groups, however, the range of response values was much wider for osteoarthritis. It is worth noting that a large number of medical (30%) and non-medical (36%) participants reported that they would most likely need 8 or more treatments and 15% reported that they would need over 12 visits in order to achieve an 80% improvement in manageability of OA.

3.8.2 (ii) Acupuncture

Table 3.7(ii) Displays the Reported Number of Visits to Achieve 80% Improvement in Symptoms.

	Median Acupuncture Treatment length for 80% Improvement in Symptoms			Mean Rank	Mean Rank	U Value	p Value
	BMAS Median (IQR)	AACP Median (IQR)	BAC Median (IQR)	Med	Non-med		
Ear Infection	4.5 (2)	5 (4)	4 (1)	24.9	21.3	116.5	**0.47**
Eczema	4 (1.5)	4 (3)	2 (2)	34.9	23.69	144	**0.02**
Osteoarthritis	4 (1)	4 (2)	3 (2)	71.1	43.9	939	**<0.01**

The median values of reported visits were assessed on a 5 point Likert scale where 1= 1-3 visits, 2=4-6 visits, 3= 7-9 visits 4= 10-12 visits and 5 is more than 12. Significant results of a Mann-Whitney test are displayed in bold in the right-hand column.

The acupuncture data, the majority of medical acupuncturists did not complete the question on ear infection, with 93% of AACP members and 81% of BMAS participants leaving this question blank, stating they did not treat those conditions. Similarly for Eczema 94% of AACP members and 57% of BMAS participants did not feel able to answer this question. Therefore only the osteoarthritis results can be

considered for number of visits to an acupuncturist. In the case of acupuncturists, medical acupuncturists needed to see patients for a significantly longer number of visits for an 80% improvement than non-medical acupuncturists ($p=0.001$), with a mean number of visits being between 7-9 visits to non-medical compared to 10-12 for medical acupuncturists.

3.8.3 Use of Assessment Tools

Homeopaths were asked the frequency with which they used certain patient assessment tools that are sometimes used as outcome measures in trials of homeopathy. This question took the form of a Likert scale on frequency of use of each point. This information was primarily to inform phase 3 of the current study. Therefore the same specific question was not addressed in the same way in the acupuncture survey. In the acupuncture survey the use of an initial questionnaire for completion prior to the start of treatment was investigated, with room for comments on other tools.

3.8.3(i) Homeopathy

The results of homeopathic participants' use of certain outcome tools are shown in Table 3.8(i).

Table 3.8(i) – Table to Show Use of Patient Assessment Tools by Practitioners

Assessment Tool	Overall Median	Faculty of Homeopaths		Society of Homeopaths		U Value	p value
		Median	Mean Rank	Median	Mean Rank		
Own patient questionnaire	1 (IQR=3)	3 (IQR 3)	92	1 (IQR= 2)	81	3037	0.10
GHHOS	1 (IQR= 0)	1 (IQR 2)	104	1 (IQR=0)	69	1955	**<0.01**
SF36	1 (IQR=0)	1 (IQR 1)	85	1 (IQR=0)	81	3105	0.15
MYCAW or MYMOP	1 (IQR=0)	1 (IQR 1)	83	1 (IQR=0)	82	3256	0.96

The GHHOS = Glasgow Homeopathic Hospital Outcomes Score, SF36 is the short form 36 questionnaire MYCAW= Measure Yourself Concerns and Well-being –The median scale was on frequency where 5 = Always 4 = Often 3 = Sometimes 2=Rarely 1 = Never. Mean ranks are shown The right hand column shows the significance obtained from a Mann-Whitney test on differences between the two groups. Significant differences are shown in bold.

The results show that generally most homeopaths never use the tools listed, except that medical homeopaths sometimes use a questionnaire prior to the initial appointment. The mean ranks of frequency values relating to the Glasgow Homeopathic Hospital Outcome Score (GHHOS) show that in spite of the median value for usage of this by medical homeopaths and non-medical alike being "never", medical homeopaths used the score significantly more frequently than non-medical homeopaths.

3.8.3 (ii) Acupuncture

Assessment tools were not generally used by acupuncturists aside from use of an initial questionnaire by some. This was most usually a self created one but occasionally the MYMOP tool (3% of respondents). Rates of use of pre-assessment questionnaire are displayed in Table 8(ii).

Table 3.8(ii) – Acupuncturists Use of Questionnaires Pre-assessment

Assessment Tool	BMAS Median	AACP Median	BAcC Median	Mean Rank		U Value	p value
				Medical	Non-medical		
Initial questionnaire Usage	1 (IQR=2)	1 (IQR =4)	1 (IQR=1)	70.2	68.5	536.5	0.732
Median Scale: - 1=never, 2=Rarely, 3=Sometimes, 4=Often 5=Always. Results form Mann-whitney test is shown in the right hand column							

3.8 .4 Commonly Encountered Conditions

Participants were asked for the five conditions they most commonly were presented with in their homeopathic practice. The results from this question are shown in Tables 9(i)-(ii) and Figure 3.

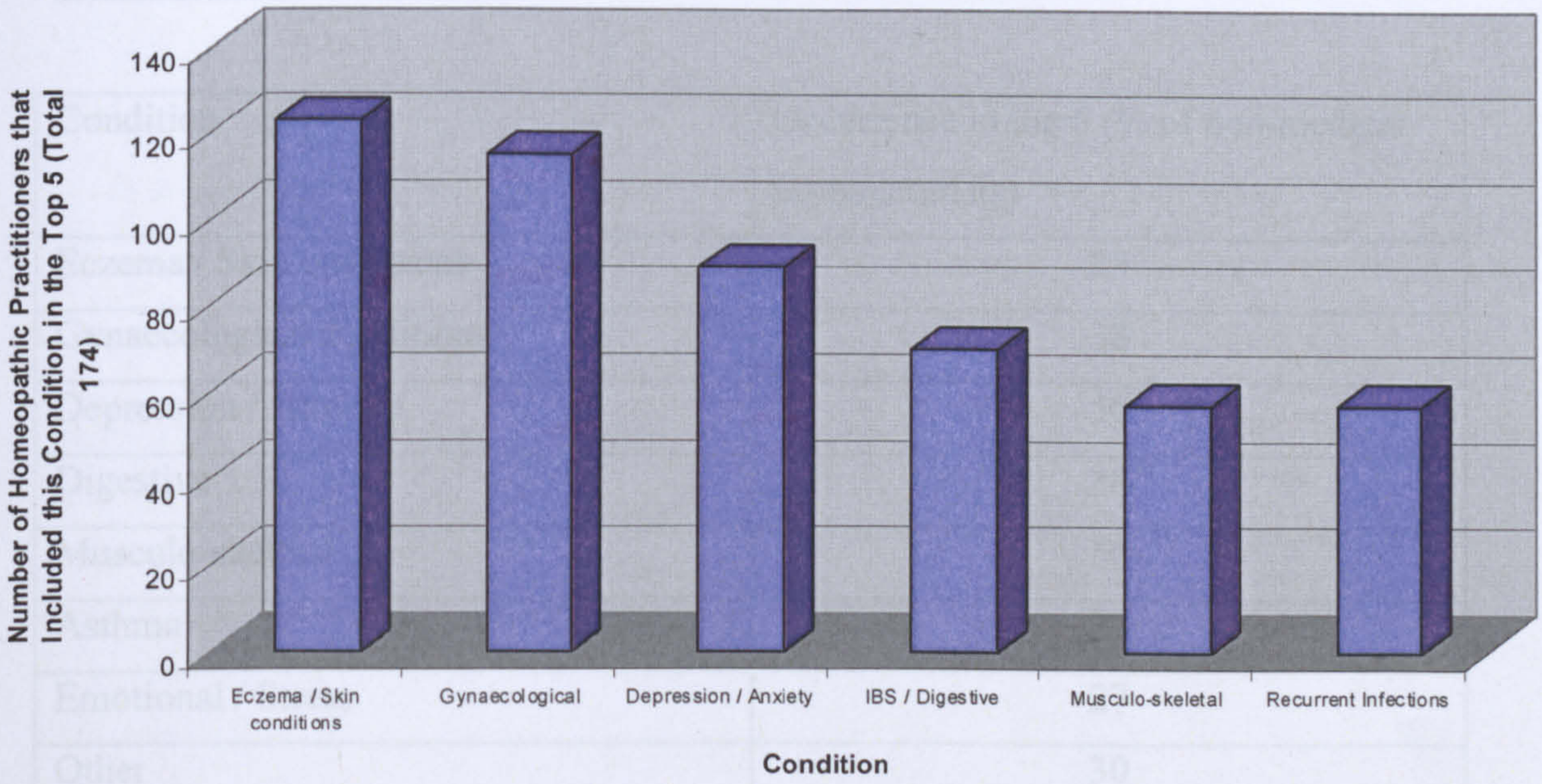
3.8.4 (i) Conditions encountered by homeopaths

The five most commonly encountered conditions were eczema, gynaecological conditions, including premenstrual stress and menopausal symptoms, depression and anxiety, digestive disorders and with tie between musculo-skeletal conditions and recurrent infections as the fifth most commonly encountered condition.

Table 3.9(i): - Conditions that Were in the Top 5 Most Commonly Encountered by Homeopaths in Their Homeopathic Practice

Condition	Number of practitioners reporting in top 5	Percentage of total (174)
Eczema / Skin conditions	123	71
Woman's Gynae	115	66
Depression / Anxiety	89	51
IBS / Digestive	70	40
Musculo-skeletal	57	32
Recurrent Infections	57	32
Asthma	50	29
Emotional / Stress	50	29
Allergy	26	15
Childhood related	26	15
General Poor Health	24	14
Head aches	21	12
CFS	21	12
Cancer	14	8
CV / Hypertension	10	6
ME	5	3
Psoriasis	5	3
Chronic Unexplained	5	3
Pain (general)	5	3
Phobias	3	2
Ear ache	3	2
Colic	3	2

Figure 3: -Chart to Show theTop 5 Most Frequent treatments Encountered



3.8.4 (ii) Conditions commonly encountered by acupuncturists

The conditions encountered by medical acupuncturists were mostly musculo-skeletal problems or other types of pain. As a large proportion of the medical acupuncturist respondents were physiotherapists this is as expected. The BMAS respondents however also appeared to mainly use acupuncture for pain relief alone, this was generally musculo-skeletal pain. However some BMAS members also used acupuncture to treat eczema and depression.

The conditions encountered by non-medical acupuncturists are shown in Table 3.9(ii) below. As can be seen in Table 3.9(ii), 50% of non-medical acupuncturists reported that musculo-skeletal problems were among the top 5 most commonly encountered conditions. The other conditions that were also reported to be in the top 5 were very similar to those encountered by homeopaths, namely chronic conditions.

Table 3.9 (ii) - Percentage of Non-medical Acupuncturists Reporting Condition to be in Top 5 Encountered

Condition	Occurrence in top 5 (% of non-medical acupuncturists)
Eczema / Skin conditions	25
Gynaecological conditions	38
Depression / Anxiety	50
Digestive	38
Musculo-skeletal	50
Asthma	27
Emotional / Stress	27
Other	30

3.8.5 Effectiveness of Treatment for Stated Conditions

Respondents were asked their level of agreement on a 5 point Likert Scale on homeopathy/acupuncture being an effective treatment for some listed conditions. The results of this are shown in Table 3.10(i)-(ii).

3.8.5(i) Effectiveness of Homeopathy for Stated Conditions

Table 3.10(i) Table to Show Median Opinions of the Two Groups with Regard to Homeopathy Being an Effective Treatment for the Stated Conditions.

	Overall	**Faculty Homeopaths**		**Society Homeopaths**		**P value**
	Median (IQR)	Median (IQR)	Mean Rank	Median (IQR)	Mean Rank	
Homeopathy is effective for musculo-skeletal conditions	4 (1)	4 (1)	94	4 (1)	80	**0.046** (U=2944)
Homeopathy is effective for skin conditions	5 (1)	4 (1)	81	5 (1)	90	0.17 (U=3176)
Homeopathy is effective for asthma	5 (1)	4 (1)	75	5 (1)	93	**<0.01** (U=2738)
Homeopathy is effective for menopausal	5 (1)	4 (1)	78	5 (1)	90	**0.04** (U=2949)
Homeopathy is effective for acute illness	5 (1)	4 (1)	72	5 (1)	95	**<0.01** (U=2547)
Homeopathy is effective for mental illness	4 (1)	4 (1)	79	4 (1)	90	0.11 (U=3031)
Homeopathy is effective for all illnesses	4 (2)	3.5 (2)	68	4 (1)	96	**<0.01** (U=1600)

Median Opinion Scale 5 = Strongly agree 4=Agree 3 =Neutral 2=Disagree 1 = Strongly disagree.

The right hand column shows the results of a Mann-Whitney test on the medians, and significant differences between the two groups are shown in bold. Mean ranks, medians and inter-quartile range (IQR) are also shown.

It can be seen from Table 3.10(i) that homeopaths in general felt that homeopathy was effective for all the conditions listed and also agreed that homeopathy was in fact an effective treatment for "All Conditions". However some significant

differences were found here between the two groups, as Society homeopaths "strongly agreed" that homeopathy was effective in treating skin conditions such as eczema and also asthma, menopausal/ pre-menstrual symptoms and acute illness. The significance values are displayed in bold in Table 3.10(i).

3.8.5 (ii)Perceived Effectiveness of Acupuncture for Specified Conditions

The results of perceived effectiveness of acupuncture for different conditions are shown in Table 3.10(ii).

Table 3.10(ii) Acupuncturists' Perceptions of effectiveness

	BMAS Median (IQR)	AACP Median (IQR)	BAC Median (IQR)	Medical Mean Rank	Non-Medical Mean Rank	*P Value – Medical trained verses Non-medical Acupuncturists*
Acupuncture is effective for Musculo-skeletal conditions	5 (0)	5 (1)	5 (0)	67	76	0.08 (U=1832)
Acupuncture is effective for skin conditions	3 (1)	3 (1)	4 (1)	51	86	<0.01 (U=795)
Acupuncture is an effective treatment for asthma	3 (1)	3 (0)	5 (1)	44	97	<0.01 (U=264)
Acupuncture is an effective treatment for Menopausal symptoms	4 (2)	3 (1)	5 (1)	47	93	<0.01 (U=460)
Acupuncture is an effective treatment for anxiety and depression	4 (1.5)	4 (1)	5 (0)	50	88	<0.01 (U=713)
Acupuncture is an effective treatment for digestive disorders	4 (1)	3 (1)	5 (0)	44	98	<0.01 (U=264)
Acupuncture is an effective treatment for Chronic Fatigue Syndrome	3 (1)	3 (1)	4 (1)	47	98	<0.01 (U=455)
Acupuncture is an effective treatment for Acute illness	3 (1)	3 (0)	4 (1)	47	95	<0.01 (U=1005)

Median Scale: 5= Strongly Agree, 4=Agree, 3= neutral, 2= Disagree, 1= Strongly Disagree The results of a Mann-Whitney significance test comparing medical and non-medical acupuncturists are shown in the far right hand side column, significant results in bold. The mean rank in the fifth and sixth to last columns gives an indication of the spread of results.

As can be seen in Table 3.10(ii), for most conditions encountered, non-medical acupuncturists believed significantly more strongly that acupuncture is an effective treatment for the condition. These results therefore follow the same pattern as the opinions of homeopaths on effectiveness shown above. Opinions on effectiveness of acupuncture for musculo-skeletal conditions, however, fell just short of significant, with both medical and non-medical acupuncturists strongly agreeing that acupuncture is effective in treating musculo-skeletal conditions. It should be noted that as many medical acupuncturists only treated musculo-skeletal conditions, their opinions on acupuncture for other conditions are more speculative in nature.

3.8.6 Methods of Prescribing

Practitioners were asked to state the frequency with which they used certain methods of prescribing in their practice. The five frequency groups were Always, Often, Sometimes, Rarely and Never. Responses were used to calculate a median frequency for each group. A Mann-Whitney Test was then used to compare the medical and non-medical responses. The results of this are shown in Table 3.11(i) and Table 3.11(ii). Significant differences are displayed in bold in the right hand column.

3.8.6.1 Modes of Homeopathic Prescribing

TABLE 3.11(i) – Homeopathic Prescribing	**Total Median**	**Medical (Faculty of Homeopaths*)**		**Non-medication (Society of Homeopath)s**		***P* value**
		Mean Rank	**Median**	**Mean Rank**	**Median**	
I use multiple remedies	2 (IQR 2)	90	2 (IQR=1)	78	2 (IQR 2)	0.12 (U=2849)
I start with a high potency and work down	2 (IQR 2)	99	3 (IQR 1)	65	1 (IQR 1)	**<0.01** (U=1662)
I advise patients to continue taking their normal medicine at the beginning of treatment	5 (IQR 1)	91	5 (IQR 1)	78	4 (IQR 2)	**0.05** (U=2804)
I give homeopathic remedies for the shortest time possible	4 (IQR 1)	69	4 (IQR 1)	85	4 (IQR 1)	**0.02** (U=2352)
I follow a course of homeopathic medicine with a placebo to allow medicine time to work through	1 (IQR 1)	83	1 (IQR 1)	86	1.5 (IQR 1)	0.70 (U=3340)
I identify the typology of the patient and use this when prescribing	4 (IRQ 1.5)	88	4 (IQR 1.5)	82	4 (IQR 2)	0.46 (U=3196)
I use the decimal scale	3 (IQR 1)	74	2 (IQR 1)	90	3 (IQR 1)	**0.02** (U=2656)
I use the centesimal scale	4 (IQR 0)	88	4 (IQR 0)	82	4 (IQR 0)	0.30 (U=3160)
I use LM doses	3 (IQR 2)	82	3 (IQR 1)	87	3 (IQR 2)	0.34 (U=3116)

* See section 3.4.2 Scale values are 1=never, 2=rarely, 3=sometimes,4=often, 5=always

3.8.6.1 (i) Common Modes of Prescribing Across Homeopathic Affiliations

As can be seen from Table 3.11(i) the median frequency for multiple remedies in both groups was "rarely" use, showing a preference for single remedy prescribing across the board. In addition, both medical and non-medical participants rarely or never used the method of following a course of homeopathic medicine with a blank placebo tablet to enable the patient to allow the remedy time to work through. The median value for both groups was "often" identifying the typology of the patient and

use this information when prescribing, with an inter-quartile range of "sometimes to always". In terms of remedy potency scales used, both medical and non-medical homeopaths "often" used the centesimal scale, the inter-quartile range indicating that the majority of participants replied "often" to this question, and "sometimes" used LM doses.

Some significant differences were also found in homeopathic prescribing methods.

3.8.6.1 (ii) Usage of initially high potencies then decreasing

The method of beginning treatment with a high potency of a remedy and then proceeding to work down to lower doses was investigated and the results are shown in Table 3.11(i). Homeopaths from the sample as a whole responded to the question with a median of "rarely" use multiple remedies. The median value for this method of prescribing among the Faculty of Homeopaths respondents was 3, equating to "sometimes" . This value among respondents from the Society of Homeopaths was 1.5, equating to the median response being found somewhere between rarely and never. The results of a Mann-Whitney test carried out on this difference between the two groups proved that the difference was significant (p=0.01).

3.8.6.1 (iii) Continuing Routine Medication During Treatment

Table 3.11(i) shows that when asked if they advise patients to continue taking their normal medication (e.g. pain killers and anti-inflammatory) during the initial stages of treatment the median response from the group as a whole was "Always". However a difference was seen between the responses from the two groups. The Faculty homeopaths stated they would "always" advise this whereas the median frequency for Society homeopaths was that they would "often" advice this. This difference was significant under the Mann-Whitney test (p = 0.05).

3.8.6.1 (iv) Prescribing Remedies for the Shortest Time Possible

The median frequency for the group of respondents collectively for placing emphasis on giving a remedy for the shortest time possible was "often". This was still the case for the two groups separately, although the mean rank shown in Table 3.11(i) was considerably higher for Society homeopaths, suggesting that they would do this more frequently than the Faculty homeopaths. This difference was found to be significant (p=0.02).

3.8.6.1 (v) Usage of Decimal Scale Potencies

Medical homeopaths "rarely" prescribed the decimal scale potencies, compared with non-medical homeopaths who "sometimes" used the decimal scale. This result was significant in a Mann-Whitney test at p=0.02.

3.8.6.2 Acupuncture Practice Methods

Table 3.11(ii) – Frequencies of Usage of Different Acupuncture Techniques

	BMAS Median (IQR)	AACP Median	BAC Median (IQR)	Medical Mean Rank	Non-Medical Mean Rank	*P Value –Medical trained verses Non-medical Acupuncturists*
I use pulse diagnosis	2 (2)	1 (0)	5 (1)	49	109	**<0.01** (U=267)
I analyse the emotional state of patients	4.5 (2)	3 (2)	5 (1)	58	90	**<0.01** (U=1098)
I ask patients to complete an initial questionnaire prior to treatment	1 (3)	1 (4)	1 (1.5)	70	68	0.73 (U=2050)
I insist that a patient has a Western diagnosis prior to acupuncture treatment	5 (0)	5 (0)	3 (2)	85	35	**<0.01** (U=527)
I advise patients to continue taking their normal medicine at the beginning of treatment	5 (1)	5 (0)	5 (1)	67	70	**0.63** (U=1941)
I practise TCM acupuncture	2.5 (3)	4 (1)	5 (1)	52	104	**<0.01** (U=481)
I practise Western Acupuncture	5 (1)	4 (1)	1 (0)	84	24	**<0.01** (U= 159)
I practise Japanese Acupuncture	1 (0.5)	1 (0)	1 (2)	60	80	**<0.01** (U=1334)
I practise 5 element Acupuncture	1 (2)	1 (0)	2 (3)	58	85	**<0.01** U= 1145)

Scale values are 1=never, 2=rarely, 3=sometimes,4=often, 5= always .

The median rank is also displayed. A Mann-Whitney test was carried out on each to determine whether any differences between the two groups were significant. Significant differences are displayed in bold in the right hand column

Many differences were highlighted by the results between medical and non-medical acupuncturists, with just two similarities found.

3.8.6.2 (i) Continue Conventional Medication

The only practice method that medical and non-medical acupuncturists shared that was highlighted by the survey was the practice of advising patients to continue their routine medication at the start of treatment. The median values for all three affiliations show that members from each group "Always" advised their patients to continue taking their routine conventional medication during acupuncture treatment. All other factors tested showed significant differences between the two groups.

3.8.6.2 (ii) Pulse Diagnosis

Results of pulse diagnosis can be seen in Table 3.11ii. It can be seen that there was a significant difference at $p=0.01$ between the frequency of use of the pulse diagnosis technique between medical acupuncturists who used it "rarely (BMAS) and never (AACP) and non-medical acupuncturists who used it "Always".

3.8.6.2 (iii) Emotional Inquiry

As can be seen in Table 3.11(ii), median values showed that emotional inquiry was used "Always" by both BMAS and BAC members but only "Sometimes" by AACP members. When the two medical groups were combined and tested against the non-medical acupuncturists the differences were found to be significant, reflecting that the sample sizes for AACP were considerably larger than for BMAS.

3.8.6.2 (iv) Use of an Initial Questionnaire

Median values showed that members of all three Acupuncture affiliations "Never" used an initial questionnaire prior to treatment in order to obtain information on the patient and save time in the consultation.

3.8.6.2 (v) Western Diagnosis

As can be seen in Table 3.11(ii) medical acupuncturists from both affiliations "Always" insisted on a Western diagnosis prior to the start of acupuncture treatment.

This was shown to be significantly more frequently, at p=0.01, than non-medical acupuncturists who only "Sometimes" sought a Western diagnosis.

3.8.6.2 (vi) Acupuncture Style practised

As can be seen in Table 3.11(ii) medical acupuncturists indicated that they "Always" (BMAS) and "Often" (AACP) practised Western acupuncture. Both medical groups also stated that they "Sometimes" practised TCM acupuncture, but "Never" practised Japanese acupuncture or 5 element acupuncture. In comparison non-medical acupuncturists "Never" practised Western acupuncture, "Always" practised TCM style acupuncture, "Rarely" practised 5-element acupuncture and "Never" Japanese acupuncture. The difference in frequencies between medical and non-medical use of all four styles of acupuncture practise were found to be significant in the Mann-Whitney test at p=0.01

3.8.7 Opinions on Underlying Theory

3.8.7.1 Homeopathy

The Opinions of homeopaths on issues regarding homeopathic theory was asked using a Likert scale of opinions. The results of this are displayed in Table 3.12(i).

Table 3.12(i) Median Opinions on Homeopathic Theory

	Total	**Medical (Faculty of Homeopaths*)**		**Non-medical (Society of Homeopaths)**		
	Median (IQR)	Median (IQR)	**Mean Rank**	Median (IQR)	**Mean Rank**	***p* value**
Consider self as classical homeopath	4 (1.5)	4 (1)	84	4 (2)	86	0.61 (U=3397)
The Placebo Effect plays a big role in homeopathy	2 (1)	2.5 (1)	93	2 (1)	81	0.09 (U=3020)
Homeopathy works on the vital energy of the body	5 (1)	4.5 (1)	75	5 (1)	94	**<0.01** (U=2740)
Homeopathy works on electrodynamics of the body	3 (1)	4 (1)	78	3 (1)	84	0.41 (U=2974)
Homeopathy is energy medicine in a similar way to acupuncture	4 (1)	4 (1)	80	4 (1)	89	0.20 (U=3136)
The mechanism by which homeopathy works is not important to me	2.5 (2)	3 (2)	92	2 (1)	82	0.18 (U=3136)

* See section 3.4.2 Scale 5= Strongly Agree, 4=Agree, 3= neutral, 2= Disagree, 1= Strongly Disagree

The results of a Mann-Whitney significance test to look at differences are displayed in the right hand column, significant results are in bold. The mean rank is also displayed, showing which group tended to have to have higher values compared to the other.

3.8.7.1 (i) Common Opinions Regarding Homeopathic Theory Across the Two Groups of Participants

Many aspects of the areas of homeopathic theory included in the survey highlighted consistent opinions on underlying theory across the two groups. When asked if they consider themselves to be classical homeopaths, medical and non-medical respondents answered that they "agreed" that they did. The median response of the homeopaths overall to the statement that the placebo effect played a big role in

homeopathy was that they felt "neutral". The respondent homeopaths' median opinion was that they "agreed" that homeopathy works on electrodynamic forces in the body. Virtually no difference was seen between the two groups on this matter. Homeopaths in both groups also "agreed" that homeopathy is a form of energy medicine along with acupuncture but that the two manipulate the energy field in different ways. The median response shows that homeopaths disagreed with the statement that the way in which homeopathy works was not important to them

3.8.7.1 (ii) Vital energy

The one area of homeopathic theory covered that highlighted a difference in the opinions of homeopathic participants was their view regarding homeopathy working via the vital force of the body. Regarding the theory that homeopathy works on the vital energy of the body, the median response of the homeopaths was that they "strongly agreed".

3.8.7.2 Acupuncture Theory

The results on practitioners' opinions on acupuncture theory are shown in Table 3.12(ii).

Table 3.12(ii)- The Median Opinions that the Acupuncturists From the Three Groups had on Acupuncture Theory

	BMAS Median (IQR)	AACP Median (IQR)	BAC Median (IQR)	Medical Mean Rank	Non-Medical Mean Rank	***P* Value – Medical verses Non-medical**
Acupuncture works on Meridians and Collaterals	3 (2.5)	4 (0)	5 (1)	54	103	**<0.01** (U= 627)
Meridian and collateral pathways run through the body	3 (2)	4 (0)	4 (1)	57	91	**<0.01** (U=1030)
Acupuncture works by causing the release of endorphins	4 (1)	4 (1)	3 (1)	82	44	**<0.01** (U=933)
Acupuncture works by stimulating the nervous system	4 (0)	4 (1)	3 (1)	82	43	**0.01** **(U=883)**
The effects of acupuncture are due to it's effects on the blood circulation	3 (1)	3 (2)	3 (1)	73	63	0.16 (U=1799)
Acupuncture causes non-local effects in the body	4 (1)	4 (0)	5 (2.5)	65	78	**0.04** (U=1630)
The effects of acupuncture are due to the placebo effect	4 (2)	3 (1)	3 (2)	76	56	**<0.01** (U=1474)
Acupuncture works on Qi in the body	4 (3)	4 (0)	5 (0)	53	103	**<0.01** (U=570)
Electrodynamic fields exist in the body	3 (2.5)	3 (1.5)	3 (1)	60	89	**<0.01** (U =1251)
Acupuncture is a form of energy medicine in the same way that homeopathy is	3 (2)	3 (1)	4 (1.5)	58	95	**<0.01** (U=577)
It is not important to me how acupuncture works	2 (1.5)	2 (1)	2 (1)	69	71	0.760 (U=2075)

Median Scale 5= Strongly Agree, 4=Agree, 3= neutral, 2= Disagree, 1= Strongly Disagree . The mean rank is also displayed. Results of a Mann-Whitney to determine whether any differences between the two groups were significant are in the right-hand column Significant differences are displayed in bold in the right hand column.

3.8.7.2 (i) Opinions on Acupuncture Theory Consistent Between Groups

Contrary to the results on homeopathy, many aspects of acupuncture theory showed significant differences in opinions between medical and non-medical acupuncturists in a Mann-Whitney test. These results are displayed in Table 3.12(ii) and discussed below. The only areas on which the two groups shared a common view were that acupuncturists from all three affiliations were "Neutral" regarding effects of acupuncture being mediated via changes in blood circulation, and that respondents from both groups "disagreed" with the statement that the way that acupuncture works was not important to them.

3.8.7.2 (ii) Meridians and collaterals

The median response from BMAS acupuncturists on meridians and collaterals showed that they had a neutral opinion on them. The median response from the AACP showed that they "agreed" that meridians and collaterals exist in the body and that acupuncture works on them. Non-medical (BAC) members "strongly agreed" that Acupuncture works on meridians and collaterals but only "agreed" that actual pathways of meridians and collaterals exist in the body. The differences in medical and non-medical agreement on the theory of meridians and collaterals were found to be significant at p=0.01.

3.8.7.2 (iii) Release of Endorphins and the nervous system

When asked if they agreed that acupuncture causes the release of endorphins, medical acupuncturists from both affiliations "agreed". Non-medical acupuncturists remained "neutral" on this matter and this difference was significant at p=0.01. Medical acupuncturists from both affiliations also "agreed" that acupuncture works on the nervous system, whereas non-medical homeopaths "disagreed" with this, the difference was significant at p=0.01.

3.8.7.2 (iv) Non-local Effects of Acupuncture

Medical acupuncturists "agreed" that acupuncture causes non-local effects in the body, whereas non-medical acupuncturists "strongly agreed" with this. This difference was significant at p=0.04.

3.8.7.2 (v) Placebo effect

BMAS members "agreed" that acupuncture's effects were due to the placebo effect, whereas both AACP and BAC members felt "neutral" on this. However the mean rank values show that medical acupuncturists felt more agreement with this than non-medical acupuncturists, a difference that was significant at p=0.01.

3.8.7.2 (vi) Acupuncture and Qi

Opinions on acupuncture working on Qi showed that all acupuncturists agreed with this, however non-medical acupuncturists agreed more strongly than medical acupuncturists. This was a significant difference at p=0.01.

3.8.7.2 (vii) Electrodynamic Fields

Median values of acupuncturists from all affiliations showed that they felt "Neutral" about the existence of electro-dynamic fields in the body. However, as can be seen by the mean ranks, non-medical acupuncturists felt a stronger agreement with this statement than medical acupuncturists and this was significant at p=0.01.

3.8.7.2 (viii) Acupuncture and Energy Medicine

Medical acupuncturists' median response was that they were "neutral" to the idea that acupuncture was a form of energy medicine, in a similar way to homeopathy. Non-medical homeopaths however "agreed" with this concept. This result was significant at p=0.01.

3.8.7.2 (ix) Mechanism of Action Not Important

The median response from all acupuncture affiliations indicated that they "disagreed" with the statement that it was not important to them how acupuncture works.

3.8.8 Research

Participants were asked their opinion on matters of research into homeopathy. They were asked to state their opinions according to the Likert scale. The results of this are shown in Tables 3.13(i)-(ii).

3.8.8.1 Homeopaths' Opinions on Research

Table 3.13(i) Homeopaths' Opinions on Future Research

	Total Sample	**Medical (Faculty of Homeopaths*)**		**Non-medication (Society of Homeopaths)**		
	Median (IQR)	**Median (IQR)**	**Mean Rank**	**Median (IQR)**	**Mean Rank**	***p* value**
More research into the effectiveness of homeopathy is necessary	4 (1)	4 (1)	99	4 (2)	78	**<0.01** (U=2696)
More research into the MOA of homeopathy is necessary	4 (1)	4 (1)	100	4 (1)	76	**<0.01** (U=2478)
More research into the synthesis of homeopathic remedies is necessary	4 (1)	4 (1)	96	3 (1)	73	<0.01 (U=2397)
I keep myself up to date in research into homeopathy	4 (1)	4 (1)	87	4 (1)	86	0.94 (U=3564)

*See section 3.7.2

Median Values: 5 = Strongly believe 4=Have some faith 3 = Neutral 2 = Disbelieve 1= Strongly disbelieve.

Results of a Mann-Whitney Test on differences between the results are displayed in the right-hand column.

Significant differences are displayed in bold.

3.8.8.1 (i) Research into the effectiveness of homeopathy

Respondents "agreed" that more research into the effectiveness of homeopathy was necessary, as was shown by the median response. When the groups were looked at separately this was still true for both groups. However the mean rank shows that

Faculty homeopaths tended to agree more strongly than Society homeopaths. This result was shown to be significant (p <0.01).

3.8.8.1 (ii) Research into the mechanism of actions of homeopathy

As with effectiveness, the median response of the homeopaths was that they agreed that more research into the effectiveness of homeopathy was necessary. When the groups were separated the medians for both groups remained the same, however the difference in mean ranks show that the Faculty homeopaths agreed more strongly that this research is necessary than the Society homeopaths. This difference was found to be significant (p=0.01).

3.8.8.1 (iii) Research into the synthesis of homeopathic remedies

The median opinion shows that respondents "agreed" that more research into the synthesis of homeopathic remedies was necessary. When the two groups were looked at individually the median remained the same for Faculty homeopaths but was "neutral" for Society homeopaths. This was a significant difference at p=0.01.

3.8.8.1 (iv) Keep up to date with homeopathy research

Homeopaths viewed collectively, and in both groups separately "agreed" that they kept up to date with research into homeopathy. The mean ranks show that Faculty homeopaths agreed with this more strongly, though this was not found to be significant.

3.8.8.2 Acupuncture Research

The opinions of acupuncturists on future research are shown in Table 3.13(ii).

Table 3.13(ii) – Acupuncturists Opinions on Future Research

	BMAS Median (IQR)	AACP Median (IQR)	BAC Median (IQR)	Medical Mean Rank	Non-Medical Mean Rank	**P Value – Medical trained verses Non-medical Acupuncturists**
More research into the effectiveness of acupuncture is necessary	**4 (1)**	**4 (1)**	4 (1)	72	68	0.514 (U=2030)
More research into the MOA of acupuncture is necessary	4 (1)	4 (1)	4 (2)	74	62	0.77 (U=1778)
More research into meridians?	4 (2)	4 (1)	4 (2)	74	64	0.151 (U=1855)
I keep myself up to date with acupuncture research	4 (1)	4 (0)	4 (1)	71	69	0.757 (U=2101)

Median Values 5 = Strongly believe 4=Have some faith 3 = Neutral 2 = Disbelieve 1= Strongly disbelieve Results of Mann-Whitney showed in the right hand column

The results shown in Table 3.13(ii) show that acupuncturists "agreed" that more research was needed on the specified areas of acupuncture. The medical acupuncturists agreed more strongly with this, but no significant difference was found in the Mann-Whitney test between the two groups.

3.8.9 Other Medical Systems

Practitioners were asked to place their views on other medical systems on a 5-point scale ranging from strongly believe to strongly disbelieve. The results are shown in Tables 3.14(i-ii).

Table 3.14(i) Table to show the median opinions of homeopaths from both groups on other medical systems.

	Overall Median (IQR)	Medical (Faculty of Homeopaths*)		Society of Homeopaths		*p* value
		Mean Rank	Median (IQR)	Mean Rank	Median (IQR)	
Traditional Chinese Medicine	4 (1)	77	4 (1)	85	4 (2)	0.25 (U=2922)
Ayurvedic Medicine	4 (1)	77	4 (1)	84	4 (1)	0.30 (U=2883)
Conventional UK Medicine	4 (1)	102	4 (1)	63	3 (1)	**<0.01** (U=1600)

* See section 3.4.2 .Median Values: 5 = Strongly believe 4=Have some faith 3 = Neutral 2 = Disbelieve 1= Strongly disbelieve.

P Value obtained from Mann-Whitney test shown on the right, significant results are displayed in bold.

As can be seen from Table 3.14(i), respondents stated that they had some faith in Traditional Chinese Medicine and in Ayurvedic medicine. The mean ranks show that for both of these systems and particularly traditional Chinese medicine, non-medical homeopaths believed slightly more strongly. The results also show that overall the homeopaths had some faith in conventional UK medicine. When the opinions of the two groups were looked at individually medical homeopaths had some faith in conventional medicine but Society homeopaths neither believed nor disbelieved in it. This result was found to be significant by the Mann-Whitney test.

Table 3.14(ii) – Acupuncturists Opinions on Other Medical Systems

	BMAS Median (IQR)	AACP Median (IQR)	BAC Median (IQR)	Medical Mean Rank	Non-Medical Mean Rank	**Mann-Whitney *p* Value**
I have faith in Traditional Chinese Medicine as a treatment	4 (1)	4 (4-5)	5 (0)	54	102	**<0.01** (U=665)
I have faith in Ayurvedic Medicine	3 (1)	3	4 (2)	52	89	**<0.01** (U=781)
I have faith in Homeopathy as a treatment	3 (2)	4	4 (2)	62	82	**<0.01** (U=1452)
I have faith in conventional medicine as a treatment	5 (1.5)	5	4 (1)	72	64	0.17 (U= 1823)

Mean ranks of the medians are also shown in order to clarify the differences. The right hand column shows the results of a Mann-Whitney test on the medians, and significant differences between the two groups are shown in bold.

As can be seen in Table 3.14(ii), non-medical acupuncturists had significantly more faith in other complementary forms of medicine than medical acupuncturists. Medical acupuncturists were more confident in conventional medicine than non-medical acupuncturists, but this result was not found to be significant.

3.9 Results 3: Summary of Key Findings

- Conditions most commonly encountered were the same for both homeopaths and acupuncturists, though most medical acupuncturists limited their acupuncture practice to pain management

- Similarities emerged with regard to many aspects of practice for homeopathy

- Differences highlighted between medical and non-medical homeopaths were most significantly in length of consultations and in follow-ups which were longer and more frequent for non-medical, and few were in actual treatment.

- Non-medical acupuncturists use different methods of diagnosis, have different needling times, and work to different theories.

- Non-medical practitioners from both groups were more confident in the effectiveness of their treatment for many conditions than their medical colleagues.

3.10 Discussion

The study aimed to assess the views and practices of homeopaths and acupuncturists across the UK. This included prescribing methods, practice details and views on homeopathic theory, and involved a comparison of medical and non-medical practitioners' responses. The fact that almost half of the total homeopathy sample were located in and around London meant that no inter- regional analysis could be carried out. The acupuncture survey received a lower response rate, as predicted, and the response rate showed some regional variability. This was attributed to the number of studies to date on acupuncture compared to homeopathy, and acupuncturists in certain geographical areas may have contributed more to previous studies compared to those in other regions. There was however no reason to suppose that the practices would differ depending on the region. No study of this kind, exploring homeopathic practice in the UK had been previously carried out. Therefore an overall picture is valuable. Acupuncture practise in the UK has, however, been looked at in some detail by other studies (Alltree 1994, Dale, 1996, Hughes 2007) and it is useful to conduct a parallel survey on acupuncture alongside homeopathy in order to compare results from the two therapies and to gain a broad view of issues surrounding integration of CAM into the NHS.

This chapter will discuss the results of this study with regard to the practice of the two CAM therapies, the methods and views used by practitioners with regard to treatment, and how the findings may shape the future of CAM and influence integrative models and future research.

3.10.1 Homeopathy in Practice

The initial consultation is considered to be one of the most important aspects of treatment (Brian, 2004, Vithoulkas 1986). The data suggest that non-medical homeopaths conduct on average considerably longer consultations than the medical homeopaths. The results also show that medical homeopaths hold more consultations per week than non-medical ones, so this may explain why consultations must be shorter. Another reason that emerged from medical homeopaths' comments was that some of them were offering treatment with NHS funding and were constrained to a 20-minute consultation period, in line with their conventional practice. Some stated that they did not believe that this was an adequate amount of time. The average time for a homeopathic consultation for both medical and non-medical homeopaths was 50% higher than the average time for medical and non-medical acupuncturists respectively. This would be a factor in the cost-effectiveness of the two treatments.

Additionally, the results show that medical homeopaths would leave significantly longer time before a follow-up appointment for eczema and osteoarthritis than non-medical homeopaths. This again may be due to the constraints placed on those medical homeopaths treating within the NHS. The questionnaire used in this study, however, did not ask respondents to specify whether their treatment was offered on the NHS or in private. Hence, it was not possible to differentiate between practice in the two settings. This topic has not been discussed in previous studies and is a potential area to address in future studies. If longer and more frequent consultations are shown to be essential to the success of homeopathic treatment, then an integrated healthcare system would need to allow for these. Although this may involve further structural changes, there is some evidence of the cost effectiveness of homeopathic treatment, in terms of similar or cheaper treatment costs and improved patient satisfaction (Fisher 2004, Slade 2004).

3.10.2 Acupuncture Practice

As with homeopathy, acupuncture consultations varied in length with medical practitioners' consultations averaging 22 minutes shorter than non-medical consultations ($p<0.01$) . Again this was partially, but not completely, explained by a relatively large proportion of medical practitioners working within the NHS and

having time restrictions imposed on them. The interval between the initial consultation and follow up was not significantly different between the two groups of acupuncturists, with non-medical participants actually reporting a slightly higher, yet insignificantly larger number of days between (p=0.41). This may reflect a difference between the two therapies, with participant acupuncturists generally giving follow-ups around a week after the initial consultation, where as homeopathy consultations would range from around 2 to 4 weeks depending on the condition. The shorter interval routinely placed between appointments with acupuncture practitioners may result in a smaller margin of difference between the two groups.

3.10.3 Use of Assessment Tools in Homeopathic Practice

The results of the question concerning the use of clinical assessment tools showed that generally homeopaths did not use those listed. The median values showed that medical homeopaths sometimes used their own patient questionnaire, compared with non-medical homeopaths who never used them. This was also the case with acupuncturists. This may be due to medical practitioners compensating for the shorter initial consultation times.

Choosing the outcome measures for clinical trials of any treatment is an important determinant in the success of the trial. Most trials to date have used the routine clinical assessments for the condition in question as outcome measures. For example in clinical trials of osteoarthritis, outcome measures have included experience of pain on a visual analogue score (Nahler et al, 1998, Shealy et al 1998, Van Haselen et al, 2000), maximum walkable distance (Nahler et al, 1998, Van Haselen et al, 2000), Other drugs used, e.g. analgesics (Shealy et al, 1998) and other symptoms and patients' overall health. Shealy et al (1998) also asked patients to keep a daily diary of symptoms.

Other assessment tools have been designed to aid diagnosis and treatment. The MYCAW, a version of MYMOP, questionnaire allows patients to identify their main concerns and the degree to which they are affected by their illness, the SF36 questionnaire is designed to assess the patient's physical and mental health, including vitality and overall health, the "GHHOS" is a score that the practitioner attributes to the overall health and condition of the patient. The Glasgow Homeopathic Hospital

Outcome Score (GHHOS), as the name suggests a tool specifically for homeopathic treatment, was not used much by either group but significantly more by medical than non-medical homeopaths. It was obvious from the comments on questionnaires that many of the homeopaths had not heard of the assessment tools listed. This may account for their low usage and the tools are relatively new so they may have potential as outcome measures for future trials. With the mechanism of action of homeopathy still much unknown and with homeopaths believing that it works on the vital force of the body (see Table 3.12(i)), tools such as the SF36 that seek to assess the vitality of the patient may be extremely useful as an outcome measure.

The fact that the results indicate that homeopaths do not use the assessment tools that have been used in trials in their routine practice suggest that there is a need to develop outcome tools that can be useful to routine practice and may then be effective as outcome tools for trials too.

3.10.4 Commonly Encountered Conditions

Homeopathy

The conditions most commonly encountered by homeopaths, in order of most encountered, were eczema, gynaecological, depression/anxiety, IBS, and musculo-skeletal and recurrent infections. These are congruent with the findings of Colin (2000) and Thompson (2004). These studies showed them in a slightly different order but the same conditions appear. The long-standing conditions most commonly reported in the UK population as a whole were musculo-skeletal, circulatory, respiratory and digestive illnesses (Charlton & Murphy, 1997). With musculo-skeletal and digestive disorders appearing among the top 5 conditions encountered by homeopaths and asthma/respiratory problems being another frequently encountered condition, it was only circulatory conditions which have a high prevalence in the population but homeopathic treatment was not sought. These results are congruent to the findings of Steinsbekk and Fonnebo (2003) who also found, from their survey of 1097 homeopathic patients in Norway in 1998, that the most commonly encountered conditions in homeopathic clinics were among those found commonly in general practice. The biggest difference was the number of patients seeking conventional treatment for circulatory disorders (Steinsbekk & Fonnebo, 2003). With circulatory diseases being the most common cause of death in the UK it is possible that patients

are more reluctant to try alternative therapies for these, and are generally happy with the conventional treatments they are offered. Steinsbekk and Fonnebo (2003) suggested that this reflects the fact that patients are sensible in their choices as they are aware that circulatory diseases are among the most serious in terms of being life-threatening. In theory, homeopathy could be used for these serious conditions, but the results of the current study indicate that practitioners generally advise patients to continue taking routine medication and request a diagnosis to explain their symptoms, suggesting that they would be realistic in treating life-threatening illnesses only for symptom relief or to control side effects of drugs.

Other evidence has been presented to suggest that homeopaths tend to be confronted with chronic conditions (Jacobs et al, 1998) and that these tend to be in the areas where people are not satisfied with conventional treatments. Of all the conditions that were identified by GPs as having an "effectiveness gap" from conventional medicine treatment, musculo-skeletal came top (Fisher, 2004).

Acupuncture

The conditions that non-medical acupuncturists were approached with were similar to the list homeopathic practitioners encountered. However, many medical acupuncturists only used acupuncture for musculoskeletal pain treatment. This was largely due to the fact that a high proportion of medical acupuncturists were accessed via their AACP membership, and hence were physiotherapists who were predominantly involved in pain management work, but GPs practising acupuncture would also more commonly administer acupuncture for pain than for other conditions.

According to the Effective Health Care bulletin produced by an NHS evidence review unit at the University of York, trials of homeopathy to date are not always in areas that homeopaths commonly treat (NHS Centre for Reviews and Dissemination, 2002). Although a number of the studies mentioned in the report do come under the common conditions identified by the current study, it is important that future trials do focus on the most common and relevant conditions, especially at a stage where homeopathic treatment is still very controversial.

3.10.5 The Confidence of Practitioners in the Effectiveness of Treatment

The results show that homeopaths agreed that homeopathy was an effective treatment for the conditions stated (see section 3.8.5(i)) and indeed for "all conditions". For some conditions, however, non-medical homeopaths believed more strongly that the treatment was effective than medical homeopaths. These included skin conditions, asthma, menopausal symptoms and acute illnesses. This could be due to medical doctors, having experience of the effectiveness of conventional and or other treatments for these conditions, are therefore being more critical and comparing homeopathic treatment to other treatment methods. This could also be interpreted as non-medical homeopaths having more success with their treatment than medical homeopaths.

A similar pattern was seen with acupuncturists, with non-medical acupuncturists more strongly agreeing that acupuncture was effective for a range of conditions than medical. Each of the acupuncture groups shared a median belief which was that they "strongly agreed" that acupuncture was effective for musculo-skeletal conditions. However, non-medical acupuncturists were the only group to strongly agree that acupuncture was effective for asthma, menopausal symptoms, anxiety and depression, and digestive disorders, compared to medical acupuncturists who were either neutral or agreed that they were effective. Non-medical acupuncturists were the only group to agree that acupuncture was effective for skin conditions and chronic fatigue syndrome, compared to the two medical groups who were both neutral in this matter. In the case of acupuncturists, however, it must be noted that many of the medical acupuncturists, particularly AACP respondents, would not routinely treat the other conditions in their practice, so having little or no experience of treating these conditions with acupuncture, it is possible that this made them more hesitant to state that they "agreed" that acupuncture was effective for treating them. These findings are congruent with those of a previous survey of AACP members who felt confident that acupuncture worked well with musculo-skeletal pain and only a small proportion commented on the effectiveness of acupuncture for non-pain conditions (Alltree, 1993). Perceived effectiveness for different conditions in members of the BMAS and BAcC is an area that has not been addressed in previous studies investigating acupuncture opinions, so the results presented in this study are

new findings. As with many other areas on the opinions of homeopaths, there is also no available literature on perceived effectiveness of homeopathy.

In summary, future research to determine whether there is any difference in the success rate of the treatment between medical and non-medical CAM practitioners may be useful to indicate whether the differences highlighted in the modes of practice between the two groups could affect the effectiveness of the treatment. In particular it would be useful for future studies to address the question of whether shorter consultation times and less frequent visits to the homeopath actually make treatment less effective.

3.10.6 Methods of Practice

3.10.6.1 (i) Prescribing Homeopathic Remedies

Generally, the results showed little difference in prescribing styles between the two groups of homeopaths. The only significant difference was the frequency at which homeopaths prescribed a high potency of a remedy initially, and working downwards to lower potencies. This mode of treatment was "sometimes" used by medical homeopaths and "rarely" or "never" used by non-medical homeopaths (p=0.001). Another interesting result was that there was a trend that non-medical homeopaths placed more emphasis on giving a homeopathic remedy for the shortest time possible. This result was not significant (p=0.195), but these results suggest that perhaps non-medical homeopaths are more concerned with the possible aggravational side effects of the remedies than medical homeopaths. As shown in section 3.7.6(i) in the results section, the main reason that emerged as responsible for initial interest in homeopathy for medical practitioners was dissatisfaction with conventional medicine. This often related to side effects, with 37% giving this reason compared with 14% of non-medical practitioners, half of whom became interested through a positive experience with homeopathic treatment itself. There is evidence that minor aggravational effects can sometimes occur from homeopathic treatment (Thompson, 2004), but these are much less severe and apparent than side effects resulting from many conventional medications (House of Lords, 2000). This may explain why medical homeopaths who are familiar with the side effects associated

with conventional medicines were less concerned over these comparatively minor aggravations.

3.10.6.2(ii) Classical Homeopathy

Most homeopaths from both groups agreed with the statement that they were classical homeopaths. As has been previously mentioned, the term classical homeopath seems to be used to refer to several different things. In this case, the homeopaths individualised their treatments to the patients, which is something that is generally considered to be necessary for classical homeopathy (Relton, 2004). Most homeopaths would usually use single remedies, a practice which some believe is the only true way to classically prescribe (Drosdovech et al, 2002). However, even homeopaths who mentioned that they tend to use multiple remedies sometimes or often, still considered themselves to be classical homeopaths. This suggests that the view that classical homeopathy indicates only single remedy prescribing is still controversial. Opinions on this matter depend on whether homeopaths that stick to Hahnemann's original or his later writings. The views of the homeopaths regarding this were no different for medical or non-medical homeopaths.

3.10.6.2 Acupuncture practice

Rather than the prescribing issues surrounding homeopathy, acupuncturists face decisions on which points to use, needling time and types of diagnoses to include.

3.10.6.2 (i) Diagnostic use by acupuncturists

The ancient art of pulse diagnosis, a TCM tradition, was "always" used by non-medical acupuncturists, and "rarely" (BMAS) or "never" (AACP) used by medical acupuncturists ($p<0.01$). This result was predictable, considering the divergence of view points on acupuncture theory adopted by the organisations, and is supported by the findings of other studies (Dale 1994, Hughes 2007). Emotional inquiry was used to some extent by all participant acupuncturists, but more frequently by non-medical acupuncturists ($p<0.01$) who "always" used this method as opposed to "sometimes (AACP) or "often or always" (BMAS), It is interesting that from these results on acupuncture practice AACP members reported using these traditional and holistic methods less frequently than BMAS members. This could be the result of BMAS members often being GPs and having the overall health of the patient to consider,

and therefore using the diagnostic processes available to them, whereas AACPs as physiotherapists are mainly concerned with their patient's musculo-skeletal problems rather than broader health concerns and their time allocation may only allow for this also. Needling time when treating OA was significantly longer by non-medical acupuncturists than medical acupuncturists ($p=0.02$), congruent to predicted findings in an acupuncture practice report (British Medical Association, 2000).

Western diagnosis prior to acupuncture treatment was significantly more frequently used by medical acupuncturists ("always") than non-medical ("sometimes") ($p<0.01$) also indicating the differing theoretical medical approaches, although participants from all groups reported that they "always" advise their patient to continue taking conventional medicine at the beginning of acupuncture practice.

3.10.6.2 (ii) Acupuncture Classification

On categorising the type of acupuncture practised, BAC members seemed more narrowly placed in stating they "always" practised TCM acupuncture. Although BMAS members stated they "always" practised medical acupuncture", they also reported to "sometimes" or "rarely" use TCM acupuncture. AACP "often " used both of these practices, appearing not to feel compelled to chose between the two approaches, but perhaps find their own happy medium. These results concur with previously conducted studies (Dale, 1997, Hughes 2008). It does appear that Japanese acupuncture and 5 element acupuncture are not recognised in UK practice, by the participating affiliations, with only 5 element acupuncture being "rarely" practised by BAC participants and the other affiliations reporting "never" to practise either of these forms of acupuncture.

3.10.7 Matters Relating to Underlying Theory of the Two Therapies

Medical homeopaths in the UK begin their medical training from a conventional view point, consisting of biochemistry of the body, pharmacology that concentrates on synthesised drugs and molecular medicines and on a Newtonian style model of the processes occurring in the body. It is after this that they embark on homeopathy training, which teaches them a whole new angle on the human body and the nature of disease. With this in mind it is very interesting that the results indicate no real differences in the opinions on homeopathic theory between the medical and non-

medical homeopaths. For a medical doctor to decide to train in homeopathy, he or she must already be open-minded about the different nature of this medical treatment and this may account for the similar views to the non-medical homeopaths. Significant differences in acupuncture theory were however seen between medical and non-medical participants, but the median opinions were not at opposite extremes, indicating that there were some mixed feelings concerning this matter. Mixed opinions of medical acupuncturists were explored in a qualitative study, finding that some medical acupuncturists were content with seeing aspects of the body and of health in very different ways simultaneously (Dale, 1997b)

3.10.7.1 The Role of the Placebo Effect

The role of the placebo effect revealed some mixed and undecided responses. The placebo effect is the psychological phenomenon associated with improvement of a patient's symptoms due to their confidence that they are being treated. Some people believe that it shows evidence of the body's ability to self-heal. In addition to CAM therapies, the placebo effect is also considered to be relevant to conventional medicine, and there is evidence that the size and colour of pills alone can influence the effectiveness of treatment (Ernst, 2000).

To some in the medical profession, homeopathic treatment itself is simply acting as a placebo, and it has been commented that placebo controlled trials of homeopathy are nothing but a comparison between placebo and placebo (Vandenbroucke, 1997). As mentioned in the literature review, although most placebo controlled trials of homeopathy have been inconclusive, there is some evidence that homeopathy has some effect beyond that of a placebo. With both the mechanism of action of homeopathy and the exact explanation for the placebo effect remaining unknown, it is difficult to say to what extent homeopathy involves a placebo reaction.

The results of the current study show that non-medical homeopaths in general disagreed that the placebo effect has a big role in the effectiveness of homeopathic treatment, and medical homeopaths felt undecided regarding the role of the placebo effect. Acupuncturist participants, however, were more convinced by the role of the placebo in acupuncture treatment. Medical acupuncturists "agreed" significantly

more strongly that acupuncture brought about health benefits via the placebo effect, compared to non-medical ones who felt undecided towards the placebo. It is possible that this difference in view on the placebo arises because medically trained practitioners are more aware of the placebo phenomenon regarding medical treatment as a whole than non-medical practitioners, who only encounter the term placebo when it is given the credit for the effects of homeopathic or acupuncture treatment. Particularly with regard to homeopathy, a large proportion of the medical community would not consider it as a treatment option if it fails continually to be backed up by conclusive evidence. To many this means that it has to be satisfactorily shown to be more successful than a placebo in placebo controlled RCTs. Acupuncture has benefitted from slightly stronger RCT evidence compared to homeopathy. It is not always possible to conduct RCTs, which were a tool designed specifically to compare an active drug against a blank tablet, for complex therapies that are placebo controlled, and pragmatic studies comparing two different treatments are also beneficial.

3.10.8 Mechanism of Action of Homeopathy and Acupuncture

3.10.8 (i) Acupuncture and TCM Theory

Nonmedical acupuncturists significantly more strongly agreed on the meridian collateral theories of acupuncture compared to AACP members who "agreed" and BMAS members who were undecided on the matter. The opposite was true concerning opinions on acupuncture working through the nervous system and endorphin release, with medical homeopaths agreeing and nonmedical neutral on the matter, a difference that was significant at $p<0.01$. This supports the idea that the two groups come from very different theoretical bases, the medical acupuncturists, particularly BMAS members, taking a view of acupuncture which they can predominantly fit into a biomedical model in terms of accounting for the majority of its effects at least. The non-medical view point which supports the ideas of TCM, whereby pathways that are not physiological or physically evident pathways, yet transport Qi around the body, however, does not fit into the biomedical model. Median values show that the opinions of the AACP members were somewhere in the middle between the BAC and the BMAS members.

3.10.8 (ii) Electrodynamic fields

The results show that homeopaths agreed with the statement that homeopathy works on the electrodynamics of the body, and with Hahnemann's original statements that it works on the vital force. This is evidence that homeopaths feel that homeopathy is a form of energy medicine and works at a level beyond molecular medicine, and this explains how it can be seen as plausible even when not a single molecule of the original substance is present. Median results from the acupuncture survey showed that participants were undecided regarding electrodynamic fields in the body. This is an area that has not been explored in previous studies on acupuncturists' opinions. However, the mean rank values show that non-medical acupuncturists believed more strongly that these fields exist ($p<0.01$).

Homeopaths also believed that acupuncture is also a form of energy medicine and works on the same electrodynamics of the body, but manipulating them in different ways. Non-medical acupuncturists also believed that acupuncture was a form of energy medicine in a similar way to homeopathy, and medical homeopaths were undecided on this matter.

Homeopaths and acupuncturists disagreed with the comment that the mechanism of action of homeopathic drugs or acupuncture (respectively) was not important to them. In the case of homeopathy, this contradicts the sentiment that they are not interested in this matter and that homeopaths still stick with Hahnemann's views that there is no reason to try to discover this mechanism (Hahnemann, 1984). It is interesting to note that though the median for non-medical homeopaths was that they disagreed with the statement, the median response for the medical homeopaths was that they felt neutral about the comment. This result was not significant ($p=0.161$) but shows the trend that medical homeopaths, who are the ones that most likely have more in-depth knowledge of the immune system and physiology of the body, were less interested in the matter.

Overall homeopaths did not show much intergroup variability in their opinions of homeopathic theory. Although significant differences were seen between medical and non-medical acupuncturists, it is interesting that in many aspects of underlying theory, AACP members held opinions that were somewhere in between BAC and

BMAS participants. In addition, in spite of BMAS participant median opinions generally supporting the western acupuncture views, the inter-quartile range of responses showed considerable variation in opinions between members, indicating that the Western medical view point is not universal among this practitioner group.

3.10.9 Opinions on Future Research

In spite of the indifference that medical homeopaths may have displayed towards the actions of homeopathy, homeopaths from both groups agreed that more research into the mechanism of action of homeopathic drugs was necessary. Medical homeopaths actually agreed this significantly more strongly than non-medical homeopaths (p=0.04). This may be because medical homeopaths are well aware that it is likely that the general medical community will not accept homeopathy fully until a suggested mode of action that they can see as plausible is presented for the treatment, even if they are not so concerned with this personally.

Homeopaths in general agreed that more research into the effectiveness of homeopathy was needed. This is a positive response as it is clear that in order to satisfy the medical community, more research into effectiveness will be necessary. All acupuncturists, regardless of affiliation "agreed" that more research into acupuncture was necessary, including effectiveness, mechanisms of action and meridian pathways. They also all "agreed" that they keep up to date with research.
The medical homeopaths were more in support of future trials in effectiveness of homeopathy than non-medical homeopaths. This result was significant (p=0.02). This may be due to the dissatisfaction of many homeopaths of the opinion that issues of external validity of clinical trials has led to so many studies that were either unfavourable or inconclusive towards homeopathy. Homeopathy has undergone far more criticism over recent years compared with acupuncture, and this could be the cause of more apprehension towards future homeopathy research compared with acupuncture research. Medical homeopaths may be more exposed to the scientific community and the rigorous conditions that surround clinical trials, so may be less affected by the outcome of these trials.

Overall the results on research show a trend that non-medical homeopaths were generally not as enthusiastic about homeopathy research as medical homeopaths. This may be due to the dissatisfaction with research to date mentioned earlier.

3.10.10 Faith in Other Medical Systems as Treatments

The results show that overall the homeopaths had some faith in Traditional Chinese Medicine and in Ayurvedic medicine. There was a marked difference between the views of the two groups of practitioners regarding conventional medicine in the UK. Medical homeopaths had some faith in conventional medicine. This was also apparent from the fact that the majority of them also still practised as conventional doctors.

The non-medical homeopaths were neutral regarding their faith in conventional medicine, and this difference was strongly significant (p=0.005). This was reflected in the results between the two groups where medical homeopaths placed more emphasis on advising patients to continue taking their normal medications and stated that they would "always" advise patients to continue this, compared to non-medical "usually advising this (p=0.05).

Hahnemann himself used the word allopathy to describe the type of medicine that the majority of conventional treatments fall under. Hahnemann argued that the effects of allopathy worked completely against the principles of homeopathy and could therefore not be an effective treatment, and this may be one reason why non-medical homeopaths would feel this way. Non-medical homeopaths would most frequently be approached by patients who had turned to them due to dissatisfaction with conventional treatments (Becker-Witt, 2004). Medical homeopaths treating people both allopathically and homeopathically would be presented with positive as well as negative effects from conventional treatment, and so this would lead them to putting more faith in conventional treatment than the non-medical homeopaths.

Acupuncturists' opinions on other medical systems very much reflected those of homeopaths, with a general open-minded attitude to other CAM systems, though this was more significantly more strongly reported by non-medical acupuncturists than

medical. This matter has not been addressed by previous studies on acupuncturists' opinions. Acupuncturists appeared to have more faith in conventional medicine than homeopaths as a whole. This less negative view of conventional medicine compared to that of homeopaths could again be due to a less defensive response as they receive less criticism from the general medical world than homeopaths receive. It could also be partly the increased likelihood of AACP and BMAS acupuncturists practising conventional medicine as an adjunct to acupuncture.

3.10.11 Impacts of the Results on the Integration of Homeopathy and Acupuncture into the UK Health System

The opinions of non-medical homeopaths, non-medical acupuncturists, and indeed other CAM therapists, towards conventional medicine together with the overall view that the medical profession holds on CAM act as a barrier towards these therapies being integrated into mainstream healthcare (Mortiz, 2004). In an integrated system, effective communication and multi-disciplinary team (MDT) working is essential to effective patient care. The results of the current study show that a much larger proportion of medical homeopaths practise other forms of medicine compared with their non-medical colleagues. This is not surprising as most medical homeopaths have first undergone training to be an MD, then taken further courses in homeopathy and sometimes acupuncture. Most medical homeopaths and acupuncturists continue to practise conventional medicine, usually within the NHS though some have private patients. The Society of Homeopathy members who did practise conventional medicine were usually nurses or allied health professionals. Nearly half of the Faculty of Homeopathy respondents also practised other forms of CAM therapy. The picture of acupuncturists' practice of other therapies was opposite, in that non-medical BAC members (47%) were far more likely to practise other CAM than medical ones (10%), AACP members were in between (27%). It therefore seems as though in order for GP homeopaths to practise homeopathy they have to become much more open minded with regard to the health models and body systems, thinking beyond the biomedical model. This, however, is not the case for GPs who practise Western acupuncture, perhaps accounting for why fewer BMAS members practise any other CAM, as they may question whether the acupuncture they practise is CAM at all. The position of AACP participants, 55% of whom were physiotherapists practising within the NHS incorporating acupuncture into their

conventional practice has by itself changed the proportion of acupuncture practised within the NHS. In addition, some contracts exist for non-medical acupuncturists and GPs trained in acupuncture to provide acupuncture on NHS funding. In fact, the very recent NICE guidelines for lower back pain (Savigny, 2009) specifically recommend acupuncture treatment for certain patients.

3.10.12 The Delivery of CAM in an Integrated System

It is interesting that the results of the Mortiz study (2004) found that arrangements in which the medical doctors are administering the CAM treatment themselves was the least preferred model for an integrated health system by both CAM and conventional practitioners. Most conventional practitioners including those in the Mortiz study would not practise or be interested in practising CAM at all.

One of the main considerations with medical doctors and other NHS health professionals such as physiotherapists practicing CAM is the time constraints placed upon them, as indicated by the shorter consultation times and less frequent appointments allowed for in the NHS setting. The time constraints placed on existing health professionals in the NHS would be relieved by more medical practices employing independent CAM therapists and/ or medically trained homeopaths having the freedom to practise only homeopathy if they choose to do so within a healthcare setting.

Highlighting the similar practices of medical and non-medical homeopathic practitioners identified by the results of the current study may help to improve relations between the two groups by improving the confidence they hold regarding their practice. This could help to encourage development of a more integrated health system. This in turn leads to another serious matter concerning acupuncture practice in that two very distinct forms of acupuncture are practised, differing in the perception on acupuncture points and the theoretical basis. Some have proposed that in actual fact the two different forms of acupuncture bring about the same response, perhaps the medical acupuncturists "accidentally" triggering the non-local effects of acupuncture whilst delivering medical acupuncture (Hughes, 2007). However this is something that would need to be further investigated in order to provide guidelines on acupuncture practice.

The financial benefits and direct improvements in the health treatment offered to patients overall that could result from an integrated medical system could be significant (Slade, 2004). Future research on how to achieve an effective integrated service is therefore necessary.

3.10.13 Limitations of the Study

There are several limitations to this study and some slight adjustments could lead to improvements in future studies in this area. The sample size of n=340 that was used for the study was enough to get a broad indication of UK homeopathic practice but with a larger sample size more complex analysis between the two groups and correlations between different parameters could be explored more thoroughly.

One aspect of the analysis that should be taken into account when considering the above results is that respondents from the Society of Homeopaths were treated as non-medical homeopaths unless they practised a form of conventional medicine that required significant medical training such as nursing, allied health professionals or doctors (n=5). This allowed for a true comparison on medical and non-medical practitioners but not on the level of training they had received in homeopathy, something that is dependent on the affiliation. Future studies may consider re-categorising the members from different affiliations differently if they were concerned with how practice is affected by training.

The questionnaire was mainly of a quantitative nature with restricted space for comments and in some cases respondents commented that the distinct categories did not enable them to feel that they had represented their views appropriately.

The Society of Homeopaths and the Faculty of Homeopaths are the two most recognised organisations of homeopathic practitioners. However, many more organisations do exist in the UK and in order to gain a truly reflective picture of UK homeopathic practice it would be useful for future studies to investigate the practices of these other homeopaths.

The questionnaire did not ask respondents to comment on the nature of their clinic, e.g. NHS, private, part of a Health centre etc. This information would be useful to identify which aspects of practice were specifically linked to NHS consultations, e.g. length of initial consultation.

A large number of comments were written on the homeopathy questionnaire, indicating that many participants struggled to choose their answers and work with a limited range of answers. Acupuncturists wrote less comments and appeared happier to tick boxes in their answers. It would therefore be useful to validate the homeopathy results by conducting a qualitative study in order to explore opinions and practice of homeopaths in a more open-ended manner and also to address whether the differences found in the homeopathy survey are still apparent in the qualitative results. This will be explored in phase two of the current study.

3.10.14 Future Research Recommendations

It seems that all parties in the medical community agree that further research into homeopathy is necessary, and this study have provided evidence that homeopaths themselves agree with this. The areas that have been identified throughout this chapter as suggested areas for future research are summarised here.

Relevant Conditions for Future Studies

The results of the current study indicate that future studies in the effectiveness of homeopathy should preferably focus on eczema and skin conditions, gynaecological conditions, depression and anxiety, digestive illnesses, musculo-skeletal conditions

and recurrent infections, as these are the conditions most commonly treated by homeopaths. Traditional acupuncture studies should also focus on these same conditions, with particular emphasis on emotional problems. Medical acupuncture research should focus on pain relief, as this is predominantly what this form of acupuncture is used for. Prescribing methodologies of homeopaths involved in RCTs should be in line with what a representative UK homeopath believes and practises as outlined in section 3.8.6 in order for treatment to be representative. This includes individualised prescribing that takes into account matters such as the typology of the patient, generally sticking to single remedy prescribing, and most frequently using the centesimal scale of remedies. To develop the evidence base on the effectiveness of homeopathy and acupuncture future RCTs are necessary. Both placebo controlled trials, and those that are pragmatic in nature, should be carried out on the conditions most commonly encountered by homeopaths and traditional acupuncturists as shown by this study and others.

Future investigations could assess whether the differences highlighted by this study in the confidence of medical and non-medical practitioners in the effectiveness of homeopathy is actually based on clinical results. A potential difference in clinical results might be due to differences in practice methods. Future studies could address the impact of these differences, in particular the consultation times and length before follow-up appointment, and additionally a broader range of factors for acupuncturists, on effectiveness of treatment. If this is the case it would then suggest that the differences in practice that have been found between the two groups do actually have an impact on the effectiveness of treatment and may also have some relevance to the nature of integration models that may be proposed for the inclusion of homeopathy into the UK health system. In particular future studies could explore the impact of the length of the initial consultation on the effectiveness of treatment, and a study of similar nature to the current study could compare the consultation length and practices of homeopaths currently working inside or outside the NHS. This would identify the amount of contact time necessary for the homeopath to obtain sufficient information to prescribe the correct remedy, and notify integrative NHS practices of a sensible length of time allocated per patient for consultation times and follow-ups.

It is clear that therapies such as homeopathy and traditional acupuncture would benefit from a more plausible explanation of the mechanism of action, and any further research, whether in vitro or in vivo, or of a biopsychosocial context, that is able to provide any clarification on this, could have a significant impact on the acceptance of the treatments by broader scientific and medical communities.

3.13 Conclusion

This research is the first in-depth study into UK homeopathic practice and the first to explore the differences in practice and views between medical and non-medical homeopaths. For the vast majority of aspects considered here in relation to homeopathic practice, this study was the first to address these.

Previous surveys of acupuncturists had been conducted on similar groups (Dale, 1997, Alltree, 1993) but having more up to date data is useful, as confirmation that the issues addressed in these former studies have not changed. Other areas on acupuncturists' views on perceived effectiveness, the mechanism of action of acupuncture has added to the literature base built by previous studies.

The results of the study have indicated that several generalisations can be made regarding homeopathic treatment in the UK with most aspects common for medical and non-medical homeopaths. The situation for acupuncturists is entirely different with practitioners using different method or diagnosis and needling and working to different theories.

Acupuncture has become an excepted therapy in many conventional circles and TCM acupuncture is even included in national guidelines of patient care (NICE, 2009). It is not clear whether bodies such as NICE are aware of this divergence in UK acupuncture practice and whether, in sight of this knowledge, they would recommend that TCM acupuncture was practised rather than Western acupuncture.

Whilst there are several limitations to the study, this research has highlighted what constitutes the essence of homeopathic treatment in the UK. It has provided information on the views of homeopaths on homeopathic theory and other medical systems and has presented information that no previous study has covered.

The comparison of medical and non-medical homeopaths and acupuncturists has highlighted issues that are of major importance when considering the possible integration of CAM into the mainstream UK health system, and in particular how affiliation affects the type of acupuncture treatment provided. The comparison also highlights which areas are issues that are associated with CAM therapies in general and which are specific to homeopathy or acupuncture. Examples of areas that may concern CAM in general include differences seen between medical and non-medical practitioners in the length of consultation times, perceived effectiveness of treatment, and opinions on conventional medicine.

Results from the study, has provided information that will help to guide future studies to the most relevant areas of treatment and aid the design of effective trials in homeopathy and acupuncture. In particular, highlighting the conditions that UK homeopaths and acupuncturists treat and the way in which they practised can help in the development of relevant studies. Acupuncture research may further address the relevance of traditional versus medical acupuncture techniques and practices in terms of clinical outcome. Advances in homeopathic research may eventually lead to a better understanding of a treatment that is commonly used by people in this country and provide conclusive evidence that will put an end to the controversy of homeopathy.

Chapter 4

Phase 2 – Qualitative Interviews with Homeopathic Practitioners

Introduction

In this phase of the study, semi-structured interviews were conducted, covering methods of delivering homeopathic treatment in addition to opinions on issues surrounding homeopathy. The opportunity was taken to probe more deeply into areas that were highlighted to be of interest in Phase 1 (see section 3.10) and gain a clearer understanding of UK homeopathic practice. In order to provide sufficient background to understand the results of the themes generated in the current phase of the study, an overview on underlying homeopathic theory is first discussed.

4.0 Homeopathic theory revisited

Homeopathic treatment originates from works and experiments of Samuel Hahnemann in the 18th Century, as discussed in section 1.2.1. Certain concepts and principles were intrinsic to homeopathy at its outset, and many of the explanations given by Hahnemann are hard to comprehend due to development of language since his time and more primitive knowledge of medical science at the time of writing. The issue of comprehension is eased somewhat by more recent works such as Kent's Lectures on Homeopathic Philosophy (1985, 4thEd). However, with a lack of extant literature available, it remains difficult to gauge current thought on the key components and fundamental basis of homeopathy. This aspect will be explored in this chapter, with an emphasis on the process of homeopathic care intervention and the nature of the consultation including perceived key events during homeopathic treatment. Sections 3.1.1 and 3.1.2 give an overview of some of the essential aspects of homeopathic theory as it emerged from the beginning through to modern teachings. This is useful in order to present the way in which the interview questions were driven and in order to understand and interpret participants' responses. It will help to gauge the extent to which homeopathic theory influences current practice. An

overview of the main theories are now presented to aid understanding of topics that emerge in the results section.

4.1 A Chronology of Homeopathic Treatment

4.1.1 Hahnemann's Homeopathy

When Hahnemann developed homeopathy, the present level of knowledge of atoms, molecules and their biochemical, organic, inorganic and industrial nature and their interactions were unknown. Yet it has not been possible so far to update his ideas with newer, more plausible scientific explanations. Hahnemann's original ideas appear to have stemmed from a few key principles and concepts. The first principle was to cure patients in a manner that did not harm the patient, the second was to truly approach the illness by tackling the disease by treating the cause, neutralising it at its very core.

"The highest ideal of cure is rapid, gentle and permanent restoration of the health, or removal and annihilation of the disease in its whole extent, in the shortest, most reliable, and most harmless way, on easily comprehensible principles." **Organon 2 (6th Ed).**

The first concept is the law of similars, treating like with like as described in section 1.2.1.

"...medicines can show nothing curative besides their tendency to produce morbid symptoms in healthy persons and to remove them in diseased persons; it follows...that medicines only become remedies and capable of annihilating disease, because the medicinal substance, by exciting certain effects and symptoms, ...to wit, the natural morbid state we wish to cure. On the other hand, it follows that, for the totality of the symptoms of the disease to be cured, a medicine must be sought which (according as experience shall prove whether the morbid symptoms are most readily, certainly, and permanently removed and changed into health by similar *or* opposite *medicinal symptoms[1]) have the greatest tendency to produce similar or opposite symptoms."* **Organon 22 (6th Ed)**

Another concept is that of the vital force and the need to restore and balance this.

"Our vital force, as a spirit-like dynamis, cannot be attacked and affected by injurious influences on the healthy organism caused by the external inimical forces that disturb the harmonious play of life, otherwise than in a spirit-like (dynamic) way, and in like manner, all such morbid derangements (diseases) cannot be removed from it by the physician in any other way than by the spirit-like (dynamic[1], virtual) alterative powers of the serviceable medicines acting upon our spirit-like vital force, which perceives them through the medium of the sentient faculty of the nerves everywhere present in the organism, so that it is only by their dynamic action on the vital force that remedies are able to re-establish and do actually re-establish health and vital harmony...." **Organon 16 (6th Ed)**

Hahnemann also developed the concept of Miasms. The term miasm has a range of meanings relating to the disease process of chronic disease. It most commonly describes a predisposition or trait that makes an individual susceptible to a particular pattern of morbidity. This can be within society, a family, or an individual, and is an inherited or acquired disposition to be ill in a certain way. This is something that Hahnemann worked on for some time and he described it as a blueprint or shadow of the illness. A miasm can be described as a pathogenic influence of a particular disease process upon an organism, responsible for a wide but distinctive range of morbidity not necessarily characteristic of the pathology of the original disease (Swayne, 2000). Hahnemann investigated three major miasms. One example, Syphilis, is the miasmic illness having a syphilitic origin in previous generations. Psora is another, which Hahnemann believed to be a result of a suppressed "itch" or scabies infection and the root of many chronic diseases. The third is Sycosis, a miasm that was considered to have a primarily gonorrhoeal root. Since Hahnemann's time several other miasms have been investigated by homeopaths such as Allen, Sankaran and Vithoulkas (see section 4.3.4). These other miasms are generally believed to be a combination of the original three, however, not something completely new.

Additionally the term miasm can be used to describe an infectious or noxious vapour or atmosphere.

Homeopathic training courses run by organisations such as the society and the Faculty of homeopathy use literature such as Hahnemann's original texts (1981, 6th Ed), Hering's and Kent's (1985) work and more modern texts written in different corners of the globe, such as those by R Sankaran (e.g. 1991, 1994) and his father P Sankaran (1996) and G Vithoulkas (1986) as reading material for the course. The exact content varies from course to course and naturally is dependent on the length of the course, with Society courses being much longer than Faculty courses. Some key points from these influential homeopathic authors are detailed in section 4.1.2 below.

4.1.2 Other pioneers of homeopathic treatment and their contribution

4.1.2.(i) Hering

Constantine Hering (1800-1880) was a conventional physician who was employed by a leading opponent of Hahnemann in order to scrutinise and undermine Hahnemann's work. However, whilst studying the work, Hering became fascinated by homeopathy and began to repeat Hahnemann's experiments on himself. Rather than undermining his work, Hering went on to become one of the major proponents of homeopathy and the first to take it to the USA, where he opened a college that is still one of the leading homeopathic colleges in America now. One contribution Hering made to homeopathic theory, which came to be known as Hering's Law, was the process whereby a disease manifests as close to the extremities as possible. However, as it progresses, or if its expression is suppressed, it strikes closer to the core organs and eventually to the mind. This order must then be reversed for cure to be restored- the disease condition digresses back out to the peripheries. Therefore the curative process can result in more outwardly obvious symptoms, for example a skin rash, during the healing process. Another addition made by Hering was the concept of a group of keynotes: these are characteristic symptoms which unmistakably point to a small group of remedies. A single keynote therefore may not be of great use in prescribing. Typically, at least three keynotes are needed for what Hering called applying the triangular test. If three important characteristic symptoms are found that

all point to one remedy then the remedy can be given with unerring certainty (known as Hering's three-legged stool).

4.1.2.(ii) Kent

James Tyler Kent, like Hering, was originally a conventional medical practitioner but went on to be a celebrated homeopath, founding a postgraduate homeopathic college in the UK and publishing his Lectures on Homeopathic Philosophy, which became a key text to shape homeopathy in the 20th Century. Kent's Materia Medica is still widely used today. Kent was a great proponent of the idea that you cannot divorce the physical body from the mental, emotional and spiritual being that you are treating. Therefore he advocated the use of higher potencies, indicated where mental symptoms need to be addressed.

Kent, in conjunction with other great contempories such as Hering, also developed "pictures" of homeopathic constitutional types. This led to the development of constitutional remedies where certain remedies, usually one of the polycrests (See section 4.1.4), have properties attributed to them. A system of identifying constitutional (personal) attributes indicates a particular remedy and has led to the development of constitutional remedies. Kent created a "picture" of characteristics in terms of their temperament and physiological configuration, e.g. Sulphur as the "ragged philosopher". Such constitutional prescribing developed from this as a method of choosing a homeopathic prescription based on the patient's constitution rather than on the clinical picture alone (Swayne, 2000) and is one of the key principles of modern homeopathic theory. To Kent the constitutional picture helped to differentiate between remedies. A constitutional remedy, if prescribed correctly is said to stimulate a vital healing reaction and a liberating feeling of well-being (Smith, 1987). In particular, recurrent problems are said to often be resolved by the constitutional remedy (Smith, 1987). Kent also spoke of symptoms as "mentals", "generals" and "particulars". Mentals were attempts to draw a picture of the diseased patient's mental state. Generals were items like feeling hot or cold, liking sweet or salty foods, always thirsty or only likes a little water. Similarly, particulars were the specifics that defined the patient's condition as precisely as practicable.

4.1.2(iii) Boenninghausen

Clemens Maria Franz, Baron von Bœnninghausen (1785-1864) was one of the most noteworthy of the early practitioners of Homeopathy. Born in the Netherlands he graduated in civil and criminal Law and worked as a civil servant for many years. He than began to study botany until he came down with purulent tuberculosis. His health continued to decline until the spring of 1828, when all hope of his recovery was given up. He contacted his friend Weihe, M. D., who was the first homeopathic physician in the province of Rhineland, who prescribed him *Pulsatilla* and by the end of the summer he was considered cured. From then on Boenninghausen dedicated his life to the study of homeopathy and a long list of his work was published between 1828 and 1846. His *Therapeutic Pocket Book*, first published in1846, is considered a great guide to many in homeopathy.

As a homeopath, Dr Boenninghausen found aggravations more significant than ameliorations in prescribing. He was a high potency prescriber, his view on remedies was that the sphere of action continually enlarges with high potencies so that in chronic ailments they hasten to cure. In acute disease Boenninghausen believed that high potencies bring about a quicker response, and high potencies are not affected by dietary sources the way that low potencies are. Dr. Boeninghausen contributed the concept of generalisation; when a sensation or modality is felt in two or more locations, this can safely be generalised. Another contribution made by Boenninghausen was the idea of contra-indications of certain remedies for certain patients. He talked of genius symptoms and contraindications. This was the idea whereby the severity of a symptom may indicate whether a remedy is suitable or not, with certain remedies working in severe cases but not so well in the case of gentler symptoms. For example the remedy Nux Vomica if given for mobility, he believed, works when given to someone with an aversion to movement but if they have a strong desire to move it is unlikely to work. This idea has been taken a step further by a contemporary homeopath, Frei, who has further developed this idea and re-termed it Polarity Analysis (Frei, 2008) and the idea may therefore become central to homeopathy.

4.1.2.(iv) R Sankaran and P Sankaran

Rajan Sankaran is a contemporary homeopath, originally from India. His father, P Sankaran, was also a prominent homeopath and Rajan set out to publish his father's work before writing his own books. P Sankaran set out what he called the Hierarchy of Symptoms. A method to guide practitioners towards choosing a remedy. He categorised symptoms into the following: 1. Mental characteristics, **2.** General characteristics, **3.** Particular characteristics **4.** Mentals common **5.** Generals common **6.** Particulars common (least important).

In his own books, the contemporary homeopath Rajan Sankaran detailed one approach of identifying the typology of a patient, classing them as Animal, Plant or Mineral, each displaying a different set of qualities (Sankaran, 1994). The label here refers to the source of the remedy. Another example of R Sankaran's contribution to homeopathic theory is the idea of compensation, whereby a shift in the vital force causes too much energy in one area and hence a lack of vital energy in another, so finding the opposite as a tool to identify the root cause and the remedy indicated (Sankaran, 1991).

Other pioneer homeopaths including Allen, Clarke and Murphy are among others who have also made valuable contributions on homeopathic theory. T F Allen (1874) compiled an encyclopaedia of homeopathy which also sought to elucidate some of the points made in Hahnemann's original texts and he continued in later years to produce his own materia medica. J H Clark (1853-1931) also wrote his own handbook of homeopathy and materia medica. He dedicated much time to his work on the proving of nosodes (see section 4.1.3). Robin Murphy is a contemporary homeopath born in 1950. He studies historical texts on homeopathy and has taught many classes, and then compiled his findings, questions and answers that emerged during his seminars in his work "Keynotes of the Materia Medica" (Murphy, 1993) and this has become a key text in many homeopathic courses.

The work of the homeopathic pioneers mentioned in this section are among the most likely to be encountered by homeopaths during their training and private study. It is

likely that they are very influential on the views and practises of the homeopaths, along side those developed during clinical experience.

4.1.3 Homeopathic Remedies

Homeopathic remedies are derived from a complete array of original organic and inorganic sources including human, animal, plant and metal sources. Listed below (section 3.1.3(i-ii)) are a few more specific sources of relevance.

4.1.3 (i) Nosodes

Derived from the Greek "nosos" meaning disease and "eides" meaning like, this is a type of homeopathic medicine derived from pathological material. It may be of plant, animal or human origin including microorganisms, diseased tissue, or the products of disease processes, such as discharges and effusions. Nosodes are used to treat or prevent associated diseases of the tissue material. In addition there are numerous homeopathic medicines derived from healthy human or animal tissue or organs. These are known as sarcodes. A particular group of remedies prevalent in modern homeopathic texts are the Bowel Nosodes (Squire, 1997).

(ii)Bowel Nosodes

The Bowel Nosodes are a group of 12 homeopathic remedies identified by Edward Bach and further developed by John and Elizabeth Patterson, who researched a series of nosodes from the non-lactose fermenting bowel organisms (Swayne, 2000). They were prepared from organisms obtained by stool culture from patients showing particular patterns of disorder who had responded to particular homeopathic remedies. They were prescribed on the indications derived from the clinical picture of those patients. Used as medicines in their own right on the basis of their clinical picture or to reinforce the action of their related group of medicines. They are said to be enormously important especially in treating chronic disease (Smith, 1987). The major bowel nosodes are Morgan, Proteus, Gaertner, Dys, Co., Sycotic Co.

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The number of nosodes and sarcodes documented ranges, this is widely dependant on when the text was written. Allen (1910) reported 29 nosodes of which 26 are included in the work of Squire (1997). The missing three are: Magnetis Poli Ambo,

Magnetic polus arcticus, and Magnetis polus australis. Squire's work however mentions over a hundred nosodes and sarcodes (Squire, 1997).

4.1.4 Homeopathic Prescribing

Very little has been documented on the actual methods of prescribing used by homeopaths. Some remedies are used more widely than others, a subgroup of major remedies has emerged through widespread use throughout the globe and are known as Polycrests. Polycrests have a therapeutic picture that shows a wide spectrum of uses for acute and chronic diseases. They are considered to affect all or nearly all the tissues in the body showing a great variety of symptomatology; polychrests therefore have a broad range of clinical applications (Swayne (Ed), 2000). Homeopathic remedies belonging to this group include: Argenticum nitricum, Arnica, Arsenicum album, Belladonna, Byronia, Calcarea carbonica, Calcarea phosphoric, Carbo vegetabilis, Gelsemium, Ignatia, Ipecac, Lachesis, Lycopodium, Natrum muriaticum, Nux Vomica, Phosphous, Pulsatilla, Rhus toxicodendron, Sepia, Silicea, Thuja. This list covers most of them but it is not a universally accepted list as the exact qualifying features of a polychrest is under debate. Inclusion under the subset polychrest is linked to the scale of proving of the remedy as well as its clinical use. There are many different ways to match up remedies to patients, Sankaran's method of characterising the person as likely to need a remedy from plant, animal or mineral source is one tool. Another principle that is key to homeopathy is the concept of the modalities of disease.

4.1 (i) Modalities

Modalities have been described as "*A factor which modifies the behaviour, level, degree of intensity or severity of a clinical state (symptom, sign, pathology or disorder). This may be another clinical condition, a physiological function, an emotional state, an activity, the behaviour of the patient, food and drink, time of day, any experience or circumstance, including environmental factors, to which the patient is exposed, or commonplace palliative measures or reactions such as rubbing or scratching.*"

(Swayne, 2000)

The exploration of modalities is another tool that homeopaths can utilise to explore the appropriate remedy picture.

4.1.4 (ii) The Choice of Potency

Choice of homeopathic potency is another area where homeopaths disagree. There are three different scales for homeopathic remedies. 1. The centesimal scale, developed by Hahnemann at the start of homeopathy. This usually has the numeral value followed by the suffix C, e.g. 200c 2. The decimal potency, evolved by Hering and denoted by the suffix X after the number, e.g. 300x 3. LM potencies, also known as the 50 Millesimal scale, and known by some as Quinquagintamillesimal or Q potencies. Potencies can be classed as either low, medium or high. Low potencies range from approximately 0-12C, medium range from 12C -200C and high from 200C upwards to DM, MM and DMM. In homeopathic circles there can be a tendency for low potency prescribers to look aghast at a homeopath who states they use high potencies and for high potency prescribers to look down on and show contempt towards low potency prescribers (Sankaran (P), 1996. In Hahnemann's lifetime he was known to use only potencies of 30C and below, but Farrington, a famous contemporary of Hahnemann quotes Madame Hahnemann as saying that he would use 200C-1000 where necessary.

It seems that each celebrated homeopath had something different to say about potencies, with some stating that high potencies gave more scope for treatment (Boenninghausen, 2005) and can work on more mental symptoms (Kent, 1985) and others including Boyd and Bell saying the gentle approach is better or in any case is usually adequate and Kishore adding that sometimes a higher potency is needed (Sankaran, 1996).

Some basic rules on potency selection were proposed by P Sankaran , (1996):

1. If a patient is very well matched to the remedy picture of a drug, especially if mental symptoms are present, then a high potency would be advisable
2. Conversely if a symptom does not match the remedy picture of a drug too well or only partially matches it to treat superficial symptoms then a low potency is advisable
3. Certain remedies seem to work better at higher potencies, including nosodes

4. If a patient has already been treated with a high potency and it has worked but caused some other symptoms or not completely shifted the symptoms then a low potency is advisable

5. Children appear to tolerate high potencies better than old people, possibly due to their vital energy being stronger

6. In patients with high sensitivity to drugs a low potency is advisable

7. Sanakaran highlights work by a homeopath named Close, proposing that it is possible that more intelligent and sensitive patients engage in mental occupations more and therefore need to be treated with higher potencies than less intelligent patients and those who do manual jobs.

8. There are some remedies that have opposite effects when given in low potencies than when given in high potency, e.g. silica given in low potency promotes suppuration, whereas if given in high potency it aborts suppuration.

9. High potencies of deep-acting medicines such as silica, phos etc. are contraindicated in advanced pathological states.

During this phase of the study, the methods used by homeopathic practitioners in prescribing and distributing remedies is explored.

4.1.4(iii)Obtaining Homeopathic Remedies

With homeopaths working in a range of settings and in most cases these being outside the conventional health service setting, traditional methods for supplying medications via prescriptions and pharmacies do not apply. Several homeopathic pharmacies exist, the main UK based ones including Helios, Ainsworths and Waleda. These sell homeopathic tablets in addition to medicated remedies that can be used by practitioners to make their own tablets. Some regular pharmacies also supply a number of homeopathic preparations. There is very scarce literature available on where homeopaths access their preparations.

There are therefore many areas of the unknown regarding homeopathic practice. This is both in terms of what homeopaths actually do and also to what extent their practice relates to the homeopathic theory that exists, in both old and newer form. Much of this they may have been taught during their training, though many will have read texts on homeopathic theory as their careers developed. This chapter aims to

achieve an insight into the practices and perceptions of homeopaths, in order to address the lack of literature available.

4. 1.5 The Concepts of Health, Healing and Cure

Although there is little literature available on the development of the perceptions of homeopathic principles, there is a good deal more on how the concept of health itself has evolved over recent times. By addressing the more general issue of concepts of health and health restoration this section will allow for a more focused approach to understand the processes and events in homeopathic treatment. In light of this, perceptions on the homeopathic intervention can be put into context of the picture of health as a whole.

Over the past century and particularly since World War Two, health has come to mean a lot more than the absence of disease in the Western world. Matters such as diet, ones environment and quality and strength of social interaction have also been considered factors associated with health. Stresses in everyday life lead to mental and emotional problems that are recognised as legitimate reasons to take sick leave from work and account for many visits to doctors and other health professionals.
The World Health Organisation gave this definition for health:

"Health is a state of complete physical and social well-being and not merely the absence of disease or impurity" (WHO, 1948)

A UK- based survey found that in the late 1980's only 30% of respondents defined health as being "not ill" or "disease-free" (Cox, 1987). A study carried out in the 1970's by Herzlick found that among middle class members of society people classed health as something to be had, a state of knowledge and a reserve of strength and ability to meet one's potential. It was associated with the emotions of feeling happy and strong, being in a state of equilibrium and ability to form good relationships with others (Herzlick, 1973). Another study carried out on older men and women in Aberdeen concluded that people defined health as not only the absence of disease or illness but also a reserve of fitness and the capacity to cope with illness or endure chronic pain and keep going (Williams, 1983).

No universal agreement has been reached on the definition of the words "health", "illness" or "disease" (Helman, 2001). As the search for a definition of health has matured, some studies have suggested that social class among other factors had a big impact on how one defines health.

Baxter concluded that health has a multiplicity of meanings that are dependent on age, gender and class (Baxter, 1983). These definitions included having a functional capacity, being free from illness, and a physical fitness. In addition, health was labelled a psychological concept allowing a functional capacity.

A study conducted by Calnan (1987) presented participants from different social backgrounds, categorised definitions of health into four different themes. The results of the study indicated that people from working class backgrounds were more likely to define health as freedom from illness and the ability to get through the day, whereas middle class respondents tended to use definitions of being fit, active and exercising and being able to cope with the stresses and strains of everyday life (Calnan, 1987).

Health can therefore be considered to span multiple components, and ability to cope generally as well as staying free from illness were two highly important variables.

Quality of life in particular is an area that is focused on in the developed world and a focus of philosophy relating as far back as Aristotle in the 4th century BC. Health is often placed as a key aspect of quality of life, and the importance of health to quality of life reportedly increases with age (Bowling, 1996). The context of health is nicely summarised by the contemporary celebrated homeopath P Sankaran who philosophised on health with the following: "Health, I realised, was the man's freedom to be in the moment and fulfil the purpose of life"

4.1.6 The Placebo Effect and its Role in Cure

One phenomenon that has particular relevance to both health restoration as a whole and homeopathic treatment in particular is the placebo effect. It has long been established that a degree of therapeutic benefit can occur as a result of the interaction

between healthcare professionals and patients alone. One of the consequences of the financial and time constraints placed on the current healthcare system, largely as a result of an aging population, is decreased amount of contact time and "TLC" in healthcare provision. Many forms of complementary and alternative medicine (CAM) include lengthy consultations and probe deeper into a patient's emotional and spiritual wellbeing in order to assist holistic healing. For this reason, benefits from CAM are often attributed to the placebo effect by the medical profession as a whole. Only recently has the placebo effect been recognised as an actual therapeutic process in its own right that may even be integral part of the healing process of all treatments. The placebo is thought to be a sequence of events resulting from psychological triggers that promote wellbeing. For example, there is evidence that even the size and colour of pills can influence their effectiveness (Ernst, 2000). The processes that result in the placebo effect are certainly not fully understood.

4.2 Rationale for a Qualitative Study

The current study was an in-depth study on areas that arose in the Phase 1 results presented in section 2.3. Unlike quantitative research which is positioned more within the positivist epistemological perspective, typically aiming to test or verify hypothesis, qualitative research is positioned more within the constructivist epistemological perspective and concerned with exploring experiences and social factors which can underpin and shape the hypotheses of quantitative research (Denzin and Lincoln, 2000). The objective of this part of the study was to obtain information on participants' experiences of delivering homeopathic treatment and also their methods and opinions on different aspects. With research questions that covered a broad range of topics in a study that was exploratory in nature, it therefore suited a qualitative approach. The study focused on areas of interest that emerged from Phase 1. Since Phase 1, which preceded this study, used a survey which was predominantly quantitative in nature, it was only able to obtain categorical information on a preconceived range of topics. A qualitative approach in phase 2 allowed for open discussions based around these topics, allowing the freedom to move in new directions and to obtain data without expecting participants to frame their answers around a set model.

Qualitative research is often used to identify key themes on a specific topic. Further analysis can then be used to link themes and identify groups from the responses. Examples of qualitative methods include discourse analysis and grounded theory, which seeks to derive new theories from the data. Phenomenology takes the process of identifying themes a step further, trying to identify what is behind the themes and explain how and or why they emerge. Interpretive Phenomenological Analysis (IPA) as described by Smith (1995) is a method that takes an approach that focuses on the meanings that participants ascribe to events. Although there are clearly a number of different qualitative approaches IPA was considered the most appropriate for the study because the primary aim in IPA is to gain an understanding of the experiences and perceptions of the interview respondents, to attempt to gain an insider perspective (Conrad, 1987). When people have a particular experience or when they are involved in decision making, they often reflect on the significance of this event or decision and IPA researchers engage in this reflection and examine how someone makes an important decision. IPA does take into account the fact that the process of doing this is very much dependent on the researcher and their conceptions as this will influence the interpretation of the data during the analysis. The interviews in this study focused on the experiences of homeopathic practitioners and how their views and perceptions shape their practice and decision making processes when providing homeopathic treatment, and therefore IPA was considered the most appropriate approach to take.

In the current study, the processes of remedy selection, events in the homeopathic consultation, review of patients and opinions on medicine and the therapy that they practise is explored. By exploring the views and practices of homeopathic practitioners, this study seeks to identify the key components of homeopathic treatment, highlighting areas that may be relevant to the integration of CAM into mainstream medicine and to future homeopathy research. More specifically, the aims and objectives are detailed in section 4.3

4.3 Aims – To further explore areas of interest emerging from phase 1 on specific approaches used in homeopathic practice, how closely practice adheres to some kind of framework and how homeopaths assess the progress of their patients at follow-up with a focus on treatment of osteoarthritis.

Objectives –

- To focus in depth on the events that take place during homeopathic treatment of osteoarthritis
- To examine how different homeopathic practices operate in terms of location, access to patients and whether treatment is funded
- To triangulate how findings from a more open questioning style corroborate with previous findings in phase 1 of the current study.
- To identify key events that take place during a homeopathic consultation
- To examine the range of approaches used by different homeopaths
- To explore the opinions of homeopaths on underlying homeopathic theory
- To gain an insight into attitudes and opinions on other medical systems

Design: -

Exploratory study using semi-structured interviews. A full description of how the interview schedule was developed can be seen in Appendix 13.

Selection & Recruitment: - In order to access approximately 30 homeopaths, the maximum number predicted to be necessary to achieve saturation of the data, 100 of the sample used for the survey in Phase 1 (See Chapter 3), including 50 from the Faculty of Homeopathy (FOH) and 50 from the Society of Homeopathy (SOH), were randomly selected and sent a postal invite for interview. Of those who replied, the first 15 from each group were contacted in order to arrange an interview at a location convenient to the practitioner. Where this was not possible to arrange or where the practitioner was no longer willing to be interviewed, the next respondent was contacted.

Inclusion Criteria: - All practitioners in the relevant geographical locations who are members of the SOH or FOH.

Exclusion Criteria - Due to practical reasons, places that could not be reached by public transport could only be included if participants were able to offer assistance or meet in a more convenient location.

4.3.1 Participants

The sample size for this part of the study was n=28, this comprised n=14 members of the medical Faculty of Homeopathy members and n=14 non-medical Society of homeopathy members n=14. Data collection stopped at n=28 since saturation of the data was achieved with this number. Table 4.1 shows the geographical location of the participants in the study.

Table 4.1 Participants' Medical Status by Location

	Location					
	North-West England	Lothian & Strathclyde (Scotland)	Yorkshire	London	South-East (Not London)	Other
Number of Medical Participants	3	2	0	3	4	2
Number of Non-Medical Participants	1	2	4	4	1	2

4.3.1 Topics Explored

The topics explored in the study were designed to address its aims and objectives. The interview schedule was essentially three parts, the first an introductory section exploring the setting in which the participant practised, their initial interest and how they accessed their patients. The second section was to probe for details on the content of initial and follow up consultations using the example of a patient suffering

from OA, as this is the condition of focus for the current study. The third was to explore opinions on factors surrounding treatment, underlyinjg theories of homeopathy and confidence in different medical systems. The full interview schedule with explanation of question development can be found in Appendix 13.

4.3.2 Procedure

The interviews were conducted in a location convenient to the participant yet practical for the researcher, most commonly this was the participants' consulting room. Once in a convenient location for the interview a rapport was developed, using general conversation, with the participant and they were asked if they would give consent for the study and for the session to be audio recorded. Memo notes were made following the interviews in order to negate the need to write detailed notes throughout the interview, a process that may have disrupted the flow of dialogue. All participants consented to the audio-recordings and signed written consent forms, which asked participants to confirm that they understood that all findings would be anonymised and audio-recordings would be destroyed within a 6 week period following transcription. After the consent was obtained the audio recorders were started. Two different recorders were used, one a tape dictaphone and the other an electronic voice tracer. This was to reduce the risk of losing data through ineffective recording and to ensure a clear recording was obtained for transcription. The interviews lasted between 45 and 60 minutes. The semi-structured interview schedule as seen in Appendix 13 was used as a guide to steer the conversation towards the areas of the study but topics were explored as they arose. Semi-structured interviews were used for the study in order to direct sufficient focus to the research questions but to allow flexibility of the researcher to further probe areas of interest in detail and to explore new avenues where this was felt to be appropriate, with the interviewer as the tool to elicit relevant discourse with the participants. The topics of interest to the study, within the three main sections, were allowed to emerge naturally in order that the interview flowed freely between topics rather than sticking to a strict order.

4.3.3 Analysis

Interviews were transcribed and analysed. A memo was kept during the interviewing, transcribing and analysis phases of the study in order to monitor the

emergence of trends and the point of saturation. The interviews were listened through alongside the completed transcripts repeatedly in order to familiarise the researcher with the data, to assist analytical and reflective practice and for validity and reliability of results. This in turn helped to develop the codes and emergent categories. In line with IPA as described by Smith (1995), this process began with the first transcript and in addition, for each major theme, data from all participants was logged on a checklist of emergent sub themes, in order to identify any interrelationships. The first two transcripts were analysed by an additional researcher and compared and contrasted with those found by the principal researcher in order to check validity and reliability of the analysis. Findings between the two researchers were consistent and so the principal researcher continued the analysis with the other transcripts. Coding was completed by hand without the aid of computer software and tables of the different themes were compiled to allow cross referencing of themes. This involved keeping lists of emergent themes and participants with whom they had arisen. Patterns and cross referencing could then be identified. In addition, this process enabled assessment of the degree of generalisability of findings and allowed any inter-affiliation or other subgroup difference existing between the practitioners to be observed. Subsequent transcripts were then analysed in the same way and the emergent themes were compiled. Where similar sentiments arose these were logged against the existing themes on a checklist and new themes were added to the list. An example of a transcript is shown in Appendix 16.

The memo notes from the original interviews were consulted throughout in order to include original impressions from the data in the analysis. The final method by which the results were ordered depended on the nature of the findings. Some parts of the data were compiled in a quantitative way, for areas where participants were stating a fact, for example where practitioners obtained the remedies, and these results are presented in tables. In some cases, for example when looking at the consultation, the themes that emerged had a similar resonance across the participants and these themes from the whole set of participants were therefore compiled together. In other cases clear divisions were identified between different groups and these are looked at in terms of proportion of participants where these themes emerged.

4.4 Results

Results in this section show the themes that emerged from the participants' responses. The results are presented in different ways depending on the type of information being reported. Tables 4.4 to 4.6 contain results on different methods used by practitioners and on the source of the remedy. Figures 4.1 and 4.2 show a summary of the superordinate and subordinate themes that emerged on homeopathic treatment and how they relate to each other. Figure 4.1 summarises the emergent themes on the homeopathic treatment process and Figure 4.2 summaries the emergent themes on the perceived therapeutic mechanism. The themes are also described individually and illustrated with selected quotes. Where quotes from the transcripts are used, the participant number or code is stated and this is preceded by m for medical homeopath or n for non-medical homeopath. Eg, "M3" "is medical practitioner 3" . Where an "n" number is displayed for a particular theme, this can only be taken as a rough guide to the proportion that generated the theme as the interviews were only semi-structured and therefore if the theme was omitted it cannot be concluded that it was not relevant to that participant. In addition, some quantitative information that was extracted from the transcripts are shown in boxes.

4.4.1 Route of Access to Clients

Table 4.2

	Route of Access to Patients/ Clients					
	Private Health Centre/ Therapy Centre	GP Practice	GP Referrals	Private Ads / Word of Mouth	Referrals from other agencies (NHS/ Charity)	Homeopathic Hospitals
Med	2	7	1	4	1	3
Non-Med	2	0	4	10	1	0
Total	4	7	5	14	2	3

Information on how participants accessed their patients is shown in Table 4.2. The main route of access for each of the participants is represented in the figures in the table, however, in some cases there was more than one main route of access. This explains why the totals exceed the number of participants. An example of multiple sources was that n=3 of the medical participants also saw some patients at a homeopathic hospital, in addition to their practices. Half of the medical GPs saw homeopathic patients via their NHS GP practices. Of these 4 would receive patients who were actively encouraged or referred to them for homeopathy by other GP partners in the practice. Most non-medical homeopaths, n=10, received patients following personal advertisements, leading to word of mouth contacts once their practice was established. Many ran this practice from their own homes. A few participants, n=2 medical and n=2 non-medical homeopaths were based in health centres and would access patients through these. n=2 participants, one medical and one non-medical received referrals via other health agencies or charities including a cancer centre and a health centre for University students.

4.4.2 The Homeopathic Treatment Process

Figure 4.1 summaries the key themes generated on the treatment process, as perceived by participant homeopaths.

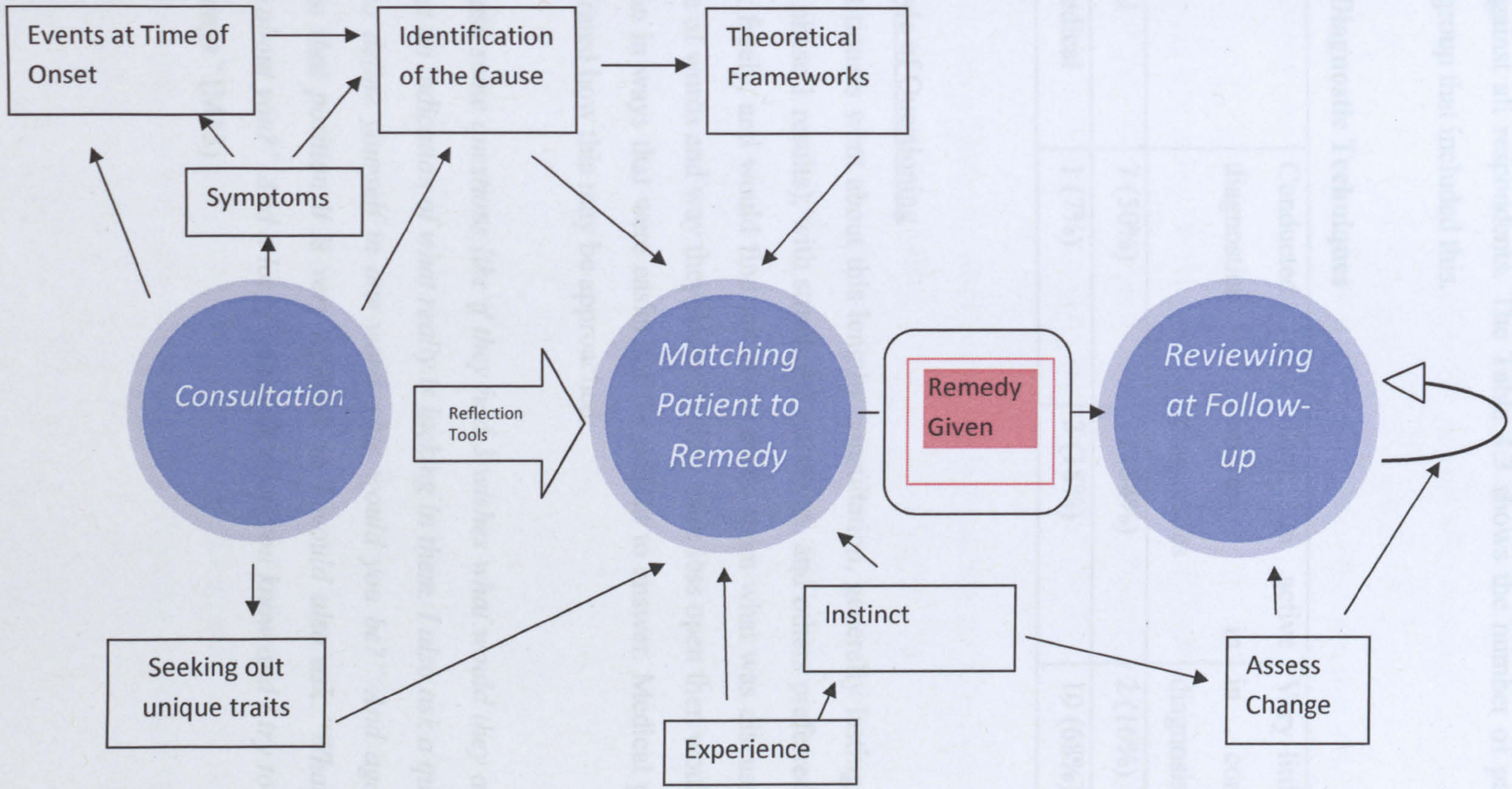
The consultation: -Case taking:

In terms of the methods of taking a case history from patients, all participant homeopathic practitioners appeared to stick to traditional methods as described in key homeopathic texts (Kent, 1985, Hahnmann, 1982). These texts advocate obtaining detailed histories from the patients on a very wide variety of areas including the condition that they had attended for, lifestyle habits, "Generals" (see section 3.2.1) for example likes and dislikes or preference for hot or cold weather, fears, self descriptions, dreams, modalities, family medical history and relationships. This was a universal approach taken by the participating practitioners. Over half of the practitioners mentioned discussion points which allowed the client to ease into the conversation and warm up to more personal topics. The exact method of doing

this varied according to personal style but essentially a very similar approach was taken.

"I'm quite thorough on food. People's food likes and dislikes and the ones that don't suit them and if they like them hot or cold. I don't find the weather makes too much difference" (M1)

Figure 4.1: Schematic Diagram of Superordinate and Subordinate Themes Generated, Related to the Homeopathic Treatment Process



4.4.2(i) Diagnostic techniques

The importance placed on diagnostic techniques during the participants' responses on what they discuss in consultations was investigated quantitatively using a checklist against all respondents. The Table 4.3 shows the number of participants from each group that included this.

Table 4.3 Diagnostic Techniques

	Conducted own diagnostics	Took an active interest in diagnostics	Very little interest in conventional diagnosis
Medical	7 (50%)	11 (84%)	2 (16%)
Non-medical	1 (7%)	3 (18%)	10 (68%)

4.4.2(ii) Style of Questioning

Some practitioners went about this lengthy consultation, generally lasting 45 min-2 hours (See phase 1 results), with structured questions, and others preferred to let the patient talk freely, and would find out about them from what was discussed and in their choice of words and way they spoke. If they were less open then would lead the conversation in ways that were easier for the patient to answer. Medical participant M13 illustrated how this may be approached:

" ...then I ask some questions like if they had 3 wishes what would they ask for and usually I get an indication of what really is lacking in them. I also ask a question " If you have to define yourself in one word what would you be?" And again, to put yourself in that position it is very difficult so I would also ask "What do other people say about you?" And a lot of things develop you know and I try to find some common things" (M13)

4.4.2(iii) Seeking out Unique Traits

One theme that emerged as a key component of what homeopaths were looking for during this discussion was to identify something that was really unique about the client:

" ..So I suppose what I'm doing is trying to find out what's characteristic about this particular person, what's striking about this person, what stands out..." (M6)

"I ask them questions like, "if you had three wishes what would you ask for? And this really tells me something about them" (N12)

Delving deeper into treatment priorities was one way of learning about the patient *"some people say "the pain is awful, but the worst thing is that I'm putting on weight now" that says something about the inner them"* (M6)

In some cases this information would come out in what was the seemingly incidental aspects of what patients were saying :

" ...the bits of information they give me that are by the by, that's usually got a few nuggets in it. Things that they bang on about and you think "why are they telling me this?" and if you were a doctor you'd just be going "next please". But if you're a homeopath you're thinking "there's something really important in this that they're trying to tell me" so be with it and let them express it and see what treasure is in there" (N8)

4.4.2 (iv) Identifying the Cause

The identification of a cause of the upset to the body system arose as a key theme to come out as a crucial part of the consultation; it seemed to be an area of extreme importance since it was mentioned by the majority of participants. Participant homeopaths took great interest over highlighting the cause, aspects of lifestyle and key events that were taking place at the time that the symptoms of their patient manifested. Again this was a theme that universally emerged amongst medical and non-medical participants alike.

"Someone last week came with a skin complaint, but when we traced it back to where it started from it was a very unhappy time in her life so there could have been a lot of unresolved grief at that time" (N3)

"...I spend a lot of time...a set of circumstances that have disordered, for example if it's an autoimmune problem, and the sequence of events that have happened coincidentally, or concurrently at those times because it can have an influence on the nature of the problem, and an influence on prescribing" (M8).

"usually, people who've got a health problem you can always relate it to a cause and the cause can be emotional, physical trauma, it can be something that happens in their life, it doesn't have to be a particular event it can be a general thing that goes on in their life, like not liking work and that sort of thing" (N5)

4.4.3 Time constraints

In some cases time constraints were a major factor in the type and depth of information gathering (n=7) but for many homeopaths the consultation naturally reached a point where things fall into place. *"...mostly, something sort of clicks and I feel that I have got an understanding even if I haven't got the remedy, I feel I have understood this...I have gained an understanding of the sequence of events and why it has manifested in that way..."* (N3)

"I know I will not have all, especially when somebody's 50, they've had a lot of life experiences, you're not going to find everything out of course you're not. Who's going to sit there for an hour and a half and tell somebody absolutely everything, it doesn't happen. But I feel more or less comfortable that I got enough to go on to make some sort of sense of what's going on and make some sort of prescription." (N10)

4.4.4 Matching up the Patient to the Remedy

The next step is the process of choosing the remedy, which is what the consultation is all based around. Several different approaches were used for this and tools such as

material medica, containing remedies and their indications for different ailments and their digitalised versions - computerised repertories, e.g. Radar were often utilised.

Some practitioners would prescribe during the consultation (n=8, see table 3.4) and others would take time following the consultation to analyse the case at length. In some ways this stemmed from time constraints and habits but preferred styles contributed too.

4.4.4(i) Forming Links

One theme that emerged from the participants' accounts was that often remedies would pop into their minds during the consultation. Some practitioners would use this as a main prescribing technique *"I'm linking to remedies all the time, I'll be writing them in the margins as things come up"*.(N8)

4.4.4.(ii) Instinctive Prescribing

A number of participants would be aware of the instinctive drive towards remedies (n=11) and this was more common with medical participants (see table 4.4) but several mentioned that they would try to avoid being focused on this and seek to analyse the case fully, as illustrated in the quotes by medical participant M9 below:

" Well I would usually go away and use my Radar programme. And I usually have a feeling of what type of thing I'd want to give them, which is bad really, I shouldn't do that really I should repertorise them properly" (M9)

4.4.4(iii)Theoretical Frameworks as a Tool for Prescribing

Some practitioners would use frameworks of classification to identify the remedy. In some cases this involved gathering information to classify a patient's constitutional type (see section 4.1.2(ii)) and often this would then lead to prescribing constitutional remedy first.

Some use other forms of symbolism and classification systems that have been passed down from Chinese medicine, Ayurvedic (ancient Indian) medicine, or systems that are described in classic homeopathic texts. The participant sometimes used such systems together with instinctive sense to prescribe.

(M9) talked of a system of classification she used: *"No, I mean, have you heard about the animal mineral and plant?... I think it's Sankaran but I wouldn't swear to it... I'm trying to get a feel for what group that person fits into from all sorts of things about them, how they talk, whether they use their hands, what they say, how they say it, what they're wearing and that sort of thing... it's a way of trying to refine the prescribing really. A way of trying to get to the right remedy for the person"*

One medical participant gave an example of the use of symbolism in her classification:

"with something like natrimurascin, natrimuriascin is sea-salt, and a salt is what's in the sea and the sea is a symbol of what's in our collective unconscious which is motherly... Which means they worry about how the other people feel, whether they're loved... although salt preserves things, which is good. It's erosive and when they put it on the road when it's icy it erodes away the metal in the cars. And some of the stuff that nat mur [a type of remedy], people keep hold of eats away at them" (M1)

(N8) stated: *"I refer to my Bowel Nosode chart quite a lot. I am referring to my knowledge of chakras in so far as I'm feeling where it is they're out of balance so if it's heart your nat mur[a type of remedy], well not necessarily nat mur but if you're thinking this is a person who is really physically but mostly emotionally is blocked, is holding dis-ease here then that's what I'll be processing"*

In this quote the Bowel Nosodes referred to are a system linking nosodes with energy centres in the body designed by Doris Beauchamp (Beauchamp, 2007). Chakras, as mentioned in the quote, are energy centres that form part of the Ayurvedic medical system.

(A) (N10) gave a detailed description of how the use of a balancing approach as a model to help her in her prescribing:

"What we see the vital forces trying to do is trying to get as near to a balance as it possibly can, so if something is happening on the one hand, it will try to balance it out by creating the opposite on the other side...because if you think of a dis-ease, 'di' means 'two', so the person is not at ease, they're at two. So you're looking for the opposites – the two sides of the case, and in order to find a good remedy you've got to have both sides covered... I think in terms of black and white here. That's very rigid thinking, so you then get that idea you get the build-up these two sides."

It can therefore be seen that various theoretical models are utilised by homeopaths in order to understand the information that they have obtained during the consultation. This involves delving deeply into the information to find patterns and a more symbolic meaning, in order to link the information to a homeopathic remedy tailored to the individual they are prescribing for.

4.4.4(iv) Matching Patients to Remedies – Summary

Table 4.4: - Methods Used When Choosing a Remedy

Practitioners	Instinctive prescribing	List comes to mind – eliminates	Routinely uses material medica	Routinely uses on line repatories	Classification of patients helps prescribing	On the Spot prescribing
Medical	8	4	9	5	2	4
Non-medical	3	4	10	6	4	4

As can be seen in Table 4.4 instinctive prescribing was a recurrent theme, particularly among medical practitioners. In some cases this took the form of certain remedies coming to the practitioner's mind or in others, past cases come to mind. On the spot prescribing would sometimes include instinctive prescribing but in some cases a practitioner would repertorise during the consultation, often using an on-line

repertory, and still prescribe during the consultation. The following quotes illustrate the instinctive aspects of remedy selection:

N3 *" Um, I suppose quite often I have got an idea or I have an idea of a certain set of remedies so I suppose what I would do if I was working on it would be go back and look in the books and in the materia medica"*

Also shown in Table 4.4, in certain cases an instinctive list would be thought up by the practitioner, and they would then delve into specific areas during the consultation to eliminate remedies from the list, or alternatively repertorise the remedies to and find out which is the better match.

On line repertories were also a popular method of selection of remedies and as shown in the table a large number of homeopaths used these. Others, however, preferred more traditional methods.

4.4.5 Obtaining the Remedy

Table 4.4 shows that approximately 1/3 of practitioners prescribed remedies on the spot. In particular medical homeopaths often did so and this was cited by one medical homeopath to be due to the expectation of the patient, to go away with something to take following consultation:

"I'd give them a prescription straight away. I think that's what people expect, they expect to walk out with a prescription and unless it's something really complicated then I ought to be able to give them something to walk away with." (M2)

Of the remaining practitioners who did not undertake on the spot prescribing, most stated that they preferred to have more time to go over the case and carefully select a remedy.

Table 4.5: Prescribing Methods

Practitioner	Multiple Prescribing	Constitutional remedy first	Commonly Liquid potencies	Polychrests generally	Placebo to follow through
Medical	5	2	2	3	3
Non-medical	2	3	3	2	1

Table 4.5 shows a breakdown of modes of prescribing and how patients accessed their prescribed remedies. As shown in Table 3.4.5 a range of different methods were used. n=7 participants mentioned that they did sometimes employ the method of multiple prescribing. This reinforces the findings of Phase 1 of this study, where of practitioners reported using multiple prescribing of remedies at least "sometimes". The method of making use of the placebo effect was mentioned by 4 practitioners. Reasons given for this method included a tool to help the patient allow the given remedy time to work, and also as a business strategy to persuade patients to make a new appointment.

*"Sometimes I use the method of split dose followed by placebos. It helps the patient to allow time for the remedy to work. Also it's a way of prompting them to make a follow-up appointment as when people run out of tablets it triggers them to think "I need to get some more of those" and they book an appointmen*t" (N14)

Five practitioners stated that they look to give constitutional remedies first, see how the patient responds and then address the symptoms.

Table 4.6: Source of Remedy

Practitioner	Remedy from practitioner	From homeopathic pharmacy	From conventional pharmacy	Makes own remedies
Medical	2	3	4	1
Non-medical	5	4	1	2

The source of some remedies ranged considerably and the results of this are summarised in Table 4.6. Some obtained them directly from a homeopathic pharmacy, often ordered through a regular pharmacy. Others, n=3 practitioners, synthesised the remedies themselves. Three very different types of machines were mentioned by these participants, which involved sending some type of electromagnetic field from a machine into a blank tablet. More commonly (n=6) the homeopathic practitioner would obtain potentised solutions from the homeopathic pharmacy and then made tablets from sugar tabs or gave liquids to the patients in order for them to take LM potencies. The chosen route of delivery of prescribed remedies sometimes depended on the practice site. This was particularly true with medical homeopaths who tended to work in multiple practices. For example, when in a homeopathic hospital, all remedies would be to hand but in other places the patient would have to get it from a pharmacy.

4.4.6 Reviewing Patients at Follow up

When reviewing a patient, practitioners would primarily be looking for anything that had changed, be it a quick change in symptoms soon after the remedy was taken or a gradual realisation that certain things had become easier. This is something that was mentioned by all participants. In some cases a quick improvement that wasn't sustained would indicate that they needed either the same remedy at a different potency or that the previous remedy had reached the limit of its use and another one may be needed for further improvement.

"Well it depends whether it's right or not. If it's right then I wouldn't change it if they were improving and it seemed to be working extremely well. If they'd reached a bit of a lull, they'd made a slight improvement but then it had stopped getting better and they had other symptoms then I might look at changing it. If nothing happened at all then I think I've got this wrong and change it."(M9)

If a patient came back saying that there was no change, over a third of practitioners stated that they would need to make sure this was indeed the case, as often if symptoms or problems had disappeared, the patient would forget all about them

"Sometimes a patient will say "no, nothing's changed, I still feel the same" and I'll refer back to the case notes from their first appointment and ask "Well how about your sleep pattern, hows that now?" and they'll say "Oh that's fine now". Since it stopped being a problem they hadn't thought about it" (N14)

4.4.6 (i) The Direction of Cure

The concept of Hering's theory on the direction of cure also emerged. This comes from homeopathic theory and, as discussed in Chapter 1, the seriousness of illnesses goes from the outside in, in that the body will try to deal with the illness at the most outward place possible, so it may first strike a superficial area such as the skin, then if it is not effectively dealt with it can then spread further internally and into the internal organs. Conversely, if this illness or imbalance is being treated at its route, the direction of cure will be from inside to out, so the internal areas will feel the effects first and the superficial effects will come last. This can therefore be a long and frustrated route for patients who, for example, have a skin condition that they are self-conscious about. With over one fifth of participants mentioning this, the quote from non-medical participant N8 illustrates how this may affect outcomes of homeopathic treatment.

"that's the thing about homeopathy, you never know how it's going to affect the person. So a person may come with a particular problem but they may have other problems and the problem that they've come for may not be the first to go as the more superficial a symptom is the slower it is to go. It's more the deeper organs that get better first, they get a feeling of wellbeing first"(N8)

4.4.7 Matters Concerning Homeopathy and Osteoarthritis

When asked specifically about homeopathy for osteoarthritis, musculo-skeletal conditions being in the top 5 most commonly encountered by homeopaths, various considerations emerged.

One theme was the consideration of the suitability of homeopathic treatment for the condition (n=7). Most commonly this was a theme that arose from medical homeopaths rather than non-medical, whether a different form of treatment may be more suitable for homeopathic treatment. Some quotes highlighting this are shown below:

"I would want to check that I'm treating suitably, for example would the patient simply be better off going for a knee replacement" (M9)

"I find acupuncture very helpful for a condition such as this and would most preferably proceed to treat the joint with acupuncture. A combination of acupuncture and homeopathy can be very helpful for osteoarthritis" (M6)

4.4.7(i) Managing Expectations

Limitations of treatment for this chronic condition, which has often been suffered for several years prior to the start of homeopathic treatment, in terms of expectations the patient may have of treatment was a key theme and a widely acknowledged point, again among medical homeopaths to a greater extent: -

"In an extremely chronic condition, it is unlikely that you will achieve a very significant improvement in the physical condition, but it can happen"(M14)

"It's important to know what a patient's expectations are. If a joint is really worn out you couldn't reasonably expect it to suddenly give them no trouble"(M3)

4.4.8 Factors That Facilitate Treatment

It was clear from the respondents that in keeping with homeopathic philosophy treatment is all about the person rather than any specific conditions they may have independently. There were, however, certain themes that were identified that made certain persons more or less easy to treat.

4.4.8 (i) Baggage

One theme that was identified (n=7) was the amount of "baggage" that a person had, that may be in the form of stored up emotional troubles, multiple pathologies or long standing conventional medical treatment. This predominantly emerged in non-medical participant interviews. Treating children was seen as being easier, as a result of there being less baggage, co-morbidities and generally a stronger vital force to work with. By this line of reasoning therefore, a higher rate of effectiveness with homeopathy in childhood illnesses may be explained when compared with effectiveness for treating long standing chronic conditions such as osteoarthritis.

4.4.8 (ii)Scepticism

Scepticism was a theme that arose as a potential barrier to the treatment process. This was mentioned (n=5) in terms of being less open in a consultation. If people were reluctant to share information then it was not possible to get a clear remedy picture.

" Sceptical people also show big improvements but need to be prepared to try it"(N5)

The above quote by non-medical practitioner P8 illustrates another problem with scepticism in that they may then decide not to follow the, sometimes complex, instructions for taking the remedy. However, on whole participants did not find that a keenness for homeopathic treatment in itself was a factor in treatment outcomes

"despite how keen a patient is it depends whether you obtain a clear picture that determines effect of treatment"(P9)

In some instances (n=2) practitioners actually stated that they prefer it when patients are a bit sceptical as they can then be certain that treatment has worked when an improvement is reported. In a situation like this it would be difficult for someone to put the improvement down to the placebo effect.

"I'll say it's better when they're sceptical....It's more reassuring for you as a patient if you're sceptical because then you know it's a true result"
(M10)

4.4.8 (iii) Engaging People

The degree to which a patient engages with treatment was seen as an important factor in the ease and enjoyment of treatment. This was a key theme mentioned (n=8) and in general this was by non-medical practitioners.

" *I try to help people take responsibility for their own health, because if people are involved in their own healing it's more exciting for them, it's more stimulating for them, and I do think people need to take responsibility for their own health"*(N11)

The above quote by non-medical participant N11 highlights the importance of empowering the patient, a topic that has been very high in the government's current public health agenda. It also speaks of the idea of the excitement of healing, in contrast to the depressing concepts of sickness and disease where one is waiting in doubt for a cure to appear.

"...what I do spend time doing is telling the patients the remedy I've picked out and its symbolism. And I haven't had time often to pick out large important details of their life but when I describe the remedy you can see they're starting to get better already" (M1)

"Something truly magical happens when one living being tunes in to another, you get a 2-way connection and this is at the heart of treatment" (N5)

The quotes above from M1 and N5 speak of the importance of patient engagement but address another issue, also a key theme, of the therapeutic relationship between the patient and practitioner, known as the patient practitioner relationship (PPR).

4.4.8(iv) Experience

Certain conditions were mentioned as being easier to treat than others, though participants reiterated that it is the patient you treat and it is factors surrounding the condition rather than the condition itself that influences this. However, many participants had gained a wealth of experience in a particular area, when successful treatment of one patient led to others with similar conditions seeking treatment due to recommendation. Successful infertility treatment in particular was mentioned as an area of expertise by some non-medical homeopaths (n=3) and this then led to a lot of babies, and hence being approached to treat childhood illnesses, leading to expertise in areas such as childhood asthma and eczema treatment. Medical homeopaths practising as GPs would generally be approached to treat a wider range of conditions.

4.4.9 Relative Role of the Remedy

" The PPR is a key component of any treatment" (M11).

The PPR is something that is often highlighted in studies of homeopathy and complementary therapies in general (Whetherley Jones, 2004). It is a common acknowledgement that one area that conventional medicine provides less and less is time to listen to the patient. In general complementary and alternative medicine (CAM) consultations provide more time for this. Medical homeopath P10 illustrated the effect of this in the quote below.

" After a consultation people will quite often say "No one has ever taken that much of an interest in me or spent that much time with me before...it's not uncommon for adults to cry in consultations; the patient practitioner relationship is definitely part of the whole process"(M9)

Some CAM sceptics largely attribute any beneficial outcome of CAM treatment to this and think of it as part of the "placebo package" of CAM. However, it was

universally clear from the interview participants that the PPR was only one aspect, and by no means the most important one, of treatment.

"I get 15 minutes for all my patients so every time I see these things that say "Homeopathy only works because it has such a long consultation, I just think well mine doesn't work because of a long consultation because they get the same as the conventional NHS ones do"(M1).

The above quote by medical participant M1 illustrates that PPR, and the length of consultation are not the only factors that link to effectiveness but it does bring up another point about consultation times and this will be addressed elsewhere.

It was clear from responses that the remedy itself was the most crucial part of treatment. Key themes on the role of the remedy, included that although the therapeutic response may start at the consultation, the remedy is responsible for fully bringing about change and preventing the re-emergence of the condition, as the two quotes below from participants N12 and M11 highlight:

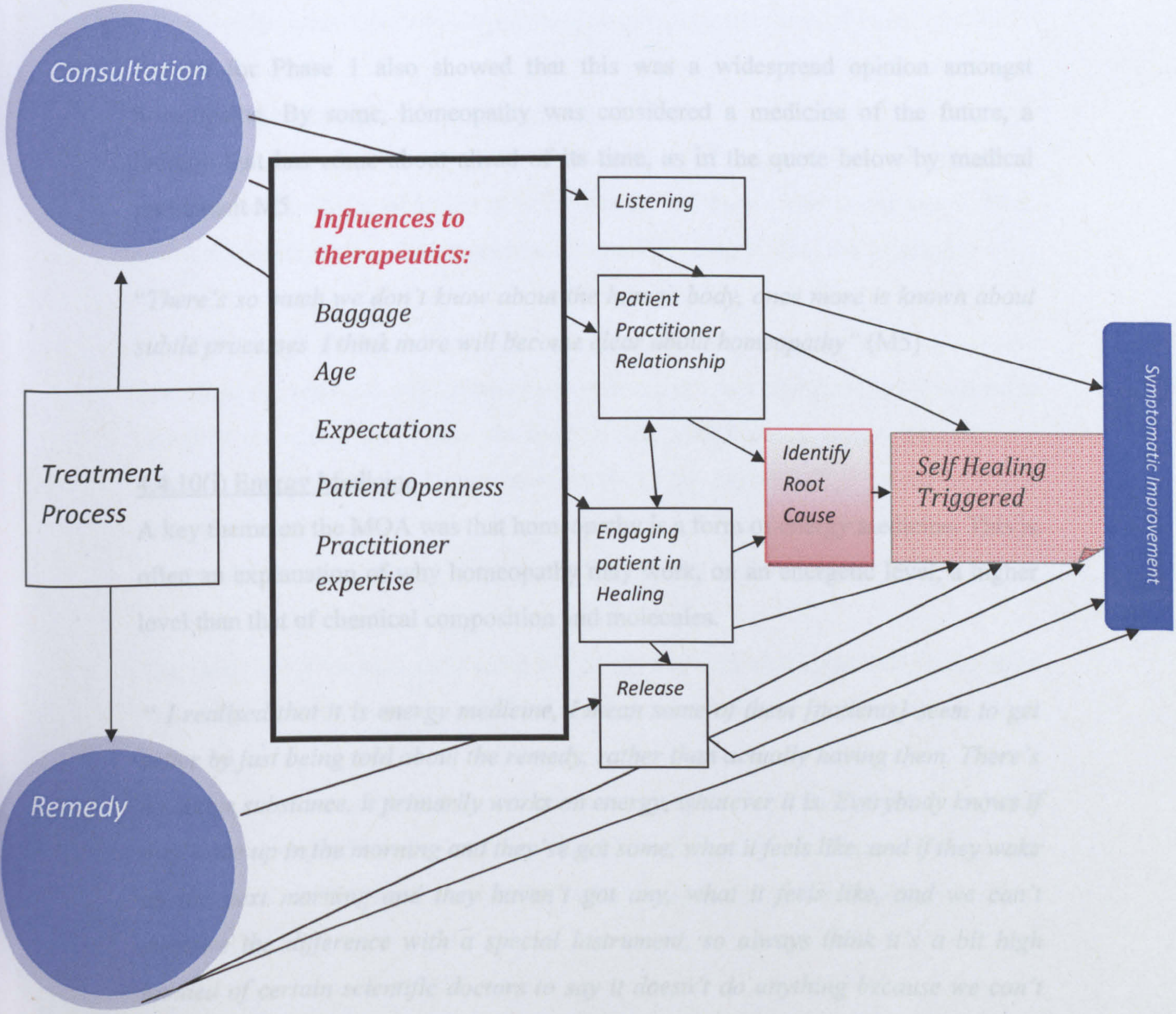
"Finding the root of the problem, together with the patient is a key aspect of initiating a therapeutic response, by identifying the cause to the patient, the remedy then carries the job on"(N12)

" At the end of the day, no matter how much empathy you give and understand them, no matter where you conduct the consultation the symptoms will continue to manifest unless the correct remedy is given"(M11)

4.4.10 Mechanism of Action (MOA) of Homeopathic Treatment

The perceived mechanism of the therapeutic process of homeopathic treatment is summarised in Figure 4.2. The superordinate themes identified were the importance of the remedy, the importance of the consultation and the importance of the trigger of self-healing mechanisms. These were interrelated via subordinate themes and these individually and jointly were seen to influence the symptoms of the person treated.

Figure 4.2: Schematic Diagram to Summarise the Ordinate and Subordinate Themes generated on the Perceived Therapeutics of Homeopathy



Superordinate themes are in colour..

Subordinate themes are in black and white boxes

When discussing the MOA of homeopathy, a classic response from practitioners (n=11) was that it was not important how it worked, it was enough for them to see that it does work.

"Sometimes people ask "But how does it work?" And I say " Well as a scientist I should know how it works but I don't. I don't need to know how it works because I have seen that it does work". If I have a bunch of patients and I don't give them the right remedy they don't improve and suddenly you get the right remedy and get fantastic results. I know it works. I'd like to know how it works but I don't need to know in order to carry on practising" (M2)

Results for Phase 1 also showed that this was a widespread opinion amongst homeopaths. By some, homeopathy was considered a medicine of the future, a therapy that has come about ahead of its time, as in the quote below by medical participant M5

"*There's so much we don't know about the human body, once more is known about subtle processes I think more will become clear about homeopathy"* (M5)

4.4.10(i) Energy Medicine

A key theme on the MOA was that homeopathy is a form of energy medicine. This is often an explanation of why homeopathy may work, on an energetic level, a higher level than that of chemical composition and molecules.

" I realised that it is energy medicine, I mean some of them [patients] seem to get better by just being told about the remedy, rather than actually having them. There's no active substance, it primarily works on energy, whatever it is. Everybody knows if they wake up in the morning and they've got some, what it feels like, and if they wake up the next morning and they haven't got any, what it feels like, and we can't measure the difference with a special instrument, so always think it's a bit high handed of certain scientific doctors to say it doesn't do anything because we can't

measure it, rather than it does work but that we haven't got the equipment that's sensitive enough."(M1)

So from the above quote by medical homeopath M1 it seems that homeopathy could work at an energy level from the start of consultation right through to the remedy. The quote also talks of energy and the participant acknowledges that from a scientific perspective, it is unknown what the vital force is, but from an individual perspective we all know. In homeopathic circles this energy is often referred to as the vital force, a term originating from Hahnemann, the founder of homeopathy, the idea being that the remedy works directly on the vital force.

"The remedy doesn't actually do anything except stimulate the vital force" (N10)

4.4.10 (ii) The Remedy Effect on the Body

Another theme that emerged was that many homeopaths liked to think metaphorically about what the remedy did in the body. The quote below from medical homeopath M3 illustrates what the remedy actually does for a person.

"..When you do the remedies it's like you're releasing some of the stuff (that people keep hold of), not so that it's coming out of it and it's just as difficult as it was when you first met it and didn't have the tools to deal with it that you have now, but it's almost as if, well it's no longer relevant. It's a bit like standing on a bridge and dropping bread crumbs in the river, you don't actually have to do anything but let go, and I feel that's what the remedies help people do"(M3)

The quote from medical participant M6 is an example of a simplified explanation that many participants used on the lock and key model of homeopathic treatment.

"the way I often explain it to you, to clients is that it's like a lock and key, and each time it's a lock and it's a complicated lock with lots of mechanisms and levers and the remedy that fits into the lock to help the person as an individual with their whole health" (M6)

4.4.10(iii) Self Healing

Perhaps the most universal theme that arose relating to the mechanisms of homeopathy was the concept of the body's self-healing mechanisms

" Homeopathy enhances natural healing responses of the body, it stimulates the body's health into restoration"(N2)

This was referred to in terms of the remedy working in conjunction with the vital force. The idea is that the homeopathic remedy, and perhaps the consultation to, help to highlight what is wrong, or where imbalance occurs and this then focuses the body on the area of need and stimulates the body to self heal

"I always say to patients that it's not the homeopathy that heals you it's just the force giving you a push and as it's being lined up with your symptoms where you might be dissipating your energy all around it makes you like with physics with a reaction, an equal or opposite reaction it makes you focus your energy on a small point and that allows you to heal yourself." (M1)

4.4.11 Homeopathy and Other Medical Systems

Other therapies and medicine systems were also discussed with participants. In general, the majority of homeopaths had a fairly liberal view of other forms of CAM and of conventional medicine.

4.4.11(i) Therapies Simply Work at Different Levels

One theme that emerged in terms of the different medical systems was that they were all part of the same system and simply worked at different levels. The quotes below highlight this idea.

" I see these methods acting at different levels of somebody's personality or being, so I'm quite happy to accept that conventional medicine can be acting at this level and that homeopathy or acupuncture can be working at that level. So I don't see a conflict"(N2)

" I always think that nutrition, herbal medicine and homeopathy run from levels of more physical to less physical, and according to the energy levels of the patient, that is where you match your treatment"(M4)

" There is no real conflict with treating patients holistically, their philosophies are in harmony and synchrony with each other, they are unlikely to clash"(M11)

4.4.11(ii) Conventional Medicine

Another theme that emerged was a place for conventional medicine. In general, participants felt that in terms of emergency medicine, surgery, and conditions such as type 1 diabetes, conventional medicine was excellent. As the quotes below from medical homeopath M7 puts this:

"I must say at times, without conventional medicine we could be causing a lot of unnecessary pain and suffering to patients"(M7)

The limitations and overuse of conventional medicine however did come up as a key theme. One medical homeopathic practitioner illustrated this point in the quote :

"well I'm just very glad I'm a homeopath because if all I could do was conventionally prescribe I'd be really depressed"(M3)

4.4.11(iii) Patient Preferences

On the matter of which therapy is suitable for treating which patients it was almost universally acknowledged that more serious acute conditions needed conventional medical treatment. One of the main themes that emerged (n=7) was that the right treatment was dependent on the preferences of the patient themselves. The quotes below illustrate this view:

" *..different therapies are right for different people at different times*"(N6)

".. *Complementary medicine is not for everyone. If a person feels strongly about taking conventional treatment then they should go along with that"(M11)*

"..Some people prefer more hands on treatment, others like to talk. The therapy to choose is down to the individual"(N7)

4.4.12 Medical and Non-medical Practitioners' Views on Each Other

Over three quarters of participants stated that if they were to recommend a homeopath to a friend or relative, they would recommend one from the same affiliation that they belonged to. Several Non-medical participants (n=5) mentioned the Homeopathic Helpline, a telephone service run by the Society of Homeopaths, as a point of call should any homeopathic emergencies arise, rather than seeing a medical homeopath.

Themes that emerged around this included distrust of the training or the methods used by those from different affiliations.

4.4.12(i) Affiliation Standards

In most cases this extended to homeopaths with the same medical status. Of the non-medical homeopaths, the key theme behind this lack of trust was the less intensive training course (n=7), though there was a degree of variability in the strength of this sentiment. One participant stated:

N3 *" ...in that situation I would go to the Society's register rather than another register because I do feel that the standards of the Society are rather higher , which is not guaranteed, other training could be just as good..."*

N10 *"I was appalled at the level of what they were asked to do in terms of their casework. I taught what students had to do for us in terms of their casework, and to show their level of understanding. The model answer wouldn't have passed. I would only do that if I knew them and I know a couple of people, or there's one particular course in XXX that GPs can do and I think if they've done that I would be much more likely to send them to someone on the society's register."*

4.4.12(ii) Safeguarding Patients

In addition to the standards of homeopathic organisations, more deep issues concerning the safeguarding of patients arose. Overarching responsibility was an

issue that was hinted at by several medical practitioners and summarised nicely by M10:

"When you're a GP you're looking to do two things, first of all to do no harm to the patient and in addition to keep your registration. A lot of lay homeopaths don't know what that's like. You have to care for the patients 24 hours a day, 7 days a week and if something goes wrong you're held accountable and can get struck off. If you make a mistake in homeopathy you can get struck off, whereas a lot of other doctors make mistakes and get away with it. Lay homeopaths don't have that problem" (M10)

4.4.12(iii) Patient Preference for Practitioner's Medical status

Others from both affiliations (n=4) voiced the opinion that they would not necessarily favour a particular homeopath based on their medical status, as it depends on patient preference (see N3 quote below) or due to the opinion that there are good and bad practitioners in both camps (e.g. M8, M10, N12)

N3 " *...I do know people who do feel more comfortable with the idea of a medical homeopath... I can think of someone I know who is keen on homeopathy but definitely feels that there's something different about a doctor giving homeopathy than a non-doctor, no matter how good a homeopath they were it was not as good as a doctor, and they came from that background so it's quite an understandable point of view. So if someone was feeling very much directed to one type then that's fine"*

One participant made another point about hierarchy within the NHS and how this can impact treatment:

" Another issue was when I worked in XXX homeopathic hospital and there was a bit of a flare up with one of the consultants about whether a patient was going to be treated or not. And I leant very early on not to ruffle feathers in the NHS, as consultants are very powerful" (M8)

4.4.12(iv) Quality of Treatment

Another theme that emerged was a negative view of the methods and thoroughness of homeopathic treatment as posed by homeopaths with opposite medical status and

a worry that they may miss something important. Both medical (n=3) and non-medical (n=1) participants used the example of cancer being missed in a patient seen by a homoeopath of the opposite medical status. This was put down to acting beyond their scope of knowledge by medical homeopaths and by the abrupt nature of mainstream medical consultations by non-medical homeopaths.

N4 *" There was one lady that came to see me who had these internal pains that no one could work out what they were. When we explored her pain in the consultation, she said that she felt like she was giving birth, like there was a big ball inside her. I advised her to get an ultrasound at the doctors and it turned out she had an enormous tumour in her uterus. Her GP had missed it because he hadn't listened to what she was telling him"*

M9 *"I'm a doctor myself and I think it's safer. Depends what's wrong with you doesn't it. You go to a lay homeopath and it may be something quite worrying. And they just treat because you don't have to make a diagnosis when you use homeopathy. You don't need to know what's wrong with them, just treat their symptoms really"*

N9 *"They worry a bit. Not xxx, he's different but many of them have only trained for three months at the Faculty. It's OK if they're honest about what they do but surely it's only going to be like GP consultations, and how can that do? I wish that all of us could have the same training..."*

4.5 Discussion

4.5.1 Common Themes and Variability in Homeopathic Treatment

In many respects, the essence of what a homeopathic treatment involved was universal to reported homeopathic practice, regardless of the participant delivering treatment. The location and the setting of the consultation varied enormously, with some medical consultations taking place in GP consulting rooms, others from both affiliations seeing patients in a holistic medical centre and a large number of

homeopaths, most commonly non-medical seeing patients in their own homes. However, regardless of the setting, a detailed case would be taken in an initial appointment and would include the history of the patient's complaint and events when the symptoms started, recent problems, lifestyle factors and other treatments used to overcome the symptoms. The strongest theme that emerged during the case taking was a detailed exploration of the events that surrounded the emergence of the initial symptoms or the events that lead to the initial imbalance. Case taking strongly reflected principles outlined in original homeopathic theory, in terms of the reasoning behind particular lines of inquiry. This demonstrated many principles of Hahnemann's original theories but classification systems such as those proposed by Sankaran, Kent's symbology and Beecham's work on Bowel Nosodes (see section 4.1.3(ii)) were also mentioned by some practitioners as part of this process.

4.5.2 Choosing a Remedy

When matching up patients to remedies several factors played a role. Practitioners would often form a list of remedies to narrow down to the chosen one. This could be using an on-line computer repertory such as Radar. Other factors, however, including previous experience and theoretical models of prescribing were also used. These later methods would often lead to what practitioners described as getting a "feeling" for a particular remedy. This implies that instinct plays a part for many practitioners, with many practitioners stating that two or three remedies would "come to mind". Knowing the remedy picture, as described in detail in Kent's work (1985(Ed)) in this case appears just as important for this approach as knowing the lines of inquiry to lead the consultation along. As has been discussed few studies have been conducted on homeopathic practice, with key homeopathic texts and courses preferring to illustrate their points by using case studies and justifying their choices using findings from homeopathic "Provings" (see section 1.4.2) rather than citing research.

Some recent studies have emerged since the main body of the current study was completed and can be considered alongside the findings here. The current findings are supported by one recent study that involved observation of homeopathic consultations with UK based privately practicing homeopaths (n=15+) and for which preliminary results have been published. The study found a range of themes around homeopathic selection and that one core theme was the role of intuition in practice

(Burch, 2008, Brian, 2008). In addition to intuition, Burch et al concluded that pattern recognition was a key part of this, providing support for the finding of the current study that previous experience feeds into this. The idea of intuition in homeopathic prescribing was also presented by a different research group during conference proceedings (Weatherly-Jones, 2005) but remains as yet unpublished.

4.5.3 Reviewing Patients at Follow-up

Reviewing patients at follow-up was possibly the area that homeopaths appeared to be the least methodical about. Looking back at the case notes to address previously reported problems was often undertaken in addition to thoroughly covering any changes since the last time. If no change what so ever was reported then this would trigger the practitioner to change the remedy. Another trigger to give a new remedy would be if the previous one had brought about an improvement but had uncovered something else in the process that needed attention, beyond the reach of the first remedy. Results from the current study also imply a strong instinctive influence would in some cases shape the treatment plan at follow up. Though the role of intuition has been identified in other studies (Weatherly-Jones, 2005, Burch, 2008), the current study findings indicated that some practitioners would have a strong conviction that a remedy was right, even if no changes were reported by the patient that they would doubt the accuracy of the patient's account before their own judgement. They would therefore really probe into previously reported symptoms plus look for other factors of influence or new aspects that have caused a shift in the focus of treatment. It seems that a more methodical approach based on particular outcomes, allowing practitioners to conduct reviews that do not solely rely on their intuitive judgement may be key to the development of homeopathic treatment.

Hence in certain ways, the results emerging from the current study suggested that participants reported fairly similar events during the consultation with different participants following a similar line of inquiry. However, in other ways, there was very little suggestion of a framework at all. No two homeopaths gave exactly the same account of what they did and a large amount of the assessments were based on feelings and impressions with no core outcome tools used to assess the progress of the recovery. The overall variation made it difficult to gain a clear idea of contrasts between medical and non-medical participants practising styles. A greater degree of

variability was seen in terms of potency and source of the remedy, with several homeopathic pharmacies used and a number of practitioners making their own remedies. This occurred regardless of medical status but could mean that the quality of the remedy given may vary immensely. There are therefore many factors could influence the quality of homeopathic treatment.

4.5.4 Quality of homeopathic treatment

From the results it can be seen that there are several aspects of homeopathic treatment that could potentially lead to a discrepancies in the treatment and quality of care a patient would get when receiving homeopathy. The success of the consultation and case analysis in leading to the correct remedy may be variable depending on factors discussed in section 4.1.4 and highlighted in results section 4.4.2 including time available, openness of the patient and tools used. Remedy selection, particularly potencies, is largely based on homeopathic theories. The actual source of the remedy may also lead to a variation in the quality of the preparation itself. With a lack of literature available comparing remedies from different sources, quality assurance and suitability of home remedy making machines, it is possible that the quality of the remedy is a serious consideration in homeopathic treatment. In addition, conflicting information exists regarding the storage of homeopathic potencies and on drug-nutrient interactions, and any information available on these is purely anecdotal with insufficient research to support it. It therefore seems that there is not only an issue of whether a therapeutic "footprint" can exist in extreme homeopathic dilutions as discussed on section 1.4.4 but whether it is still present at the time the remedy is consumed or administered. With the nature of homeopathic remedies and the lack of chemical content of an active ingredient it would be difficult to subject homeopathic medicines to the same quality control checks that are used routinely in the pharmaceutical industry. This is the first study to explore the source of homeopathic remedies used by UK practitioners. The current results indicate that should homeopathy achieve widespread use, the matter of the accessing the highest quality remedies and the conditions in which they should be stored and taken would need to be addressed further.

4.5.5 Homeopathy for Osteoarthritis (OA)

Managing expectations and keeping them realistic was a major part of homeopathic treatment of OA. OA was identified in Phase 1 of this study as among the top 5 conditions homeopaths were approached with. The hesitation more commonly came from medical homeopaths reflecting a slightly higher focus placed on clinical conditions as opposed to the notion that it is the person you treat not the condition. One theme was the suitability of homeopathy for treating OA, as an extremely worn out joint may need to be replaced or it may be unrealistic to expect significant increase in function. Another was the use of homeopathy combined with acupuncture that was mentioned by n=2 participants who suggested that a better result could be achieved for OA when homeopathy was combined with acupuncture. The phase one results suggested that OA is an extremely difficult condition to treat and that it may take a long time to achieve a greater than 80% improvement both with acupuncture and homeopathy (see section 3.8.2). This could be due to the difficulty that health professionals and therapists from all disciplines have with OA as it is an extremely difficult condition to manage with patient satisfaction levels from conventional treatment showing lowest levels for musculo-skeletal conditions (Fisher et al, 2004). Alternatively it may indeed be that homeopathy is not the best option and that a therapy that can physically manipulate the joint such as acupuncture or osteopathy may be more appropriate.

4.5.6 Suitability of Homeopathic Treatment

Medical practitioners appeared to focus more on suitability of HP treatment for osteoarthritis (OA) and if they felt it appropriate either provide another treatment themselves or to refer elsewhere. In many ways it is quite likely that this difference stems from the fact that medical HPs continue to use practise habits that they are used to from conventional medicine, whereas non-medical most commonly only practise homeopathy and do not have the means to refer patients on for other treatments. Some homeopaths work in therapy centres where other CAM is offered, but then they have a limited range of services to recommend compared to the long list of health professionals and therapists that a homeopathic GP could refer onto, possibly funded by the NHS. Practitioners' awareness of their limitations, and the knowledge of other services and means to refer patients, is an important aspect of patient care. The differences in the assessment of the suitability of homeopathic

treatment by medical and non-medical homeopaths is therefore a finding that could be a consideration to the integration debate and who should provide homeopathic treatment.

4.5.7 Achieving Success in Homeopathic Treatment

4.5.7(i) Factors that facilitate treatment

When factors that facilitated homeopathic treatment was explored two overarching themes emerged. These themes were 1) key factors on an individual basis that would make a person easier or harder to treat and 2) Experience of treating similar cases With respect to the later theme, the factors of influence were largely focused around level of vitality, freedom from co-morbidities and other "baggage" such as age, prior use of medication, dietary and environmental contaminants. These were seen as things that might mask the real problem and make it hard to target the root of the cause. Some stated that you would have to strip off a layer of this "baggage" with one remedy and then prescribe another and another before you could really settle the cause.

Another key theme relating to individual variance mentioned was the openness of the patient to share information during the consultation. This came down to rapport and open dialogue. The difficulty with lack of openness was obtaining the unique information from the patient necessary to accurately prescribe. The problem was seen as nothing to do with the level of confidence a patient had in the homeopathic treatment, many stated they had great results with sceptical people, one practitioner actually mentioned that they preferred it this way as confirmation of a cure (M9). However there was a danger here that they might not be prepared to give it a go, or would not be compliant with the advice given. This is a key limiting factor in all treatments and the matter of compliance is one that many have tried to tackle in recent times. It may be particularly important to address compliance in homeopathic treatment due to the lengthy timescale the improvements may take to occur.

The second core theme, experience, was a slightly different matter, relating to how familiar the practitioner was with treating a particular health problem or set of symptoms. Some homeopaths gave a suggestion of developing a speciality. A homeopath would be approached with a particular condition, treat it successfully and

through word of mouth be approached by other patients for the same condition. In some cases this would lead to other things, for example a homeopath who treats a lot of women for infertility results in a lot of babies being born to clients which results in seeing a lot of patients for childhood illnesses. This was something often applicable to non-medical participants. Many medical practitioners see a wider range of patients within the scope of their general practice, but when medical practitioners were particularly successful in treating a certain conditions some participants from the study reported that colleagues or medical partners would refer patients to them. Perhaps in the future, if homeopathy becomes more mainstream this will lead to development of consultant homeopaths in particular medical fields as we see in conventional medicine, who are then able to produce guidelines for other practitioners. Such development could lead to guidelines and support that may allow homeopathy to be seen as modernised therapy and a more attractive option in an integrated health care setting.

4.5.7.2 The Practitioner-patient relationship

There was a universal opinion shared by participants that the paractitioner-patient relationship (PPR) is an extremely potent and important part of homeopathic treatment. Several participants mentioned the emotional impact of the detailed consultation and the frequency of patients crying in consultations. It was also acknowledged by several participants that the PPR is key to all therapeutics not specifically to homeopathy, though perhaps the lengthy consultation generally associated with homeopathy (see section 3.2.2) enhances this. The inability to divorce the PPR and the consultation from the remedy in homeopathic treatment has been discussed in former studies (Milgrom, 2004; Weatherly-Jones, 2004) and this has been an issue in the use of placebo controlled RCTs for homeopathy. This is because, where a patient undergoes homeopathic treatment yet receives a placebo remedy, they would still have received the benefits of the consultation so it could not be classed as a true placebo.

The healing journey appeared to be seen to start at the consultation, with the mapping of the time and events that led to the initial imbalance, or disturbance in vital force. However, it is possible that non- medical homeopaths put more emphasis on the therapeutic relationship, journey of the patient and counselling aspects of homeopathy than medical homeopaths who concentrate more on the health problem

to hand. The terminology used is also indicative of this – medics often say "patient" whereas non-med more commonly would say "client" and there was suggestion of a life coaching role by many non-medical homeopaths.

There is a shift in current policy within the NHS of referring more to clients rather than patients and this has come about with recent changes to modernise the NHS and empower patients (Department of Health, 2004; Department of Health 2009b).

4.5.7(iii) The Role of the Remedy

Once the therapeutic journey has begun in the consultation the role of the remedy was seen as carrying on the job of healing, an essential component to achieving sustained improvement. Some participants sited that this would not happen if they had incorrectly prescribed but would suddenly happen once they had the right remedy, reinforcing their certainty that the remedy plays a key role. The theory involved here is very much based on Hahnemann's original theories on the role of the remedy. In line with Hahnemann's theories, one remedy was often seen as enough, but occasionally, with a chronic condition the remedy may need to be topped up from time to time. Or the remedy could have taken a patient as far as it can in a healing journey and another remedy may then be needed to continue the healing or work on the next layer.

Animal studies were also mentioned as adding to participants' conviction that there is something in the remedy, and in the case of animals it could be argued that any improvement can be attributed solely to the action of the remedy. However, it cannot be ruled out that the owner of the animal who sought homeopathic treatment for them could be influenced and engage in some form of consultation, and the effect that this has on the owner for example in alleviating their anxiety over the health of the animal may exert some influence on the animal itself.

4.5.8 Proposed Mechanism of Action for Homeopathy: -

It appears that from a homeopath's perspective, the process of homeopathic treatment begins at the consultation where the time of imbalance is first identified, together with the patient, and this perspective can initially help the patient, the recognition of exactly what needs correcting. The remedy is then specifically selected to tackle this imbalance and further treat the problem. It is an inside out

approach and the physical symptoms are often therefore the last to change. The current study is the first to investigate practitioner opinions on the mechanism of action of homeopathy and some interesting issues have emerged that may influence homeopathic research. When using themes that emerged from the study to inform us on a mechanism of action, this illuminates a plausible explanation for the difficulties posed concerning homeopathy and the placebo. Essentially if a therapy is stimulating self healing then how can it be measured against a placebo which itself is a phenomena labelled as idiopathic "self delusional" healing, the processes of which are not fully understood alone? Further, if the whole treatment package of homeopathy is in part responsible for bringing about a cure, this poses difficulties on how parts can be separated out (Milgrom, 2004) and how one could create a true placebo without a consultation and the development of a PPR.

Perhaps future homeopathy research could be divided into two. One a scientific arm that may explore areas such as homeopathic provings and the ultra high dilutions (UHD) research areas plus branches of water research – agriculture research etc. The other a pragmatic arm that focuses on homeopathy in practice and global patient health with both in qualitative and quantitative approaches.

4.5.9 Inter-professional Opinions

Some differences between the two affiliations, medical and non-medical homeopaths, were observed and some of these have been discussed during the preceding subsections of sections 3.7-3.9. However, the issue of medical verses non-medical practitioner appeared less pronounced in the current phase results than in phase one. This may be due to the variation in described practice that was apparent throughout the sample of participants, making distinctions less clear. Another explanation could be that more differences were highlighted in phase one as it is really the opinions that differ between the two affiliations, more so than their actual practice (aside from timings etc.) and they were forced to choose between boxes in phase one which may have brought out their staunch opinions on what they ought to think whereas the qualitative interviews allowed them to express views and practices more freely and not be tied to these preconceptions.

The issue remains regarding who should practise and the degree of uniformity achievable in homeopathic practise. One particular participant practised in an extremely different way to any of the others, who showed a lot of overlap in what they do. There was more variability between medical homeopaths than non-medical, and saturation of the data for medical practitioners took a larger number of interviews to achieve rather than non-medical, who were saturated by n=10 participants. n=14 participants were interviewed from both groups, however, to keep an equal number from each affiliation.

The increased degree of variability seen in medical homeopaths could be due to shorter training courses, or it could be an expression of freedom for them in a profession where things are usually tightly controlled. It is possible that homeopathy appeals to medical practitioners due to its lack of regimentation compared to other forms of treatment.

The setting in which homeopathic consultations are based may have an influence on the nature of the consultation and subsequently the treatment, with many non-medical homeopaths practising in their own homes, providing a very different environment to a clinical consulting room, especially one traditionally used for GP consultations on the NHS. This is an area that could be addressed in future studies.

There is a clear difference between the degree of prestige of medics versus homeopaths, something that was mentioned by medical practitioner (M9) as a reason she could never be solely a homeopath. This may be an influencing factor in some medical homeopathic practitioners clinging on to some of the more conventional techniques in their practise. An example of this was the suggestion from the results that it was possibly more common for medical homeopaths to practice on the spot prescribing and non -medical to take things away and consider them, though this may also be influenced by time available in consultations which is often longer in private verses NHS consultations.

4.5.10 Implications for Integration of Homeopathy

From the results of the current study it can be argued that to a greater extent, homeopathy practised by the two main affiliations in the UK, the FOH and the SOH, is a cohesive range of techniques that can safely be grouped together for their commonality and classed "homeopathic treatment" in a way that acupuncture is not (Dale, 1994, Hughes 2007) as shown in the phase 1 results However, enough variables were identified to ask serious questions regarding what should an integrated homeopathic service consist of if it were to be offered across the board? Currently, a few pockets of homeopathy are offered on the NHS, predominantly by GPs who have gone on to train in homeopathy and incorporate homeopathy into their regular practice or at a homeopathic hospital or department, and a minority of non-medical homeopaths who get NHS referrals from GPs, often funded by charities. In some countries homeopathy is much more widely integrated. This includes much or Europe, such as Germany and Italy, Switzerland and further afield in countries such as India and Brazil. In Brazil, though homeopathy has been offered as part of the health service it was only medical doctors that were allowed to practise it. This has recently been changed and non-medical homeopaths who have undergone appropriate training are also eligible, however, currently there are no courses there set up for them to train and some even come over to the UK to train. A similar situation occurred when Homeopathy became further integrated into the Swiss health system and only medical homeopaths were included in the model. So the question of who would practise homeopathy in a routine NHS setting is one that may need to be addressed, should integration occur. On the whole, as has been discussed, practice of homeopathy was universal, however, issues to do with diagnostics, the role of a homeopath in terms of life coach or principle health advisor (GP type role) may need to be considered.

Other issues would need to be addressed if homeopathy found its way into mainstream health, such as guidelines on prescribing and preparation of remedies. Prescribing guidelines would need to consider what potencies to use in what circumstances, what form the tablets should be in or whether liquid preparations are better for some conditions. In terms of how to make preparations effectively, some guidelines would be useful to identify whether homeopathic pharmacies all work to

the same standard and whether home preparation devices, as used by three participants, also meet this standard. Also guidelines on how frequently patients need to be followed up, how to identify when homeopathy is not an appropriate treatment and a means for referral from non-medical practitioners or review of the patients at certain intervals by GPs if seen by a non-medical homeopath within the NHS. This is likely to happen anyway, as it does when a GP refers a patient on to any service.

Is it conceivable that homeopathy could lose its appeal to many practitioners if it were this tightly controlled and therefore lack that freedom factor that many homeopaths, particularly medical ones, report to endorse.

4.5.11 Limitations to the Study and Future Considerations

These results cannot be extended to other homeopathic affiliations or those who practise but do not belong to an affiliation.

Some areas not covered here in terms of how remedies should be stored, drug or nutrient interactions with homeopathic preparations, for example there is an opinion that coffee affects homeopathic treatment.

A potentially interesting future study could be in terms of patient's understanding of homeopathy and how this may affect their compliance in taking homeopathic preparations effectively.

4.5.12 Reflection on Methods Used

IPA was considered suitable to address the research questions and for the nature and depth of material gathered. The researcher embarks on making sense of the participant making sense of an experience or process, creating a double layer of the hermeneutics associated with phenomenology. IPA is primarily concerned with the lived experiences of participants, rather than focusing on theory-level conclusions as is the case with grounded theory. IPA can be used to explore opinions, experiences and how these affect each other, including decision making. It was therefore appropriate in order to match the research questions of the study. However, it was sometimes difficult to move participants on from reciting learned theory and more onto the processes they employed in practice and experience of these. Perhaps a

more in depth phenoloenological study would be useful in order to fully probe arose such as the decision making processes that lead to remedy selection and the therapeutic components of homeopathic treatment. The results indicate that in order to reach a decision on a remedy, in part homeopaths are employing techniques consistent to IPA to trace back the events round the time of the manefestation of the symptom and how these events or experiences may have triggered imbalance. Homeopathic practitioners and authors of homeopathic texts very much focus on case studies and perhaps an area of development and future research by practitioners could be a systematic use of case by case IPA analysis that could then be collated to further advance an understanding of and a set framework for homeopathic practice.

Concluding Remarks

When interviewing the patients it was easy to get absorbed in the homeopathic world, the practitioners having such strong convictions regarding the treatments they offered, on the one hand following a framework, but when this framework is looked at in detail, it appears based on ancient theories and extremely vague. If homeopathy is to undergo rigorous research and adhere to a code of practice for treatment, it appears that the practitioners themselves may need to be clearer on what they actually do.

A specific chain of events occurs in UK homeopathic consultations that provides a characteristic for the label of homeopathic treatment. A large amount of individual style, a varying degree of underlying theory and different printed and computerised resources act as aids in remedy selection. A multitude of different approaches are used throughout the homeopathic affiliations with fewer opportunities to differential between medical and non-medical practitioners than were identified in Phase one of the current study (see sections 3.7-3.9). Differences that can be highlighted between the two groups include the setting where homeopathy is offered, which is far more likely to be a clinical environment for medical and a private home for non-medical. Also the role undertaken by the homeopath which could be more closely described as a clinician for medical homeopaths and as a life coach or counsellor for non-

medical. The importance placed on diagnostics emerged more commonly with medical practitioners but both groups were equally vague on assessment of outcomes at follow up. The source of the remedy showed huge potential for discrepancies in treatment, in addition to the degree of telephone review that was provided to insure that the patient was taking the remedy correctly.

Opinions on homeopathy highlighted that the PPR is extremely important, not least to ensure that sufficient information can be gathered from the patient. The healing was seen to begin during the consultation, particularly the discussion of how the remedy was decided upon and exposing the source of initial imbalance, however practitioners felt sure that the correct remedy was essential to achieve sustained improvement. The mechanism through which homeopathy could work was something that remained largely unanswered, with a general consensus that the mystery would be unravelled once we know more about subtle processes in the body. Here was a consensus that homeopathy stimulates self healing in the body.

Lack of trust between homeopaths of different affiliations was very apparent and in general a respect towards conventional medicine and other forms of CAM were expressed.

It is clear that a large degree of variation occurs within homeopathic treatment. Future studies of homeopathy may therefore benefit from conducting multi-centre trials and large sample sizes that would allow for more representative data collection.

Chapter 5

Phase 3 – A Patient- Centred Approach to Explore Homeopathic Treatment for Osteoarthritis in Primary Care

5.1 Introduction

In this chapter, a study that focused on patients receiving homeopathic treatment from the NHS in a primary care homeopathic department, focusing in particular on patient perceptions of treatment, outcomes from validated tools and biochemical data is explored for its possible use in future studies.

5.1.1 OA patients and the management of their condition

The quality of life of OA patients is often limited by pain and poor functioning related to their condition. The plight of patients with OA struggling to find suitable treatments to aid the manageability of their condition with the limitations of conventional medicine and hence incentives to try complementary and alternative medicine is highlighted in sections 1.0-1.2. Musculo-skeletal conditions such as osteoarthritis were highlighted by 20 out of 22 GPs in semi-structured interviews in a study to identify effectiveness gaps in conventional care (Fisher et al, 2004). Lack of efficacy of treatments, adverse effects and unacceptability to clients were among the top reasons given for unsuitability. 73% of the GPs in the study referred their patients for CAM, which is higher than the national average, reported at 40% (Thomas et al, 2001) and may suggest a bias towards the limitations of conventional medicine in GPs agreeing to participate in the Fisher study. However the reported national average increased by 25% between 1993 and 2001 (Thomas & Coleman, 2004; Thomas et al, 2001), and is likely to have increased again by the time the Fisher study was conducted. Fisher et al (2004) therefore highlight an acknowledgement among the medical profession that OA is not well managed. This enhances the need for an increased evidence base on CAM treatments such as homeopathy that may be of benefit to OA patients. Limitations of previous studies on effectiveness of

homeopathy for OA are discussed in section 1.3.1. New approaches to research are needed in order to overcome issues of external validity that have limited previous studies. Exploration of patient perceptions is one area that may have the potential to inform future studies.

5.1.2 Patient focused research

Patient perceptions of health and disease form an area of growing interest within the field of health research, though there is limited research in this area to date. One study that looked at patient perspectives of hand OA at 5 centres across Europe, used focus groups to explore 5 open ended questions on functioning in OA, based on the biopsychsocial model in daily life (Stamm et al, 2008) in order to test appropriateness of tools measuring function (n=56). The results of the study showed that different qualities of pain identified by patients, including "fever like pain", "Pain like a knife cut", "itching", "ache" "tenderness", "killing pain" were important for the patients but not covered by the tools. This study concluded that areas that were important to patients including aesthetic changes, and leisure activities, and their psychological consequences were generally not covered in the instruments. The study was limited by language, as all were conducted in English despite 4 of the 5 being in non-English speaking countries and there were some discrepancies over the exact translation of some English words, for example "sore" and "pins and needles". The findings of this study were corroborated by another study that looked at Japanese patients' experiences of OA before and after hip arthoplasty (Fujita et al, 2006) and found that aesthetic factors, in addition to frustrations due to limited functioning associated with OA, were the main concerns for OA patients.

The addition of qualitative studies, nested within clinical control trials, is not a new idea. By including qualitative data collection into a study, it is possible to tap into perceptions and experiences of complex interventions to achieve new ideas and concepts that are likely to be missed when purely quantitative methods are used. One study of this type on osteoarthritis patients was an RCT on exercise therapy for OA which included a qualitative study on n=20 patients (n=8 at follow-up) to identify causes for non-compliance with physiotherapy treatment (Campbell, 2001). The study concluded that compliance was only

partially dependent on the belief of participants that the treatment was effectively ameliorating symptoms. Another key determinant of compliance was the ease of fitting the physiotherapy practice into their current lifestyle (Campbell, 2001).

Another study that looked at perceptions of 10 participants who were being treated with sham acupuncture during an RCT comparing true and sham acupuncture included a qualitative arm that allowed for a deeper interpretation of the results (Patterson et al, 2008). In particular, qualitative results highlighted the fact that although the Sham group were unaware that they were not receiving true treatment, patients' expectations and feelings of participation in the study led to an enhanced relationship between practitioner and patient. This extended their roles beyond that of "patient" and "practitioner" and may have influenced the outcome of treatment (Patterson et al, 2008). This transpired to be in terms of the patient expectations and participation, with therapists and patients taking on different roles due to the trial than "patient" and "doctor".

5.1.3 CAM research in the NHS setting

Most CAM and therefore most CAM research is undertaken within private practice so it is worth considering the impact of setting on the current study. CAM users typically are middle-class educated adults, between the ages of 25-45 (McDonough et al, 2007; Thomas & Coleman, 2004). Conversely, visits made to NHS health professionals in primary care show a very different patient profile with 80% of visits made by patients over 65 and from a range of socio-economic backgrounds. Many musculo-skeletal patients turn to CAM and other non-pharmalogical interventions due to dissatisfaction with the side effects associated with conventional drugs (Fisher et al, 2004; Fraenkel et al, 2004; Moe et al, 2006). Very little research has been conducted on the attraction of CAM and experiences of CAM use in a patient group that more typically represents populations seen routinely in primary care. One study did address patient experiences of treatment at the Glasgow Homeopathic Hospital, an integrated NHS setting where a range of CAM and orthodox treatments are offered. The study involved n=14 patients hand-selected for socio-economic status and on responses to a questionnaire distributed more widely to patients at the centre. The study found that receiving the treatment within the NHS was highly important

due to an inability to cover the cost privately but also as they felt they had a right to treatment on the NHS and also felt safer using CAM in an NHS setting (Mercer & Reilly, 2004). The study is useful in providing some data on patient experience of integrated CAM use within the NHS on a small selection of users, though particular CAM treatment received was not considered and results cannot be extrapolated to a particular therapy. The current study will therefore focus on osteoarthritis patients receiving homeopathy in an NHS setting, addressing a group which has been under represented in the literature to date.

5.1.4 Research Approaches to CAM in the NHS

Clinical trials of OA and homeopathy to date have been inconclusive, as discussed in Section 1.3.2. This has largely been attributed to methodological constraints and a lack of representation of "true homeopathic practice". The RCT model has also been declared unsuitable for a complex individualised therapy such as homeopathy by some influential authors e.g. Verhoef et al (2005) and Walach et al (2006). In Chapter 4 the difficulty of separating out the components of homeopathic treatment were discussed. In Chapter 3, sections 3.7-3.9, the results of a survey to identify homeopathic treatment as practised in the UK were presented. It is clear that new methods are required to enhance research into homeopathy. Pragmatic studies have become a more popular approach to test two treatments against each other rather than using the much disputed placebo.

Conducting a study of homeopathy in a purely NHS setting provides an opportunity to tap into issues that are directly relevant to integrative healthcare debates. With the popularity of homeopathy growing (Thompson et al, 2001) at the same time as the traditional integrated homeopathic hospitals struggling (Campbell & Fitzgerald, Sunday 8 August 2007) it is particularly useful to conduct a study in one of the few remaining historic NHS homeopathy settings in order to inform the integration debate.

5.1.5 A History of Homeopathy in the North-West of England

The emergence of homeopathy in the UK began with Dr Quinn in the nineteenth century, and is discussed in section 1.21. Homeopathy in the North West became

an increasingly popular form of treatment and it was Henry Tate, who ran the Tate and Lyle sugar industries in the North West, who funded the opening of a Homeopathic Hospital and Dispensary in the area, based in the centre of a city, in 1886. When the NHS was founded in 1948 the hospital was renamed and naturally incorporated into the healthcare system. It functioned as a hospital for a total of 100 years, however in recent years the service was moved to primary care and became a homeopathic Department imbedded in a mainstream community medical practice. There are now over 50 GPs in the North West registered with the Faculty of Homeopathy and this includes some examples of the most integrated homeopathy settings in the NHS.

A study into homeopathy based at a centre that has provided homeopathic treatment within the NHS in the North West of England for many years is therefore an ideal setting for a study that can test the feasibility of different aspects of clinic trials and provide an insight into how suited homeopathic treatment is to an NHS setting.

5.2 Background to Osteoathritis andAssessment of Pain

Before considering the best ways to monitor changes following homeopathic treatment of OA it is first necessary to understand more about the nature of pain in osteoarthritis. It is also necessary to explore tools and methods that can be used to measure the outcome of treatment.

5.2.1 Osteorthritis Pain

Musculo-skeletal pain is the most common cause of chronic pain worldwide (Brooks, 2005). Pain relief in addition to improved function is primarily the reason why osteoarthritis patients seek medical advice (Hadler, 1992). Nociception is the term used to describe the transmission in nerve fibres following a noxious stimulus. Pain itself is derived from nociception but involves a cognitive and emotional element. Arthritic pain is thought to be derived from nociceptors sensing the damaged joint. This signal is transmitted via the afferent A δ and C nociceptor fibres which are part of a network that stretches into the periosteum and also innervates subcondral bone, joint capsule

and fibrocartillagenous structures. A δ fibres are more associated with acute stimulus whereas C fibres are responsible for aching pain. Once nociception occurs the signal is then conducted to the dorsal horn neurone of the spinal cord and impulses above threshold level cause a depolarisation in post-synaptic spinal neurons where the impulses are then transmitted to one of the four supra-spinal centres (brain stem, cerebellum, cerebral cortex and cerebral sub-cortical areas) where they are processed.

The nature of osteoarthritis pain is a subject that has troubled scientists and physicians up to the present day (Gwilym, 2008). The reason for this is that it is not understood why the joint degeneration associated with OA sometimes, but not always, causes pain. In addition, pain associated with osteoarthritis does not always seem to be joint-specific and there is evidence to suggest that patients with OA of the hip also have changes in pain perception and feel increased skin sensitivity at ipsilateral and contralateral sites (Ordeberg, 2004). In addition, more than one in ten patients who have joint replacement surgery frequently still feel pain following the surgery (Elson and Brenkel, 2007; Nicolajsen et al, 2006) and conversely, positive results have been demonstrated with placebo surgery indicating that there is more involved than just the technical enhancement (Moseley et al, 2002; Moseley et al, 1996).

Recent research has begun to investigate the possible contribution of pain derived from neurogenic mechanisms in addition to that derived by joint damage (Hochman, 2008). Neurogenic pain is a broad term referring to types of pain which are generated by dysfunction of the nervous system itself in the absence of nociception. Neuropathic, deafferent and central pain are all distinguishable types of pain that are subsumed by the term neurogenic pain. Neurogenic pain accounts for over 25% of visits to pain clinics, and a high proportion of these are cases of Chronic pain. It is possible that neurogenic pain can therefore help to explain why pain can be felt in the absence of identifiable damage and following surgical joint interventions.

The assessment of OA pain has caused clinical difficulties and several studies have shown that the relationship between radiologically identified joint damage and pain level does not show a clear correlation (Gwilym, 2008) possibly due to the fact that pain is subjective in nature and is defined by the person experiencing

it. As a result the medical community's understanding of chronic pain now includes the impact that the mind has in processing and interpreting pain signals.

From a physiological view point, neuropeptides are believed to have a large role in the modulation and sensation of pain in osteoarthritis. The role of these, and in particular the role of Substance P, is considered in section 5.2.2 below.

5.2.2 Substance P

Substance P belongs to a group of neuropeptides released from primary afferent neurones during an inflammatory response or nociceptive process. There is considerable evidence to suggest these neuropeptides have a significant contribution to the initiation of neurogenic inflammation (Holzer,1988; Jang et al, 2004).

The neuropeptide group of tachykinins includes Substance P together with Neurokin A, neuropeptide K, neuropeptide γ and neurokinin, and these act at NK_{1-4} G-protein coupled receptors (O'Connor et al, 2004). There is evidence to suggest that each tachykinin preferentially targets one receptor distinctly in low concentrations but at high concentrations they can all target all four. Substance P, for example mediates most of its proinflammatory effects via NK_1 receptors which are positively coupled to phospholipase C (Chapman et al, 1996, Traub, 1996, Wajima et al, 2000). Evidence to support the role of Substance P in the pathophysiology of pain is based on observational studies in animals, which show that nociception in rats can be enhanced or blocked upon intraplantar injection of NK_1 receptor agonists or antagonists respectively (Carlton et al 1996). It is thought that following the binding of Substance P to the NK_1 receptor, Substance P modifies Ca^{2+} and K^+ currents at cellular level causing the activation of an enzyme called phospholipase C. Phospholipase C causes the release of two second messengers which in turn cause the release of CA^{2+} from intracellular stores, the elevation of cyclic adenosine monophosphate (cAMP) in cells, and elevation of cyclic guanosine monophosphate (Radhakrishnan & Henry, 1995) causing depolarisation and increased sensitivity to C Fibres.

Substance P is stored within a subset of small diameter sensory neuronal cell bodies (Ma et al, 2003; Ohtori et al, 2002; von Blanchet et al, 2002) and is transported to the periphery where it is released following primary afferent fibre activation (Carlton et al, 1996). The release of Substance P, along with CRLP not only activates neurogenic pain but also causes dilation of microvessels and hence brings about an inflammatory response. Substance P causes indirect vasodilation via nitric oxide and induced plasma extravasation (neurogenic inflammation) by acting on endothelial cells. Substance P has also been found to mediate effects on non-neural cells including Mast cells, lymphocytes, monocytes and macrophages (O'Connor et al, 2004, Millan, 1999). It has been suggested that Substance P has a role in the pathophysiology of arthritis directly (Levine et al 1994).

Studies involving a novel technique of using saliva samples to run a substance P assay to determine the concentration of substance P have recently been publicised (Adams, 2005; Fields, 2002; Mackawan et al, 2005). Salivary substance P was used in these studies as an indicator of the severity of pain felt by an individual at the time the sample was taken. The involvement of Substance P in neuropathic and inflammatory pain (Nichols et al, 1999) may make it an ideal neuropeptide to include as a measure of OA pain in a clinical study.

5.2.3 Assessment Tools Used

In clinical trials of homeopathy, the outcome measures chosen for the study are a determining factor on the success of the trial. Most trials of homeopathy have solely used the clinical assessments used in routine medicine (Jonas, 2001). The outcome tools used in clinical trials of homeopathy and other therapies for OA are displayed in Table 1 in Chapter One of this thesis. The most commonly used tools used for OA trials included the validated WOMAC tool (Bellamy et al, 1988), which is targeted at knee osteoarthritis and consists of a series of visual analogue scores (VAS), 10 cm in length, upon which participants place a mark to indicate the level of pain and stiffness they have whilst undertaking certain activities. As has been previously mentioned, homeopathy is also believed to work on the vital energy of the patient, but this tool is primarily concerned with perceived pain levels. Participants in the current study are sufferers of osteoarthritis in different joints, not necessarily the knee, but it is useful to have a

measure of pain in one joint that is consistent for all participants so VAS from the WOMAC are used for this.

Several assessment tools have been designed to determine the overall health of a patient. This allows for the mental and physical factors of health, together with vitality, to be monitored. One such tool is the MYCAW (Measure Yourself Concerns and Well-being) questionnaire allows patients to identify the main concerns and the degree their lifestyle is affected by their illness. It is a variation of the validated MYMOP (Measure Yourself Medical Outcome Profile) tool, designed by Patterson (1996). The MYCAW tool was first used by Peace and Mannase (2002), and has the benefits of containing questions that ask patients in the follow up part of the tool what other events they may have experienced since the last assessment that may have affected their health, other than the treatment they have received. It also omits questions on activity that are well covered in other tools used in the study.

The SF36 (Short Form 36) questionnaire contains a series of short questions designed to assess the patients' physical and mental health, including vitality and overall health. It was first developed in 1992 (Ware & Sherbourne, 1992) and as a health related but not disease specific tool the SF36 use is growing and has been used in thousands of studies to date. The questionnaire contains 10 main questions, with varying numbers of subcomponents adding up to a total of 36 questions. These answers can then be grouped into eight subscales that correspond to a particular aspect of health, and further grouped into a score for mental and for physical health. These are then transformed and coded into a scale for each subcomponent from 0 (worst possible health) to 100 (best possible health) and can then be treated as continuous data and be tested using parametric statistics (McHorney et al, 1993; Ware & Gandeek, 1998). Although use of the SF36 tool is now widespread, some studies have commented on its lack of sensitivity to change (Smith et al, 2000) (Dempster & Donnelly, 2000) and the need to ascertain whether it is a suitable tool for a particular trial has been

reported (Jenkinson, 1995). The current study will provide some pilot data on the use of the SF36 for assessment of overall health of OA patients.

Another factor that many studies have included, and the current study also includes, as an outcome measure is use of analgesics at baseline and throughout treatment. Dissatisfaction with conventional medication and concerns over side effects is an aspect of coping with OA, particularly as many OA patients have other co-morbidities. By measuring change in the usage of analgesics and other OA medication, another outcome of treatment can be monitored.

5.2.4 A Need for New Assessment Tools

Many of the clinical trials that have used tools such as the SF36 and VAS scores have had inconclusive results (see Table 1, sections 1.2-1.3). This suggests that new outcome measures are required in order for homeopathy research for OA to progress. The tools require participants to self- report the scores of pain and other outcomes. This leaves the results susceptible to mood changes and inconsistencies. A biological measure may be a more reliable option as it bypasses the subjective factors involved in choice of response. Studies into biological effects of homeopathy are discussed in Chapter 1, section 1.21. These studies have been few and far between, particularly since the ground-breaking research by Benveniste (Poitevin et al, 1988) was undermined by the journal Nature, subsequent to him publishing his work (Maddox et al, 1988) (See Section 1.4.6). If strong evidence was provided to highlight an effect at a biological level in the body, this would warrant a re-evaluation by sceptics who question the scientific basis of homeopathy.

Obtaining a reliable indicator of pain is therefore an area that has proved difficult in clinical studies and clinical practice. New methods of measuring pain in a number of different ways are needed in order to ensure an accurate process. In this study, levels of salivary Substance P will be measured to pilot its use as a biochemical indicator of pain.

By looking at self- reported pain, biological markers, and self-reported measures of vitality and gaining qualitative information on patients at different time points of the study, a diverse amount of data will be generated. Comparing and contrasting results will provide information on which tools would be useful for future studies.

The aim and objectives of this study are as follows:

5.3 Aim: - To observe homeopathic practice for Osteoarthritis (OA) in an NHS setting and highlight practical issues and potential benefits relevant to future research

Objectives:

- To measure levels of reported pain and to explore manageability of pain and other symptoms of osteoarthritis patients receiving homeopathy
- To explore homeopathy in the NHS setting and implications for integration models
- To explore the experiences of OA patients in their manageability of symptoms in everyday life.
- To explore patient expectations and experiences of homeopathic treatment.
- To consider how qualitative and quantitative findings compare, and assess suitability of certain outcome measures in determining change in a clinical trial environment
- To highlight considerations for future research

5.4 Method

Design: This was a feasibility study with a repeated measures design to investigate homeopathy for OA. The study followed a cohort of patients who attended a homeopathy department for treatment of osteoarthritis during a set

time period to highlight practical issues and potential benefits of conducting a full trial on homeopathy for OA in primary care.

Setting: A Homeopathic Department run by a Primary Care Trust in the North-West of England. The Department is the remnants of a regional homeopathic hospital with provision of homeopathy within the NHS since the NHS was founded in 1948. The department employs 5 medically qualified homeopaths and sees approximately 1,800 patients a year.

Participants: Patients who were referred to the practise for treatment of osteoarthritis and who fit in with the inclusion and exclusion criteria, including fulfilment of a case definition of osteoarthritis according to the American College of Rheumatology (Altman et al, 1991) were invited to participate in the study. For pragmatic reasons, the sample depended largely on the referrals that came to the clinic and therefore no specifications on gender, and age were included.

Inclusion / exclusion criteria:

1) Pain in the joints (at least 3 days a week for more than 2 months)

2) X-ray evidence of OA (reduction of space or osteophytes)

Plus any of the following

3) Early morning stiffness

4) Swelling

5) Reduced mobility

6) No presence of co-morbid major illness such as diabetes, heart disease or cancer

7) No steroid intake in the previous 15 days

8) No recent homeopathy or other CAM intervention in the preceding 6 months.

9) No severe pain whilst seated, that would make the extension to the consultation due to the study inappropriate.

Ethics:

Ethical approval was sought and granted from the NHS Research Ethics Committee (Liverpool Paediatric Research Ethics Committee) in August 2006

(see Appendix 1). Approval was also granted from Research & Development at Central Liverpool PCT and an honorary contract to the Trust was produced for the lead researcher. Ethical approval was also sought and obtained from Liverpool John Moores University Research Ethics Committee.

Recruitment: The targeted number of participants for the study, based on feasibility, was n=14. At the time of planning the centre received approximately 16 osteoarthritis referrals per month and it was anticipated that recruitment would take place for 1 month. However, due to several factors, discussed elsewhere in this thesis (see discussion), the rate of referrals had declined considerably by the data collection period of the study. Recruitment therefore took place over a 5 month period and the number of participants in the study fell short of the target number at n=11.

Data Collection

The study involved the use of questionnaire outcome tools that have been used in previous studies and also biochemical data to assess the sensitivity of these tools as much as any changes resultant of the treatment. Qualitative data was also included in order to highlight areas relevant to the conduction of a study, in addition to obtaining data on patients' experiences of homeopathic treatment. This is particularly useful as the patient group in the study is atypical of the population that commonly used CAM (see section 5.1.3), and previous studies on patient perceptions have tended to be focused on the typical CAM user rather than a more representative osteoarthritis patient group.

Outcome Measures

Objective and subjective assessment was conducted by using quantitative standardized scales as advised by Altman et al (1996). In addition a saliva sample was taken to test for concentrations of substance P. Additionally some separate open and closed questions were asked during the interview, relating to patients' experiences of using homeopathy.

Specifically, the following outcomes were assessed:

- Expectations of Homeopathic Treatment (interview)

- Experience of Homeopathic Treatment (interview)
- Pain intensity on a visual analogue score (VAS) in WOMAC tool (see section 5.2.3)
- Stiffness on visual analogue score (VAS) in WOMAC tool
- Patient global assessment (MYCAW, SF36, open questioning) (see section 5.2.3)
- Intensity of suffering from patients' most pressing concerns (MYCAW self-assessment questionnaire)
- Use of analgesics (interview)
- Salivary concentrations of substance P (see section 5.1.8)

Patients were assessed on the above measures at baseline (initial appointment at the centre), after 6 weeks, 12 weeks, and at 6 months.

5.4.1 Procedure

In order to boost the number of referrals received, at the Department of Homeopathy in the North-West of England, a letter detailing this study and a reminder of the homeopathic service provided was circulated to all GP practices in the area. This encouraged GPs to suggest homeopathic referral for patients with established osteoarthritis, who were not managing well on conventional treatment. The patients were also given information about the study by their GP. The letter was circulated 3 months prior to the target start date of the study, to fit in with the Trust's policy of seeing patients within 12 weeks of referral. Once the referrals had been received at the Department of Homeopathy where the study was based, patients received a letter inviting them to make an appointment. Patients who fit in with the inclusion and exclusion criteria were then given the opportunity to give written informed consent for participation in the study.

The study took place around patients' routine appointments at the Centre. Patients' initial appointment with the homeopathic doctor last approximately 45 minutes and subsequent follow ups were 20 minutes long. Patients seen at the centre are routinely invited for follow-up every 3 months, however for the purposes of the study an extra follow up at 6 months was agreed upon by the centre, a change that the centre was piloting. Where necessary, extra

appointments were absorbed by the consultant medical homeopaths through extra clinics. Homeopathic treatment at the centre would begin with an allopathic assessment and continue on to a homeopathic case history. This would then lead to individualised remedies chosen by the medical homeopath, a prescription being generated and remedies ordered from Helios homeopathic pharmacy and posted out to the patients.

The initial contact between the researcher and patient for the study was therefore to take place in the 15 minutes prior to appointment with the homeopath. Patients were asked to identify two Patient Preferred Complaints (PPCs) in the MYCAW questionnaire, to identify pain on VAS, use of analgesics and other medication, overall health and impact of medical condition using the SF36. Some additional questions on expectations of treatment were included. A 2ml saliva sample was obtained from each patient for analysis of Substance P concentration, see below for detailed procedure. The sessions held between the patient and researcher were audio-recorded and transcribed in order to identify emergent themes according to IPA methodology (Smith et al, 1997). The focus of the interviews was on the experiences of participants in seeking treatment for their condition, and their expectations from receiving homeopathic treatment. Audio recordings were destroyed within 6 weeks of transcription, in accordance with the university research ethics committee requirements. Follow-up interviews took the same format, but with the follow-up version of MYCAW and open questions on experiences of homeopathic treatment.

Any further medical intervention seen as necessary by medical homeopaths was actioned and recorded. Patients' medical records kept by the Department of Homeopathy were available to the researcher to view. All confidential material was anonymised and kept in locked filing cabinets.

Follow up: Some participants were lost to follow-up due to self discharge from homeopathic treatment (n=2), moving away from the area (n=1) and non attendance at appointments (n=4) which meant that in some cases data was not collected at each time point. This reflects the nature of medical treatment within

the NHS. The follow-up interview followed the same format as the initial interview, of face-to-face delivery of questionnaire outcome tools, the difference at follow up being in the open ended questions asked, in order to obtain more discussion from participants on their experiences of treatment.

Substance P Assay

Once 2ml of saliva was obtained from each participant, the sample was split into two, and 10 µl of protease inhibitor cocktail was added to one of these. Samples were then placed in an ice box and transported to a –80°C freezer at the university for storage. Matched saliva samples were obtained from healthy volunteers of the same age and sex as each participant in the study, with no existing Musculo-skeletal problems, and treated and stored as outlined above. Participants to obtain matched samples were recruited through an email request to members of the workplace of the principle researcher. The Correlate-EIA substance P enzyme immunoassay kit, made by Assay Designs, was used for the assay. The procedure outlined in the assay kit manual was followed (Assay Designs, 2005), including making up standard solutions with varying concentrations of substance P. In order to determine the concentration of Substance P in biological fluid samples, the assay uses a polyclonal antibody to Substance P to bind competitively to the Substance P in the sample, or an alkaline phosphatase molecule with Substance P covalently attached to it. Following mixing and incubation and completion of the assay process, the yellow colour generated was read on a microplate reader at 405 nm, this process was carried out twice on two different plate readers. The yellow colour intensity is inversely proportional to the concentration of substance P in the sample, as it represents the antibody bound to the alkaline phosphatase-substance P complex. Results of the assays were analysed and plotted against the standards.

5.4.2 Analysis of Data

The data gathered in phase three of the study was a mixture of quantitative and qualitative, and each component was analysed accordingly. Quantitative data

underwent statistical analysis to investigate differences between pre- and post-intervention indices. Continuous outcome variables such as VAS scores were tested for significance using paired T-Tests between baseline data and each follow-up time point. Non-parametric data was analysed using the paired Wilcoxen-Sign test.

Qualitative data was analysed in accordance with IPA methodology (Smith et al, 1997) and as described in section 4.4.3. A general review of all data allowed reflective notes and production of initial summaries. The data was categorised and themes and patterns emerging from the data were identified. This was all done by hand with coding of transcripts and compiled lists of themes. The first two transcripts were coded by an additional researcher to check consistency and so validity of the findings. Themes and patterns were coded and codes used to facilitate inter-rater reliability checks.

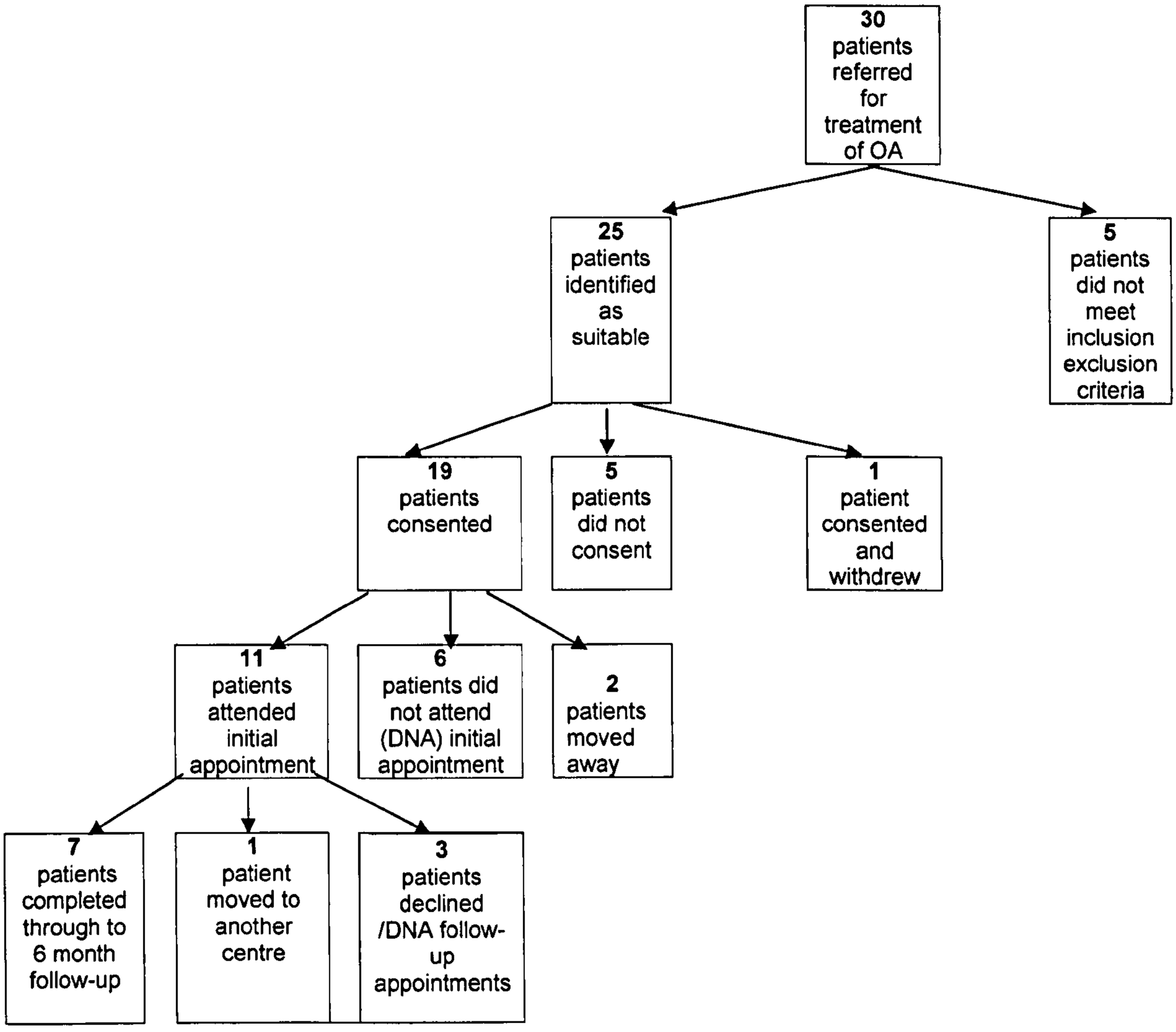
Qualitative and quantitative findings were then compared to examine the extent to which outcome measures adequately tapped the dimensions of the homeopathic interaction. The suitability of outcome tools as assessments of homeopathy for OA was considered.

5.5 Results 1:

5.5.1 Recruitment details.

Figure 5.1 summaries the recruitment, inclusion, exclusion and drop out of the participants in a CONSORT flow diagram. This shows how the participants of the study, n=11, was obtained from those participants originally referred to the Department of Homeopathy, n=30.

Figure 5.1: Patient recruitment into the OA study at an NHS Homeopathic Department



Patients who did not meet the criteria: 2 were inappropriate referrals 2 presented with different musculo-skeletal disorders and 1 failed to show x-ray evidence of OA

Participants were all recruited from the Department of Homeopathy where they were due to receive homeopathic treatment. Information on the participants is summarised in Table 5.1.

Table 5.1

Participant	Gender M/F	Age	Occupation	Postcode Area	Estimated Total deprivation rating from full postcode	Estimated Health Deprivation rating from full postcode
1	F	67	Retired	L25	9	13
2	F	37	Physiotherapist	CH61	6	11
3	F	52	Sales assistant	L16	10	14
4	F	58	Unemployed	L15	19	20
5	F	79	Retired	L7	19	20
6	F	67	Retired	L19	14	17
7	M	48	Manual Labourer	L15	12	15
8	F	55	Receptionist	PR9	7	12
9	F	74	Retired	L4	20	20
10	F	50	Entrepreneur	PR9	11	15
11	F	72	Retired/ Not worked	L8	20	20

In Table 5.1, the estimated socio-economic status (right-hand column) are generated from the full post code and are taken from the Office of National Statistics website, based on results from the 2007 census (Office of National Statistics, 2010). The deprivation scores shown in the right hand columns are a score of 1 to 20, with 20 being the highest deprivation. The participant numbers (left hand column) shown in bold are those who continued with their treatment at

the Department of Homeopathy. Those not in bold, 2, 5, 7 and 11, are not in bold. As can be seen in Table 5.1, no differences are detected on examination of the details, although the only participatory male dropped out. The numbers involved are too small to form a reliable impression of any between group differences.

All participants were over the age of 48 and most had some form of multiple pathology, though no serious co-morbidity. All suffered from OA in more than one joint, and the joint that gave them the most trouble tended to vary from time to time. Some patients, n=2, had actively sought out homeopathic treatment, in one case because they had been treated with it previously by a senior partner at the Department of Homeopathy. Another had heard about the study through family friends. The remaining participants, n=9, had received the suggestion of homeopathic treatment from their GP who was keen to refer them. Many of these were therefore patients who were struggling with the manageability of their condition with conventional medicine alone.

Patient Perspectives

5.5.3 Key Themes Generated From the Qualitative Data Obtained From Interviews

Themes that emerged during discussions with the participants are discussed in this section. They are grouped in terms of areas relevant or brought up at the initial consultation and areas that developed in follow up consultations. Table 5.2 summarises the superordinate and subordinate themes discussed in this section and their links to each other.

Table 5.2 Emergent Superordinate and Subordinate Themes

Superordinate Themes	**Subordinate Themes**	**Links**
Strong mentality	Coping	*
	Optimistic about health compared to that of peers	+
Open to Homeopathic Treatment	Suggested by GP	> ¬
	Happy to try anything that might help	
Expectations	Improved manageability	*
	Reduced medication	+
	Anxiety relief	
Experiences	Listened to	^
	Less emotional distress	
	Decreased need for medication	+ ^
	Holistic Therapy	^
Setbacks	Life Events	*
	Non-compliance	
	Interrupted remedy delivery	
Specific to setting	Trusted medical homeopaths	>
	Combined therapy- openness	>
	Accessibility	
	Peer acceptability	¬

Initial Appointment

Indeed, one key factor that stood out from the participants in this part of the study was that these patients, who had suffered with arthritis for an average of 8 years, were a very strong patient group. Participants were reluctant to make a fuss about their condition and seemed to be trying to remain cheerful about things. This came across both in the way they spoke and their responses.

Responses concerning limitations to activities showed a real drive towards manageability, adaptability and an attitude of the "need to just plod on" eg. P1, P4, P9, P6 at T1 (time point 1).

P9 *"I think I know that I've got to put up with it, for a start, so I'm not letting it get me down. I've learned my limits, apart from going to the footie, the physios helping. I've got to just get on with things. And it isn't as bad as it was, ...I haven't cut down on the amount of time because I can't. No one else is going to do the work."*

P1 " *I just manage. Things have to be done, so I just get on with it*"

Many had developed coping strategies to allow them to get things done and so they did not feel that their lifestyle was being affected, e.g. P1, P8, P9.

P8 " *I just don't use the stairs, I have moved to a bungalow now so I can avoid the pain of going up and down stairs*"

P4 *"I still do the same things but I'm just slower than I used to be"*

P5 " *I'm not limited in doing vigorous activities because I don't do those kinds of things*".

5.5.2 (ii) Optimistic about their own health

When they spoke of their over- all health there was an almost universal opinion that their health was relatively good and they were as healthy as anyone else they knew.

P4 " *When I look at the troubles that some of my friends have, I seem to be alright really. I guess part of it is age, and you have to expect some health complications as you get older*"

P1 " *Well I do seem to have a lot of little problems, if it's not my legs then it's my mouth or it's my back or my fingers, but these are all minor things and are a lot less serious than the things some other people have to deal with.*"

5.5.2 (iii) Expectations of homeopathy prior to treatment

A key theme that emerged concerning the participants' views on homeopathy prior to treatment was that they had entered the process blindly, with very little knowledge of what to expect. This was true for n=9 of the patients. Most reported taking an open-minded view and being so exasperated by their symptoms that they were prepared to try anything.

P8 " *Well I didn't know what to expect really but I just thought "well if it might help, then why not try it"*"

P1 *"My GP suggested it and my initial reaction was "Yes I'll give it a go"* "

When talking of their expected outcomes from homeopathic treatment, a common theme evolved around pain reduction, but also pain management. Some hinted at what sounded like a magic cure, but it was clear that in general, these patients had suffered too much with their condition and for too long to expect any quick fix and were happy to ride out the homeopathic treatment process.

Follow up interviews

It was noted that patients became much more open and willing to talk about other factors in their life that might complicate treatment or add to the condition, as familiarity and rapport were established with participants. This was partly reflected in the length of the interviews increasing as time went on, but also the personal issues that were discussed, for example difficulties in work or family troubles.

5.5.2 (iv) Observed Benefits

For those who did continue treatment and take their remedies throughout the 6 month observational period (n=7) there was a clear sense of finding the homeopathic treatment useful. However, in some cases, the patient's treatment did not go as planned, either due to a mix up with the prescriptions e.g. P9, P6, a misunderstanding of the instructions, or a patient self- discharging (see the practical constraints section at the end of this chapter), e.g. P7, P11, P4 or moving to a different centre for treatment, e.g. P3. The following quotes are examples of perceived benefits:

P6 *".. It's not as bad as it could be, but there's still quite bad pain. No but I do think the tablets are doing something because since I started taking them it's never woken me up in the night since I started them so that's a good thing, coz sometimes it would wake you up, you know, the pains in me fingers, coz it's mostly in the hands..."*

P1 *"My hands look terrible [shows red swelling] at the moment but they don't seem to be bothering me so much"*

Interestingly, as can be seen from the above quotes, it was not so much the pain itself that had shown improvement, more other factors such as interference with sleep patterns and suffering brought about from the condition

5.5.2 (v) Medications and Analgesics Used

Patients generally were reluctant to take pharmaceutical treatment and often this was a reason for choosing homeopathic treatment initially, but many other

patients did indicate at follow up appointments that they were now able to use less medication:

P6 " *When I was first referred to the homeopathic clinic, I went in there [to the GP] because I'd been using those ibroprofen gels , my husband's and so I went to the doctors for this and he gave me a tube. He also said, "would you like to try homeopathy?" And I thought well why not. And since then I haven't really used the gel. I've still got the same tube. I don't actually think it did much good anyway but I don't seem to need it so much now, since I started the tablets".*

P1 " Taking painkillers, I Have done but very occasionally recently. I have found that I haven't really needed to since I started with the homeopathy"

5.5.2 (vi) Obstacles to Health Improvements

Fluctuations in the Severity of Symptoms

One key theme that emerged regarding improvement of symptoms was the natural fluctuations in severity of OA that participants were naturally used to. This could be due to cold weather, damp weather or just down to the nature of the symptoms themselves.

P6 *" Well, I do feel a lot better... but then it's not the winter yet and it tends to be worse in the cold"*

P10 *"...I sometimes wonder if part of the improvement is due to the dry weather we have had recently. The stiffness is worse when it's wet and damp"*

The above quotes show that participants were used to fluctuations in their condition, and would therefore be cautious to recognise an improvement, in case the symptoms re-emerged following a change in weather.

Life Events Creating Obstacles

Another key theme that emerged was that obstacles that were counter-productive to health improvements would sometimes crop up and that in serious incidences, these were felt to be a real set back to improvements. The type and severity of such obstacles ranged from social activities or special occasions which involved further exertion than normal and had knock-on effects on health but were none the less a part of routine life, to significant events involving family member's health or family relations that put extra stress and strain on the participants.

P9 *"I went to watch Everton play last week for the first time in a long while, I used to be a season ticket holder, and the cold and damp conditions have caused my joints to play up again since..."*

P8 " *... since my mum got ill...I've been rushing backwards and forwards to the hospital to visit her... it's very tiring...and I do worry*"

These are all examples of activities and life events that can challenge people at any time. Homeopathy is a holistic treatment thought to assist in the manageability of all life events and symptoms and it is therefore worthwhile considering these factors, as they arose during the study period and may have influenced outcomes.

(vi) Setbacks to the receipt of homeopathic care

One theme that emerged concerning considerations of treatment was ineffective delivery of homeopathic treatment, e.g. P6 at time-point 1, P9 at time-point 2. This was sometimes concerning patients inaccurately following the instructions given to them due to lack of understanding.

P6- at 6 week follow up *"... you see I've been taking the tablets wrong...I should have been taking them before food and once a day... where as I was taking them once a week after food. I've got some more now and discussed it with the doctor so I can start taking them properly now*"

In other cases it was external events that prevented the remedy being taken as suggested.

P8 at 12 week follow up " *...the parcel didn't arrive in the post. I was waiting for the tablets to arrive and when they didn't after 3 weeks I asked at the post office and they said due to the postal strike they could not guarantee when old post would arrive... I got them and started taking them 2 weeks ago*"

The above quote was following a large scale nationwide postal strike that lasted several days in 2007 and was continued in Liverpool for over a week more. This led to chaos at the postal sorting offices and delayed some post for over a month.

(vii) Experiences of Homeopathic treatment

With participants' expectations in mind, it was interesting to examine the participants' experiences of homeopathic treatment. One key theme that emerged here was one that has cropped up many times during studies on a wide range of complementary therapies, the matter of attentive care. Most of the participants who attended follow up (n=7) reported that they had a more profitable experience during homeopathic consultations than they were used to in mainstream medicine:

P1 " *Nice to know people are interested and trying to do something, whether it's the homeopathic way or not. It's nice to discuss it, well this is just questions, but with the doctor.*"

P4 " *It's really nice being listened to and people paying real attention to my wellbeing*"

(vii) Holistic Therapy

Another theme was appreciation of the holistic nature of homeopathy.

P9 "[the treatment has been]*very helpful , knew what to expect anyway from the HP treatment I'd had previously. I like the way it deals with the whole person, not just like getting pain killers and then getting a stomach upset from them and having to take some tablets for that, and then something else to counteract those*

side effects. I think it's because you get to look at the whole person and the remedy's tailored to the individual".

The above quote from participant 9 also highlights the frustration of this patient group with long standing pharmaceutical treatments and multiple tablets to handle symptoms and side effects of the medications treating these symptoms simultaneously.

(viii) Participants' Opinions on Receiving Treatment From a Medical Homeopath as Opposed to a Non-medically Trained Homeopath

The participants in this study were not typical of homeopathy patients, in that they had been directed to a homeopathic practitioner by their GP and in that they were receiving the treatment on the NHS. This made homeopathic treatment accessible to certain participants that would otherwise not have had the opportunity for the treatment.

P9 *" It was extremely important for me to see a medical homeopath in this way as I couldn't afford it if it was not on the NHS"*

(ix) Combined Therapy

Another quote by the same participant at a subsequent visit highlights another theme in utilising conventional medicines and homeopathy concurrently.

P9 *"I think so [importance of seeing a medical homeopath] because some of these practitioners who are purely homeopaths who haven't got the conventional medical training, they don't approve of me taking ibuprofen or whatever, when you're having a really bad day. I think that if you see a medically trained doctor who practises homeopathy, then you're able to have the two in tandem so they can work together.*

The above quote by participant 9 also illustrates the point that in some complementary medicine circles there is an attitude of objection expressed towards any kind of allopathic, or conventional, medication, primarily by non-medical practitioners. This point was also discussed in phase 2 of this report. In chronic illness it can be unrealistic to manage all symptoms with one therapy

alone and for an increased quality of life it makes sense to utilise all means available to increase manageability of symptoms .

Another theme that emerged concerning a preference for a medically trained homeopath was due to pressures felt in terms of social acceptance.

P1 *"Yes, definitely, because my husband's a doctor. People sometimes think of these alternative treatments as airy-fairy nonsense, but if its medics doing the treatments they can't say anything"*

The importance of acceptance by the sceptical medical community was clearly of particular relevance to participant 1 since her husband was a doctor. It was however, a feeling that was echoed by other participants.

Summary

In summary, the comments of participants highlighted a perceived benefit of treatment for many cases. Most patients attended with little prior knowledge of homeopathy but were happy to try it. Expectations were generally to improve manageability of their OA. NHS provision by medical doctors was considered extremely important to participants.

The quantitative results of the study are presented in section 5.6 below.

5.6 Results 2: Patient Global Assessment Results

Quantitative results obtained from the MYCAW and SF36 health questionnaires are displayed in this section.

5.6.1 MYCAW Results

Using the Measure Your Concerns and Wellbeing (MYCAW) questionnaire, participants were asked at consultation 1 what their two main concerns were with

their osteoarthritis. These concerns would be addressed at subsequent consultations. The concerns that were reported are displayed in Table 5.3

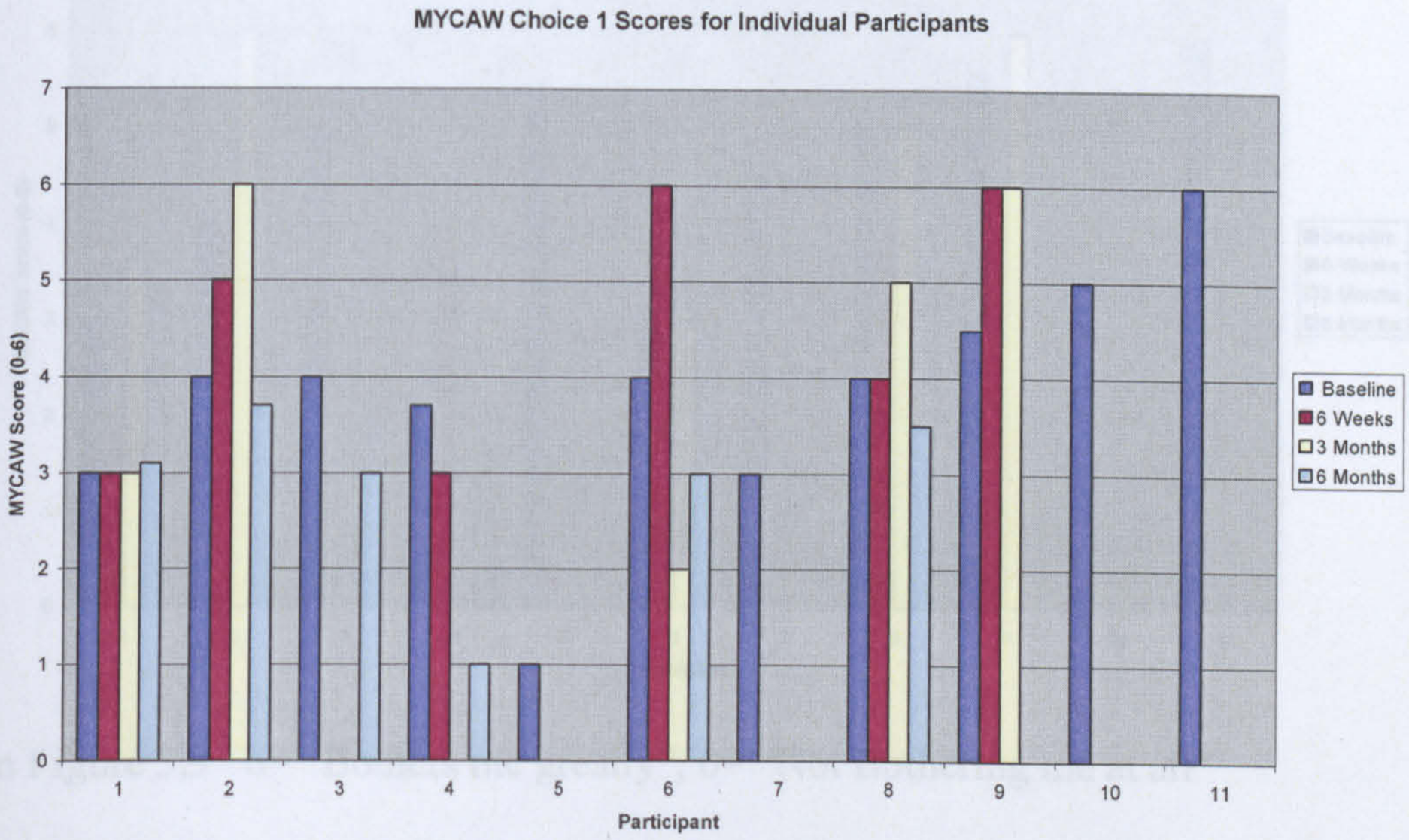
Table 5.3 – This Table shows the Two Stated Main Concerns of Participants Regarding their Osteoarthritis

Participant	MYCAW Concern 1	MYCAW Concern 2
1	Stiffness	Soreness of hands and feet
2	Stiffness in Feet	Pain in finger
3	Pain in wrist, hands and Feet	Functions Limited
4	Constant Pain in hands and knee	Frustration of limited activity and stress of relying on other people
5	Bodily Pain: back, shoulders, knees, arms	Stress of the limitation
6	Pain: Wrist, thumb and fingers	Limited grip/activity with hands
7	Pain from spine down to leg	Fear – rash developed, stress
8	Uncertainty /progression of condition	Frustration due to limitations imposed by pain/stiffness
9	Limitations with fingers – knitting/gripping lids	Stiffness when walking
10	Pain – knuckle	Fear of progression of OA
11	Joint and muscle pain in back	Pain/stiffness in Legs

The changes in MYCAW for each participant are shown in Figures 5.1. to 5.3

MYCAW Choice 1

Figure 5.2

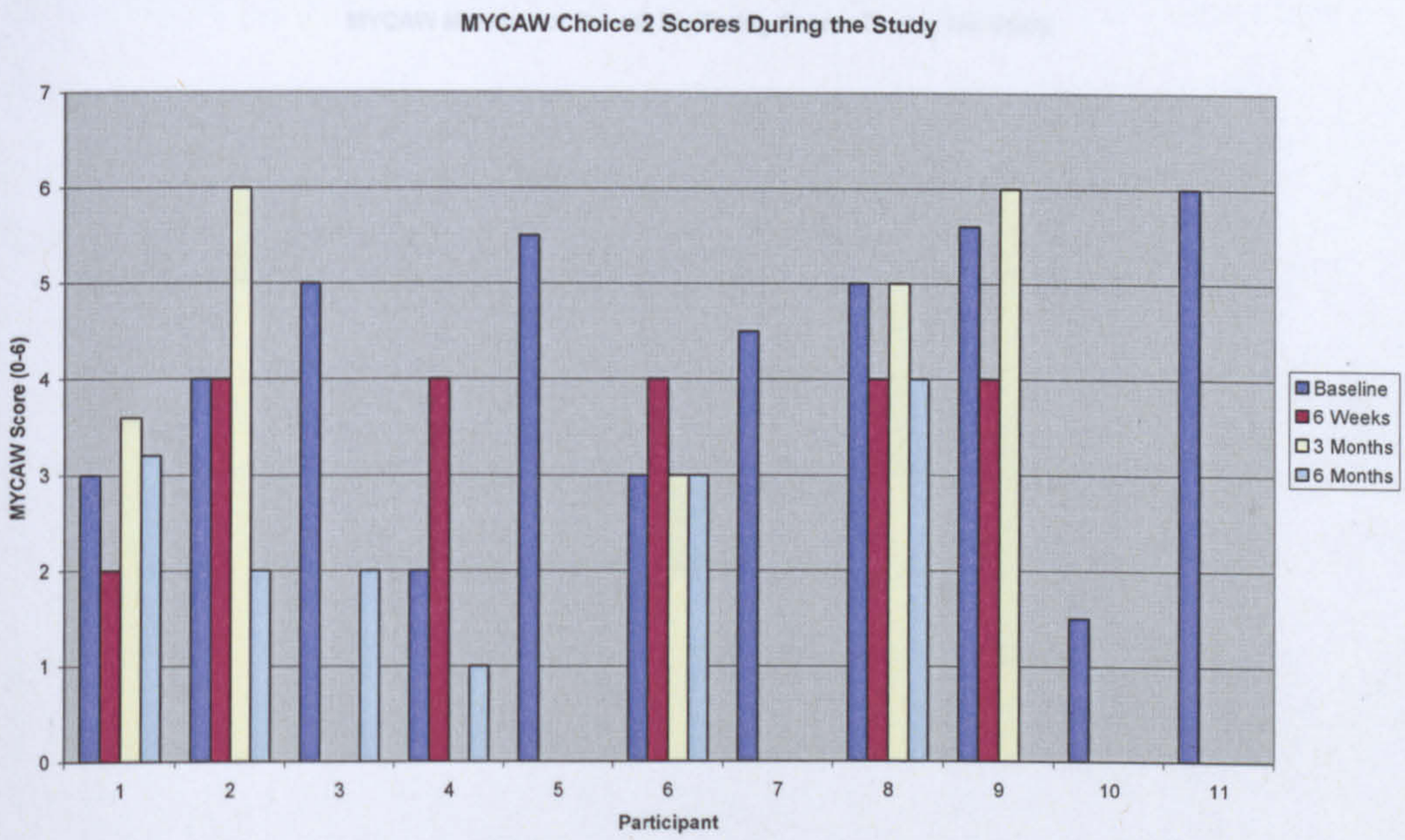


As can be seen in Figure 5.2, some of the participants were lost to follow up along the way due to self-discharge or do not attend appointments. The scale for MYCAW was 0= not bothering me at all to 6= bothers me greatly. As can be seen in figure 5.1, most participants reported a change in MYCAW choice 1 (main complaint) score in some cases indicating a decrease in the degree that the complaints were bothering them at one time point and reporting an increase at other time points. These varied results did not prove to be significant in a Friedman test (χ^2 = 1.286, p= 0.733). A significant difference was found in a Wilcoxon test on the degree that the primary complaint was bothering participants at 6months (n=6) compared to at the start of homeopathic treatment (P=0.046).

MYCAW Choice 2

Results of MYCAW 2 can be seen in Figure 5.3

Figure 5.3



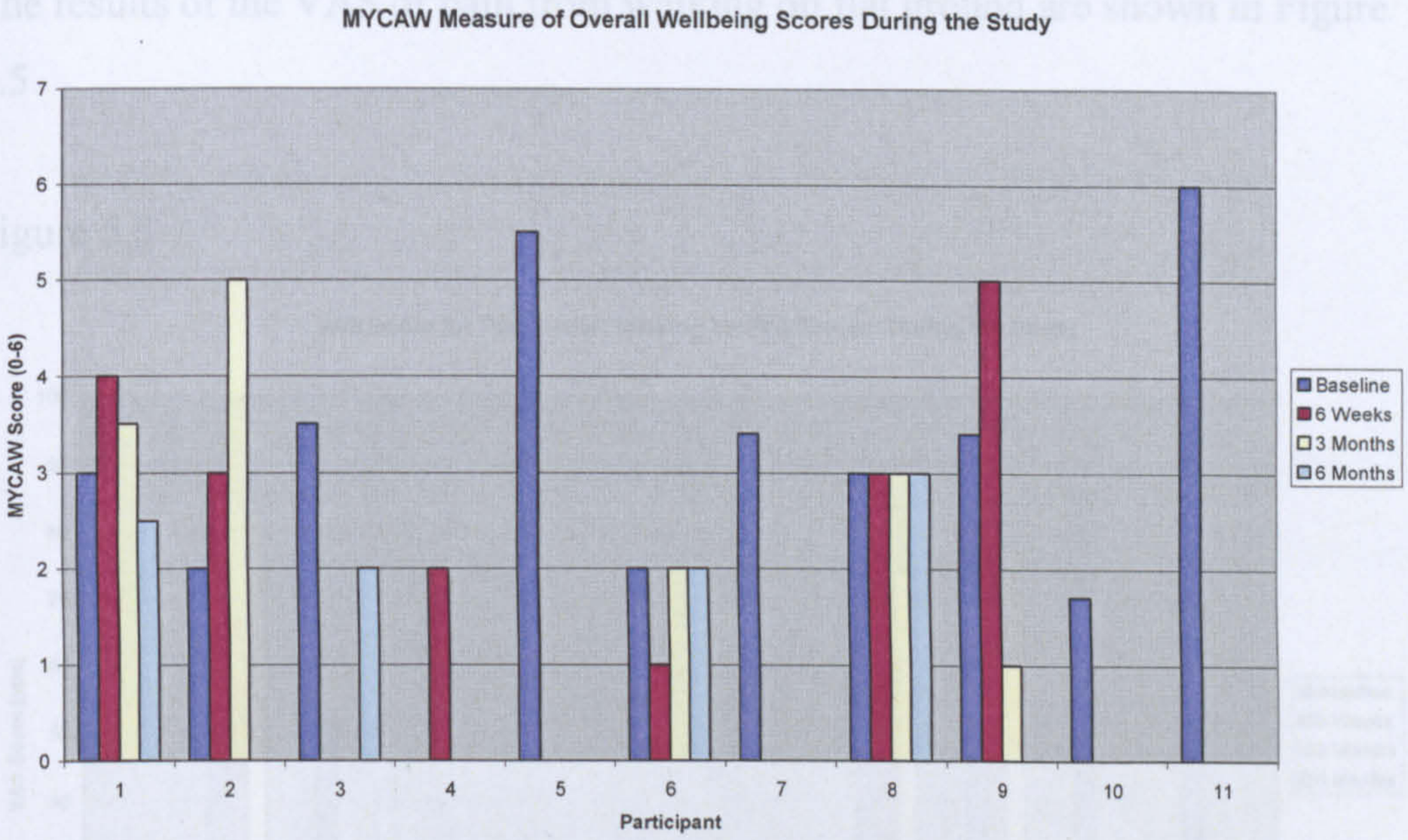
In Figure 5.3 6= "Bothers me greatly", 0= "Not Bothering me at all"

The results of the MYCAW 2 (second most pressing complaint) score were very varied with most participants expressing a high degree of bother from their second complaint at some point during homeopathic treatment in the study period, but this was not always greatest at baseline and no clear pattern in visible. No significant difference was found in a Friedman test, χ^2=3.545, p=0.315. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test (p=0.078).

MYCAW Overall Wellbeing

Participants were asked to rank their overall wellbeing on the MYCAW scale of 0-6, where 6 indicates "As bad as possible" and 0 indicates "As good as possible". The results of this are shown if Figure 5.4

Figure 5.4



In Figure 5.4 a MYCAW Score of 6 indicates "as bad as possible" and 0 indicates "As good as possible"

No clear trend can be seen in the MYCAW overall health score and in some cases the reported score did not change at all between the different time points. There was no significant difference in a Friedman test between the scores at the study time-points $\chi^2 = 3.0$, $p=0.392$. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test ($p=0.109$).

The follow up MYCAW contained a question on other factors since the last appointment that may have impacted upon the participant's health. Some participants stated factors such as holidays, key family events or extreme weather in this section.

5.6.2 Assessment of Pain

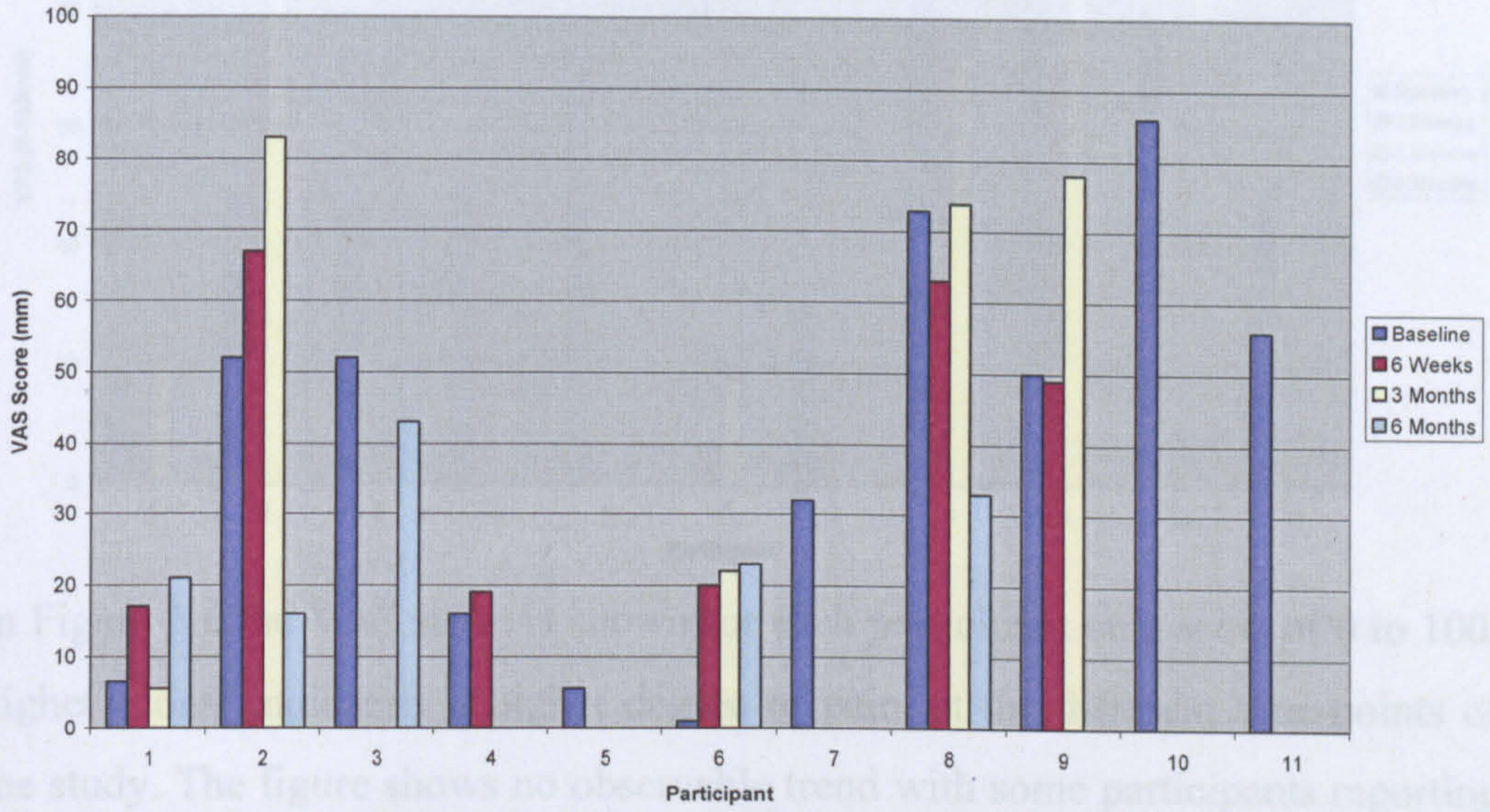
The WOMAC tool consisted of a series of Visual Analogue Scores (VAS).

Trends in the score values from the visual analogue scales that were taken from the WOMAC tool are shown in figures 5.5 to 5.10

(i) VAS of Pain From Walking on Flat Ground

The results of the VAS of pain from walking on flat ground are shown in Figure 5.5

Figure 5.5

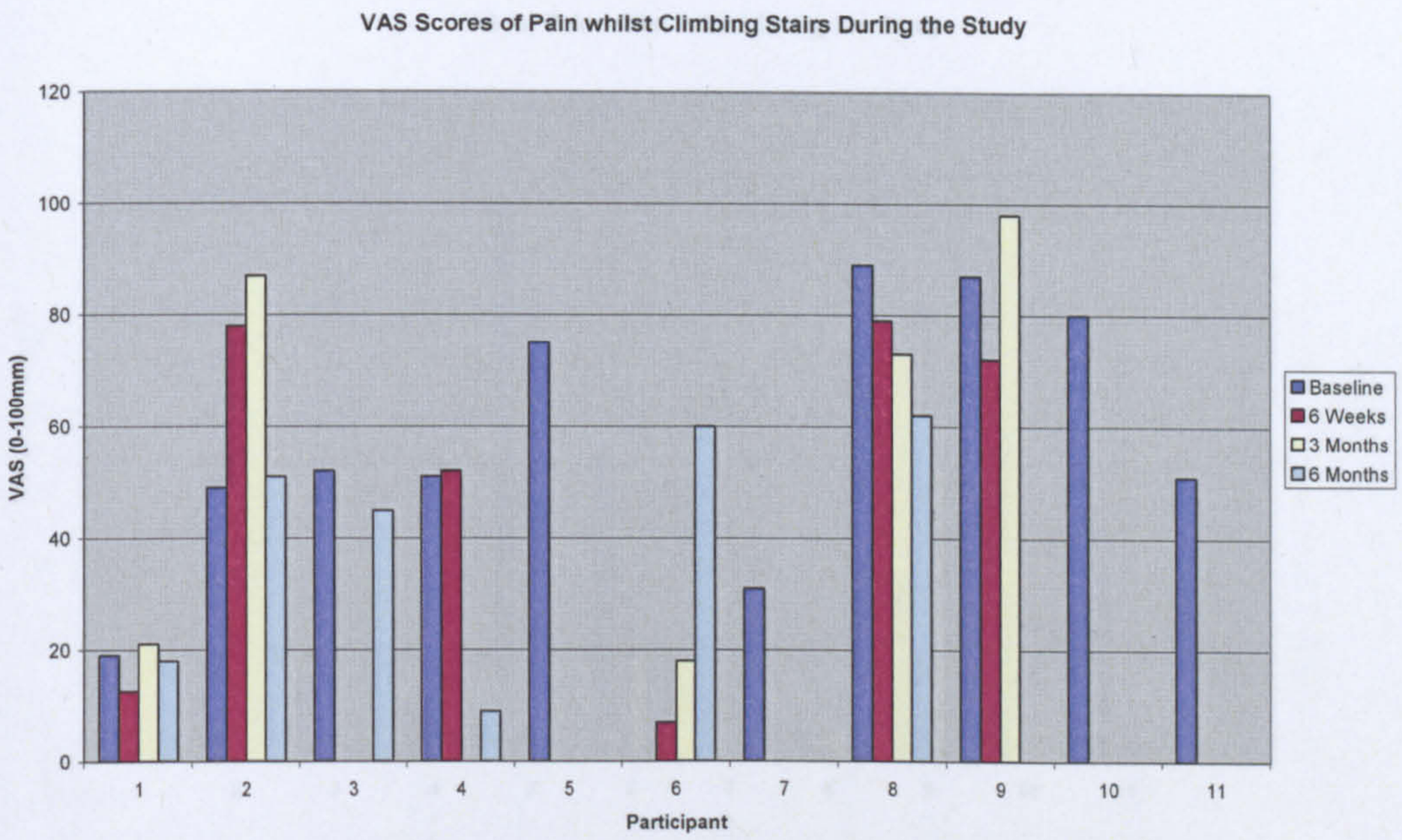


As can be seen in Figure 5.5 few clear patterns in the trends could be observed, with some participants improving at one time point and then going downhill again. No clear trend in pain when walking on flat ground is observable, and there was no significant difference in a Friedman test, $\chi^2=1.2$, $p=0.753$. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test ($p=0.345$)

5.6.2 (ii) VAS pain whilst climbing stairs

The results of VAS pain whilst climbing stairs are displayed in Figure 5.5

Figure 5.6

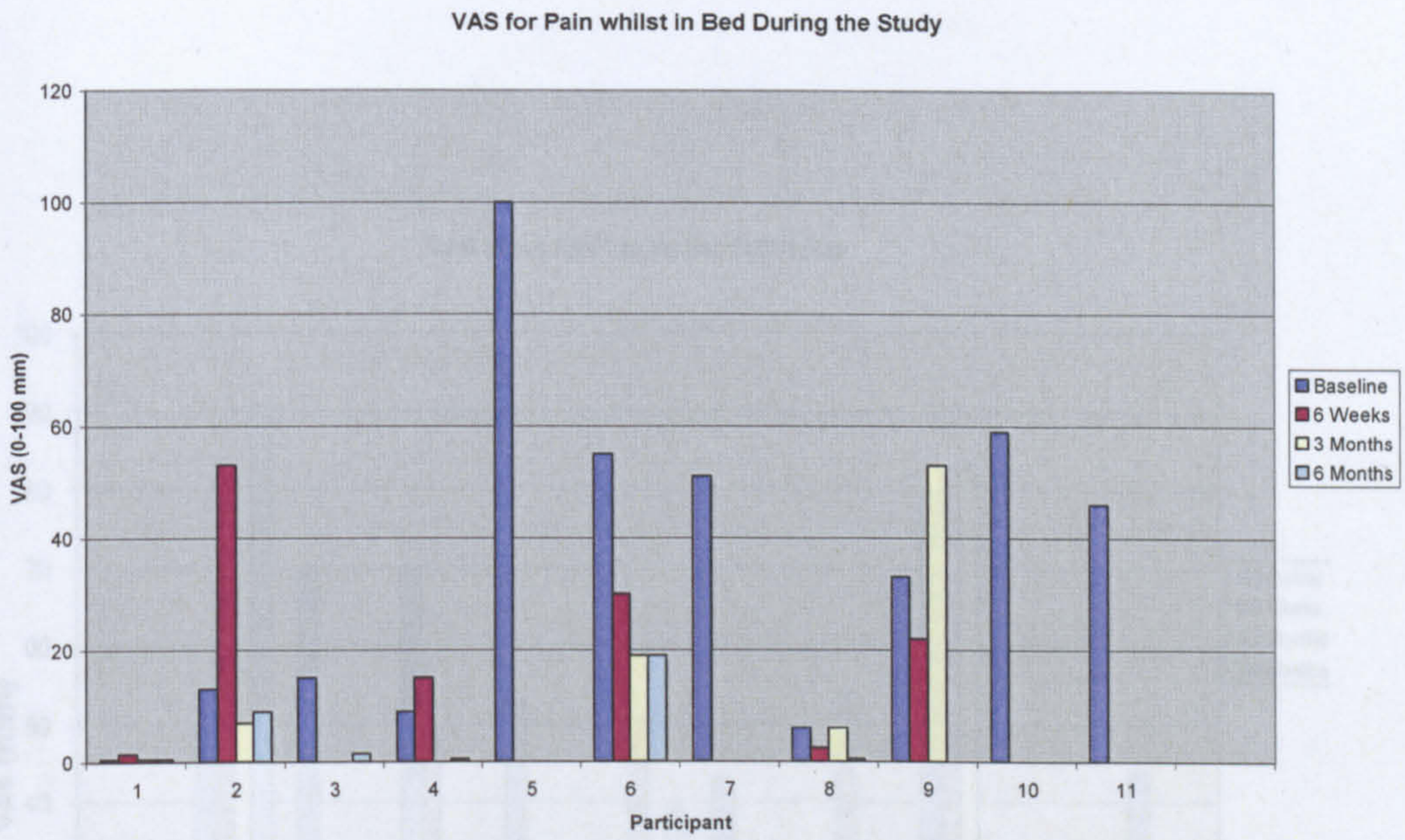


In Figure 5.6 the VAS score is shown for each participant on a scale of 0 to 100, higher scores indicating a higher degree of pain, at the different time-points of the study. The figure shows no observable trend with some participants reporting a higher score as their treatment progressed and others indicating a decreased score. The results were not significant in a Friedman test $\chi^2 = 1.8$, p=0.615. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test (p=0.601).

5.6.2 (iii) VAS Pain Whilst in Bed

Results from the participants' reported level of pain experienced whilst they were in bed , marked by hand on the 10cm VAS scale are shown in Figure 5.7

Figure 5.7



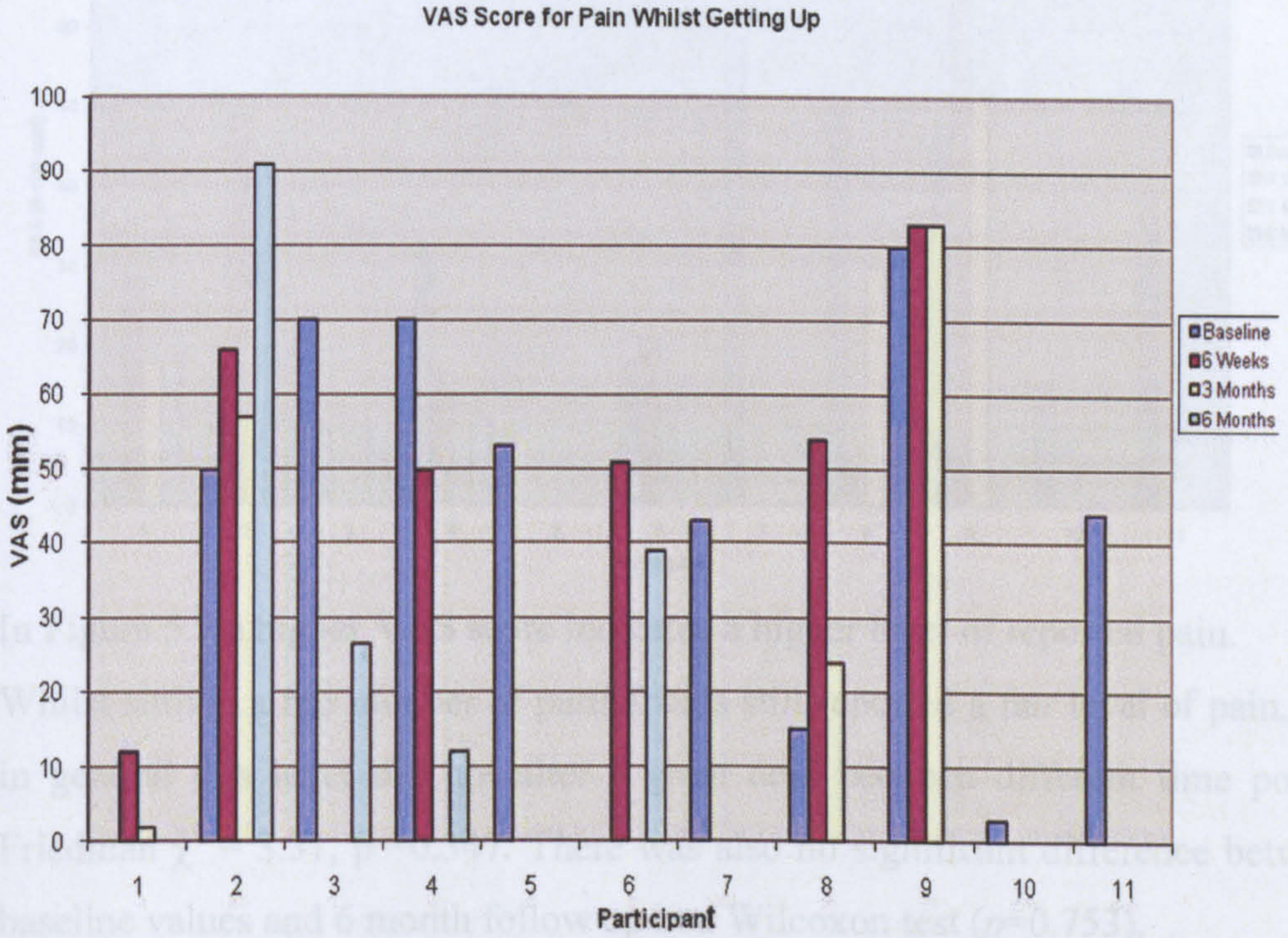
In Figure 5.7 a higher VAS score indicates a higher report of pain level.

As can be seen in Figure 5.7, about half of the participants did not feel much pain whilst in at any point in the study. Others did feel some pain but there is not enough data to identify any clear trends. The results were not found to be significantly different within the different time-points of the study in a Friedman test $\chi^2= 5.60$, $p=0.135$. There was however a significant difference between baseline values and 6 month follow up in a Wilcoxon test ($p=0.043$).

5.6.2 (iv) VAS pain when getting up

Results of VAS pain identified when getting up the study are displayed in Figure 5.8.

Figure 5.8



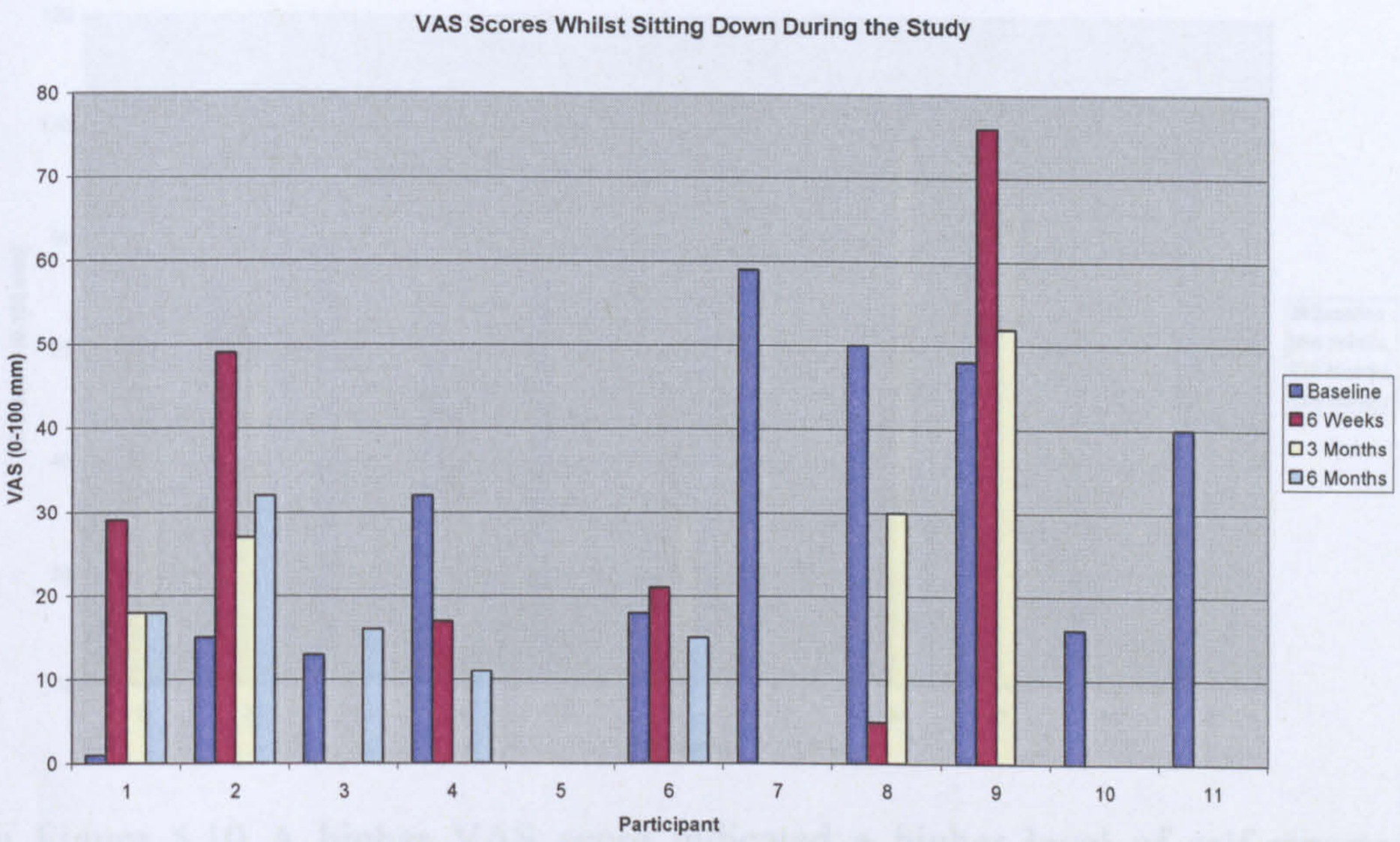
In Figure 5.8 the further up the VAS scale the participant marked their pain, the higher the level of pain they felt, so higher VAS scores indicate more severe pain whilst getting up from bed.

The data displayed in Figure 5.8 show that there is insufficient data to draw firm conclusions but also that no clearly observable pattern is present and the results were not found to be significantly different in a Friedman test between baseline and follow-up scores $\chi^2 = 6.55$, p=0.088. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test (p=0.501).

VAS Pain Whilst Sitting

Results of VAS pain whilst sitting are displayed in Figure 5.9

Figure 5.9

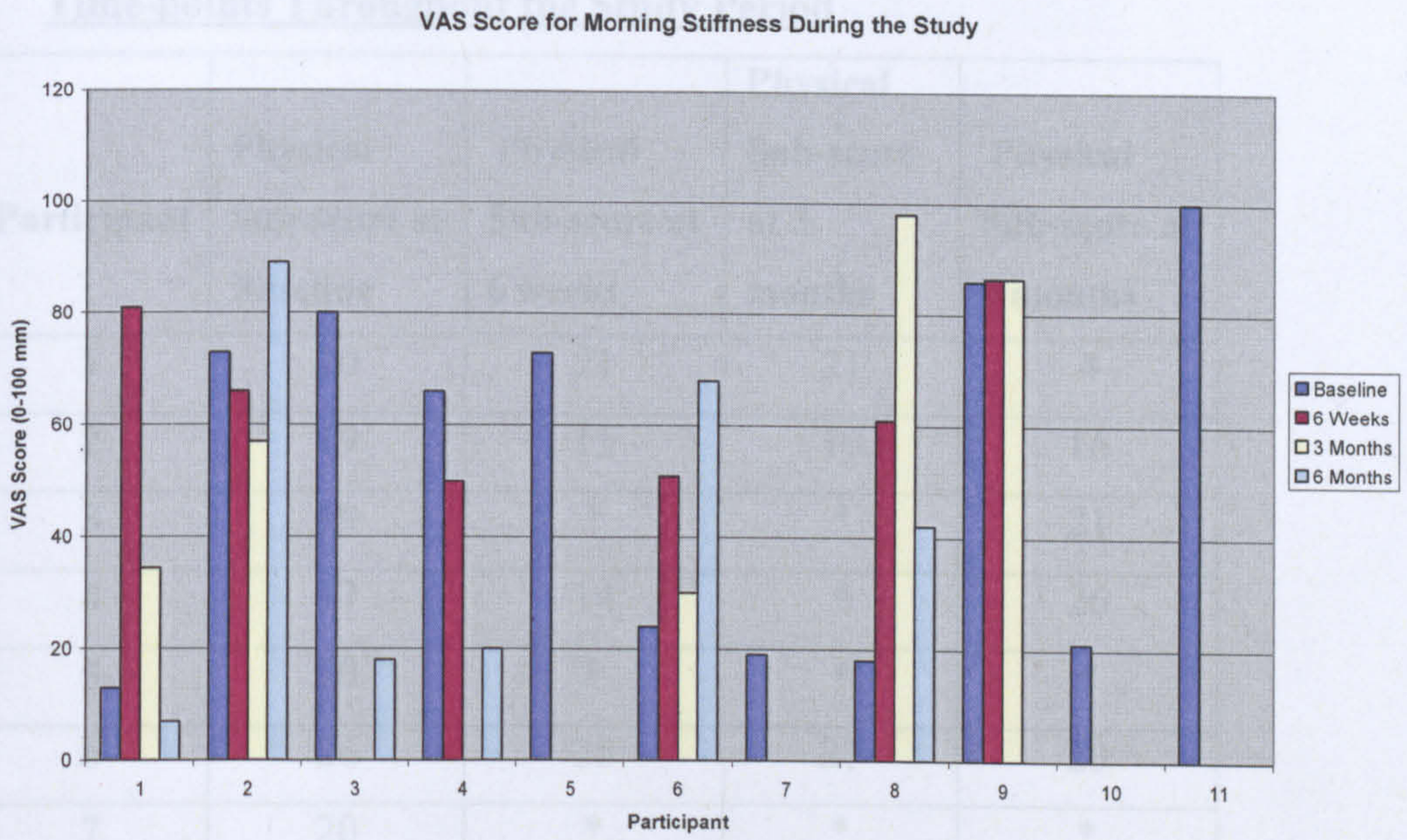


In Figure 5.9 a higher VAS score indicates a higher level of reported pain. Whilst sitting, a fair number of participants still reported a fair level of pain, and in general this level did not alter a great deal between different time points, Friedman $\chi^2 = 3.31$, p =0.347. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test (p=0.753).

5.6.2 (vi) VAS Stiffness in the Morning

Results of VAS stiffness in the morning are displayed in Figure 5.10

Figure 5.10



In Figure 5.10 A higher VAS score indicated a higher level of self-reported stiffness. As can be seen in Figure 5.10 most participants reported a large fluctuation in the degree of stiffness they felt in the morning. There was however no clear pattern into the direction of change and no significant differences were found in a Friedman test $\chi^2 = 2.1$, $p= 0.552$. There was also no significant difference between baseline values and 6 month follow up in a Wilcoxon test ($p=0.753$).

5.6.3 SF36 category results

The SF36 questionnaire has a validated scoring system that allows certain aspects of health to be looked at separately. These include mental and physical aspects and the scores are shown in tables 5.4 to 5.12 below. In each table the subcomponent headings are listed 1 to 4, 1 being baseline, 2 is the 6 week time point, 3 is the 12 week time point and 4 is the 6 month follow up. Where an asterisk is marked in the table, the data for that patient at that time point was not available, due to unattended appointments.

Table 5.4 – Results of the SF36 Physical Sub-score for Participants at Time-points Throughout the Study Period

Participant	Physical Sub-score at Baseline	Physical Sub-score at 6 weeks	Physical Sub-score at 3 months	Physical Sub-score at 6 months
1	20	21	21	4
2	19	15	16	16
3	19	*	*	21
4	17	14	*	26
5	10	*	*	*
6	26	25	27	23
7	20	*	*	*
8	20	21	17	22
9	14	15	14	*
10	18	24	*	*
11	18	*	*	*

*Denotes unavailable data

Results of the physical subcomponent of the SF36 questionnaire score are shown in Table 5.4 above. The score was calculated for each patient at the four time points. A higher score indicates less limitations physically than a lower score which indicates a large degree of limitation. Physical results between baseline and 6 months were not significant in a Friedman test $\chi^2 = 0.711, p = 0.871$

Table 5.5 – Results of the SF36 Physical Limitations Sub-score for Participants at Time-points throughout the Study Period

Participant	Physical Limitations at baseline	Physical Limitations oat 6 weeks	Physical Limitations at 3 months	Physical Limitations at 6 months
1	0	3	4	2
2	0	1	0	1
3	2	*	*	0
4	3	2	*	4
5	0	*	*	*
6	4	4	4	4
7	2	*	*	*
8	0	2	2	3
9	3	0	0	*
10	0	0	*	*
11	0	*	*	*
*Denotes unavailable data				

Limitations with work and other daily activities are displayed in Table 5.5. A lower score indicates a higher level of limitation, whereas a higher score is indicative of little or no problems. The results between time points were not found to be significant in a Friedman test $\chi^2 = 5.00$, p=0.172

Table 5.6– Results of the SF36 Emotional Limitations Sub-score for Participants at Time-points throughout the Study Period

Participant	Emotional Limitations at baseline	Emotional Limitations at 6 weeks	Emotional Limitations at 3 months	Emotional Limitations at 6 months
1	0	3	3	3
2	1	1	2	1
3	0	*	*	3
4	2	3	*	3
5	0	*	*	*
6	*	3	3	3
7	2	*	*	*
8	0	1	1	2
9	1	0	0	*
10	3	2	2	*
11	0	*	*	*

*Denotes unavailable data

Moving away from physical factors, Table 5.6 shows the SF36 emotional limitation subcomponent scores at the different time points for the study. A lower number indicates a higher degree of limitation due to emotional problems. These results were not found to be significant in a Friedman Test, χ^2= 5.29, p= 0.152. They were however found to be significant between baseline and 3 months in a Wilcoxen test p=0.037, with a lesser degree of limitations described by patients due to emotional problems, although this can only be used as an indication of the trend due to the possibility of type 2 errors.

Table 5.7 – Results of the SF36 Social Sub-score for Participants at Time-points throughout the Study Period

Participant	Social Sub-score at Baseline	Social Sub-score at 6 Weeks	Social Sub-score at 3 Months	Social Sub-score at 6 Months
1	8	10	11	9
2	8	9	6	4
3	6	*	*	5
4	11	6	*	11
5	3	*	*	*
6	11	11	11	10
7	6	*	*	*
8	6	10	7	10
9	5	5	9	*
10	8	10	*	*
11	2	*	*	*

*Denotes unavailable data

Table 5.7 shows the results of the SF36 social subcomponent scores for the participants at each time point. A lower score indicates a higher degree of interference in a patient's social life due to their physical and emotional health. The results were not found to be significant in a Friedman test $\chi^2 = 4.03$, $p=0.258$.

Table 5.8 – Results of the SF36 Mental Sub-score for Participants at Time-points throughout the Study Period

Participant	Mental Sub-score at Baseline	Mental Sub-score at 6 Weeks	Mental Sub-score at 3 Months	Mental Sub-score at 6 Months
1	20	23	20	26
2	15	26	18	15
3	22	*	*	27
4	28	27	*	29
5	20	24	*	*
6	24	24	21	24
7	11	*	*	*
8	24	24	24	23
9	21	20	15	*
10	24	23	*	*
11	*	*	*	*

*Denotes unavailable data

Table 5.8 shows the SF36 mental subcomponent scores for participants at the different time points of the study. A lower score is indicative of a highly reported feeling of nervousness and depression all of the time, whereas a higher score indicates a feeling of calm, peacefulness and happiness all of the time. These results were found not to be significant in a Friedman test $\chi^2 = 2.5$, $p=0.475$.

Table 5.9 – Results of the SF36 Vital Energy Sub-score for Participants at Time-points throughout the Study Period

Participant	Vital Energy Sub-score at Baseline	Vital energy Sub-score at 6 Weeks	Vital Energy Sub-score at 3 Months	Vital Energy Sub-score at 6 Months
1	11	15	12	14
2	14	20	13	13
3	10	*	*	12
4	20	15	*	16
5	12	*	*	*
6	15	16	16	16
7	12	*	*	*
8	11	14	12	15
9	14	14	9	*
10	18	15	*	*
11	*	*	*	*

*Denotes unavailable data

Table 5.9 shows the results of the SF36 vitality subcomponent scores for participants at different time points. A higher score indicates a greater feeling of being full of energy all the time. These results were found to be non-significant in a Friedman test $\chi^2 = 6.257$, $p=0.1$

Table 5.10 - Results of the SF36 Pain sub-score for each participant at different time points

Participant	Pain Sub-score at Baseline	Pain Sub-score at 6 Weeks	Pain Sub-score at 3 Months	Pain Sub-score at 6 Months
1	5	3	3	3
2	5	4	7	6
3	5	*	*	4
4	4	3	*	1
5	8	*	*	*
6	4	2	1	3
7	5	*	*	*
8	7	5	6	4
9	7	7	7	*
10	9	4	*	*
11	9	*	*	*

*Denotes unavailable data

The results shown in Table 5.10 show the degree of pain participants reported at different time points, a lower score indicates more severe pain. It can be seen that there is a degree of variance in the pain scores at different time points for the participants who attended follow-up, and differences were not found to be significant in a Friedman test, $\chi^2=2.15$ $p=0.542$.

Table 5.11 – Results of the SF36 Health Perception Sub-score for Participants at Time-points throughout the Study Period

Participant	Health Perception Sub-score at Baseline	Health Perception Sub-score at 6 Weeks	Health Perception Sub-score at 3 Months	Health Perception Sub-score at 6 Months
1	15	17	17	16
2	14	17	17	15
3	21	*	*	16
4	15	12	*	12
5	16	*	*	*
6	16	15	15	16
7	18	*	*	*
8	14	15	14	15
9	15	15	18	*
10	12	16	*	*
11	15	*	*	*

*Denotes unavailable data

Table 5.11 shows the results of general health perceptions of participants at different time points. A higher number indicates a more positive health perception. These results were found to be significant in a Friedman test χ^2= 9.8, p=0.023. Wilcoxon tests were performed between the different time points to identify where the difference was placed and significant results were seen between baseline and 6 weeks (p=0.028) and at 3 months (p=0.007) but fell just short of significant between baseline and 6 months (p=0.059).

Table 5.12 – Results of the SF36 Overall Change in Health Sub-score for Participants at Time-points throughout the Study Period

Participant	Health Perception Sub-score at Baseline	Health Perception Sub-score at 6 Weeks	Health Perception Sub-score at 3 Months	Health Perception Sub-score at 6 Months
1	4	4	2	2
2	4	2	4	3
3	3	*	*	1
4	3	3	*	1
5	4	*	*	*
6	3	3	3	3
7	4	*	*	*
8	4	4	3	2
9	4	4	4	*
10	3	4	2	*
11	4	*	4	*

*Denotes unavailable data

Results of overall change in health from the SF 36 are shown in Table 5.12. This sub-component was based on just one question, in which participants marked where their health was at each time point, compared to 1 year ago.
No significant difference was found in a Friedman test $\chi^2 = 4.269$, $p=0.234$.

With such a small sample size the results would have to have been very strong to derive significant results in a Friedman test. This is a non-parametric test that was used here due to the small sample sizes, making it more suitable than using ANOVA in order to avoid type 2 errors. However, from looking at the tables and the high p values it can be seen that in some cases there was not much of a pattern or direction of change seen at all.
There were no significant results except interference with social life, which was worse after 6 months of treatment than at baseline.

Summary

As can be seen in section 5.6 that there were very few clinically significant results identified using the patient global assessment scores. The findings listed below are highlighted as they can reflect an improvement in patient well-being.

- The MYCAW primary complaint was reported as significantly better at 6 months compared to baseline (p=0.046). This tool requires a move to the next clinical category.
- The VAS of pain whilst in bed was significantly lower at 3 months compared to baseline (p=0043).
- The SF36 health perception sub-score was significantly improved between baseline and 6 weeks (p=0.028) and baseline and three months (p=0.07). This tool requires a move to the next clinical category.

Clearly the issues is whether these small changes do in fact reflect clinical significance. The small sample sizes involved also make it impossible to draw firm conclusions from these significant findings due to the possibility of type 2 errors, however they do warrant further investigation. It is a consideration that the statistical impact of some results could possibly have been diminished due to an increased degree of rapport between the participant and researcher during interviews further down the 6 month study period, allowing the participant to be more open about sensitive issues.

5.7.0 Results 3: Changes in medication used

The usage of painkillers and non-steroidal anti-inflammatory drugs for each participant is displayed in Table 5.13. As can be seen there was some variation and a decrease in these medications for some participants were observed. Others however did not use significant amounts of medications anyway due to worry about side effects. This may explain why these individuals turned to homeopathy in the first place.

Table 5.13 – Change in Medication

Participant	Medication at Baseline	Medication Change
1	Codrydamol 4 times a week, ibuprofen gel 4 days per week	Codrydamol twice a fortnight, Ibruprofen gel stopped (at 6 Months)
2	Paracetamol 3 times per week	Paracetamol twice a fortnight (at 6 Months)
3	Paracetamol 3 x daily,	Paracetamol once a day 5 times a week (at 6 Months)
4	Chodrydamol daily, paracetamol 3 days a week 3	No Change
5	Codrydamol 3 times per week	N/A Patient moved to another centre
6	Ibroprofen gel 5 times a week, paracetamol	Paracetamol once a fortnight (at Week 6)
7	Occasional codrydamol,,1 a fortnight, paracetamol 3 days per week	N/A (unable to follow up, patient self-discharged)
8	Pyroxicam Gel, 8 days per month, codrydamol twice per week	No piroxicam gel, codrydamol twice a month (6 months)
9	Parcetamol if needed, less than once per week	No change (three months)
10	Codrydomol approximately twice per week	Codrydamol approximately three times per week (at three months)
11	Codrydamol daily, piroxicam gel daily	N/A, non-attendance at follow-ups

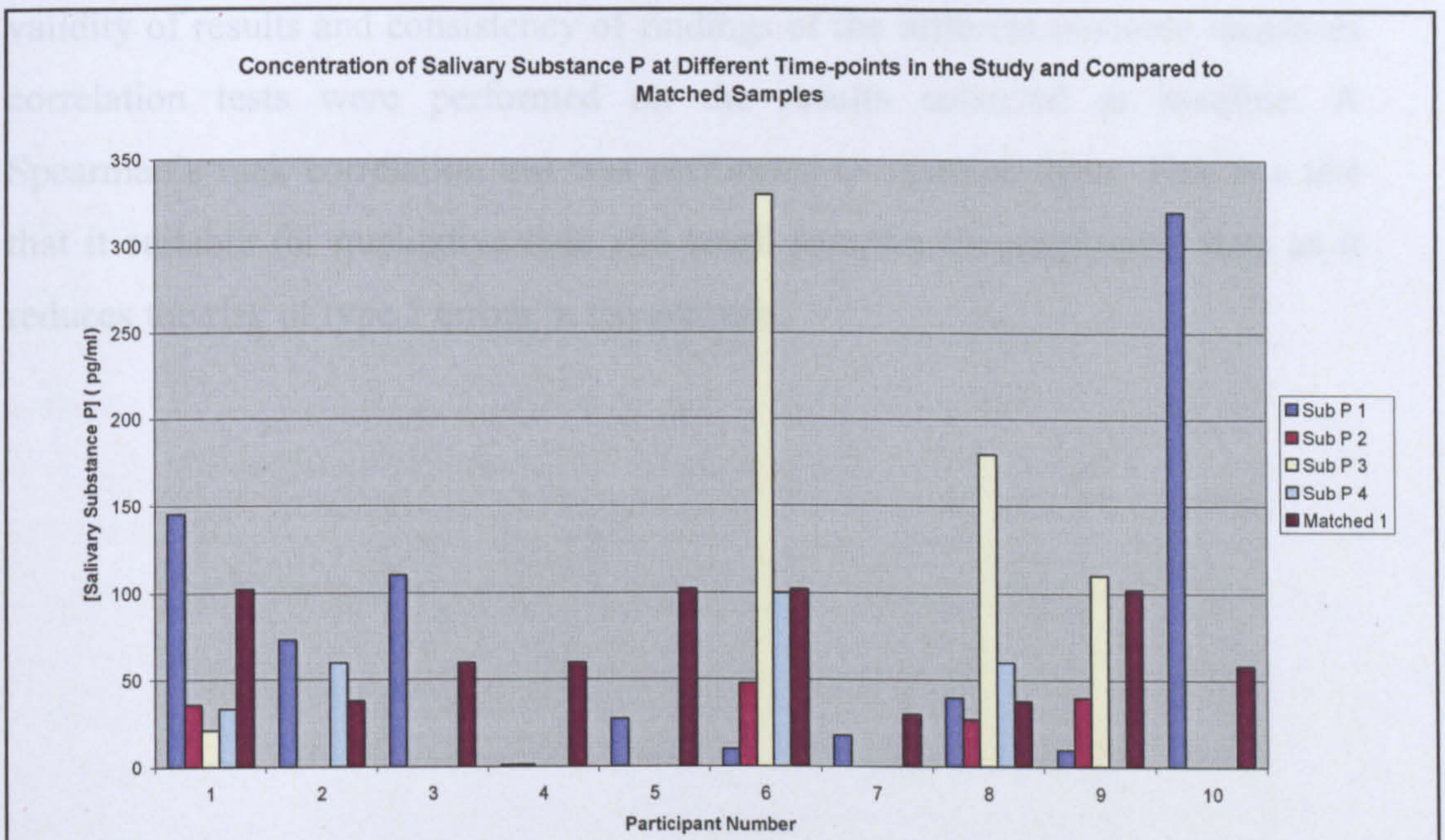
5.7.1 Substance P Saliva Assay

The results of the salivary concentrations of substance P tests are shown Figure 5.11 below, together with the calculations. The bottom row shows the value of Substance P. As can be seen in the tables, most patients had at least one substance P value that was very high and the time point that this occurred varied. OA is notorious for flare ups in various conditions. These showed to be in the range published and were supported by the matched samples. There were no

significant changes, each participant had one time point when the substance P level was elevated and this seemed to vary with no obvious pattern.

The results of substance p concentrations were not found to be significant in a Friedman test, χ^2 =1.00, p=0.801.

Figure 5.11



In Figure 5.11 Sub P 1= Baseline Substance P concentration, Sub P2= Salivary substance P concentration at 6 week Follow-up Sub P 3= Substance P concentration at 3 month follow up, Sub P 4= Substance P concentration at 6 month follow up, Matched 1 = Substance P concentration in matched sample.

Matched Samples

Matched samples of substance P were taken from healthy working people matched in age and gender to each individual in the study, without existing musculo-sketetal problems. These are displayed in Figure 2 alongside the test sample they were matched to. The matched samples showed a range of values that showed no particular correlation with age.

When comparing the substance P results to the matched samples, in some cases the levels were similar to the upper-most value from the matched participant in the trial. There was no significant difference in a paired T-Test between matched

and baseline samples, p= 0.792 due to the high degree of variance, with the baseline participant Substance P levels having a standard deviation of 98 and the matched samples having a standard deviation of 30.

5.8 Results 4: Correlations between outcomes

Several outcome measures focused on different aspects of pain. In addition, some of the outcome measures relate to aspects of functioning. In order to test the validity of results and consistency of findings of the different outcome measures correlation tests were performed on the results collected at baseline. A Spearman's rank correlation test was performed to examine these. This is a test that it suitable for qualitative data and small samples of quantitative data as it reduces the risk of type 2 errors in the analysis.

Table 5.14 Correlations Between Outcomes Measured

Variables	Sample n	r_s	*P* value
MYCAW Choice 1 and VAS score of pain on flat ground	11	0.692	0.018
VAS pain up hill and SF36 physical function sub-score	11	-0.729	0.011
VAS morning stiffness and VAS pain walking up stairs	11	0.732	0.012
VAS morning stiffness and SF36 physical function sub-score	11	-0.617	0.043
MYCAW choice 2 and morning stiffness	11	0.618	0.43
VAS pain climbing stairs and SF36 pain sub-score	11	0.631	0.036
Salivary Substance P and SF36 physical limitation	10	-0.767	0.010
MYCAW overall wellbeing and MYCAW choice 2	11	0.890	0.001
MYCAW overall wellbeing and SF36 sub-score of emotional limitation	11	-0.64	0.045
MYCAW overall wellbeing and social functioning	11	-91	0.001
MYCAW overall wellbeing and SF36 SF36 vitality sub-score	11	-74	0.01

The significant results from the Spearman's correlations tests are shown in Table 5.14 (See appendix 22 for a full list). A significant positive correlation was seen between MYCAW choice 1 at VAS score of pain walking on flat ground , with a correlation coefficient of 0.692, p=0.018. Table 5.2 shows that in the vast majority of cases MYCAW choice 1 related to pain. The MYCAW score 1 was not correlated with any of the other VAS pain scores contained in the WOMAC tool. The score marked on the different VAS for pain whilst performing different

activities (as contained in the WOMAC tool) showed no significant correlation with each other. A correlation was seen between pain when walking on flat ground and pain climbing stairs, with a correlation coefficient of 0.594, but this was not found to be significant (p=0.054)

The VAS score of pain felt whilst walking up hill was negatively correlated with the SF36 sub-score of physical function with a correlation coefficient of -0.729, p=0.011, showing that increased pain felt when climbing stairs was strongly correlated to decreased physical functioning.

The WOMAC VAS score of stiffness in the morning was positively correlated to VAS score of pain whilst walking up stairs with a correlation coefficient of 0.723, p=0.012, and negatively correlated to SF36 physical functioning sub-score with a correlation coefficient of -0.613, p=0.043).

The VAS score of pain whilst climbing stairs was positively correlated with the SF36 sub-score of pain, with a correlation coefficient of 0.063, p=0.036.

Salivary concentration of Substance P showed a strong negative correlation with SF36 physical limitation sub-score with a correlation coefficient of -0.767, p=0.01. This showed that the more limited the physical function, the higher the concentration of salivary substance P at baseline. No other significant correlations were found between the physical functioning sub-score or salivary substance P concentration with any of the other factors.

The MYCAW score of overall wellbeing correlated with the value of MYCAW choice 2, with a correlation coefficient of 0.890, p=0.001, in addition to some of the SF36 sub-scores. These were a negative correlation with the SF36 sub-score of limitations due to emotional factors, correlation coefficient -0.64, p=0.045, a strong negative correlation with the SF36 sub-score of social functioning, correlation coefficient of -0.91, p=0.001, and SF36 sub-score of vitality with a correlation coefficient of -0.74, p=0.01.

5.9 Discussion

The results of the current study highlight some interesting points regarding homeopathic treatment for osteoarthritis, patient perceptions of receiving homeopathy in the NHS and management of osteoarthritis in general. The sample size of the study was small, but the results highlight matters that would still be apparent with a larger number of participants, many of which are relevant to studies looking at effectiveness.

5.9.1 Collective view of the outcomes of the study

As can be seen from the qualitative data, some perceived benefits of homeopathic treatment were apparent from the data derived via open ended questions (see section 5.5.2). These improvements were not generally reflected in the results from the outcome questionnaires used in the study, and may have been largely missed if the study had not contained qualitative aspects, reduction in medication for some participants being perhaps the next best indicator that they had benefitted from treatment. In addition, certain other matters such as lack of compliance, may not have been identified had these aspects not included. It is possible that the SF36, MYCAW and WOMAC tools were not sensitive to such changes as those reported in the qualitative results.

The outcome tools generated a mix of parametric and non-parametric data, but a non-parametric significance test was used for all variables due to the small sample sizes, to reduce the incidence of type 2 errors. Friedman tests comparing each SF36 data sub-score item generated only one significant result, the SF36 general health perception sub-score showed a significant improvement from treatment ($p=0.023$). The only other significant result was a Wicoxon test of emotional limitations SF36 sub-score between baseline and 3 months ($p=0.037$). The sensitivity of tools such as the SF36 in measuring change for certain studies is a subject which has been scrutinised in other studies (Smith et al, 2000) (Dempster & Donnelly, 2000) (Jenkinson et al, 1995). It may be that the use of the SF36 during an interview with the researcher aiding the participant to fill it in is not a suitable method, due to the increased rapport between them at subsequent

visits, allowing participants to be more open with the researcher regarding the problems they are having and their emotional health.

No significant results were found in Friedman tests on the WOMAC or MYCAW scores. Outcome values at baseline and following 6 months of treatment were also compared for WOMAC and MYCAW using a Wilcoxon test and this yielded significant values between MYCAW symptom 1 at baseline and at 6 months (p=0.046) and VAS pain whilst in bed (p=0.043) but no other items . The VAS results could be dependent on the mood and the pain that the patients were feeling during the consultation, and may have been influenced by their mode of transport to the clinic. The MYCAW results however, may have involved more careful thought, as they were addressing their own identified problems which in some cases involved pain. It was interesting that participants in follow-up consultations were sometimes surprised by their choices of their most pressing complaints with their condition, and yet still generally placed a high score on the degree that the complaint was currently bothering them. The MYCAW score range is 0-6 and perhaps this small scale makes it harder for changes to be identified.

Sample sizes were low and a very strong pattern would have been necessary to achieve significant results. However, from small sample sizes one can get an indication. Few patterns were seen at all at the different time points in the current study, suggesting that even with bigger samples sizes than in the current study, many more significant results would still have not been yielded.

In the current study there was some overlap in what the various tools were assessing, and in some cases, for example level of pain, poor correlation was seen between the results of the different tools measuring pain and indeed on pain medications used. This may be a result of the multi dimensional nature of pain and the different outcome tools measuring different aspects of the experience of pain. Therefore this may indicate that pain is best viewed in terms of the biopsychosocial model.

If improved manageability of symptoms occurs due to biopsychosocial effects, there is a problem as to how these can be measured. Different patient groups are subject to different biopsychosocial influences, and therefore require different approaches to identify the impact of these. In schoolchildren factors like educational performance and engaging in activities have been measured in studies, but it would be difficult to measure similar types of improvement in adults. This becomes a more complicated issue in an older patient group due to the complexity of factors involved. Outcome measures are perhaps the second largest barrier to advances in homeopathy research, after lack of funding for this research. This is highlighted by the fact that the phase 2 results of the current study indicated that homeopaths do not actually use outcome tools at all in their follow-up appointments, and rely on their own feelings and those of the patients to determine success.

The implications of this issue on future research and trial models need to be considered if homeopathy is to be fairly tested. Appropriate outcome tools would need to be designed. It has been commented that the randomised controlled trial (RCT) method, designed specifically for testing an active drug against a blank tablet is not suitable for complex interventions such as homeopathy (Weatherly-Jones, 2004) (Milgrom, 2005). Pragmatic studies comparing two different treatments and also qualitative research and / or mixed methods studies may prove to be more useful in clinical studies of homeopathy.

5.9.2 The Use of a Biochemical Correlate of Pain as an Outcome Measure

The use of markers of pain in OA and the use of salivary Substance P is a new direction in this field of research. This new dimension offers a potential to enhance studies on health interventions, which have been so far reliant on subjective pain measurements, the problems associated with which are discussed in section 5.9.1 above. There are few studies that address the use of salivary Substance P measurement and very limited literature on the assay technique generally. This makes it difficult to analyse results of the assay in the current study. No consensus on normal ranges for salivary Substance P levels has been published. In addition, there is no clear evidence to recommend the correct handling of saliva samples prior to the conduction of the assay. Suryssawadi

(1998) showed substance P level changed immediately after 10 minute massage, suggesting that Substance P assay results readings only give a snap shot of the Substance P level present in saliva. In the study there was no suggestion of the long term effects that certain actions or therapies may have on salivary substance P, or indeed the degree of fluctuation in levels over a day or given period of time. If the level of salivary substance P can change so quickly, it cannot be ruled out that patients' walk to the surgery may have altered the level. Some patients may have taken different forms of transport to one appointment than to others and this may have affected the results obtained in the current study.

Substance P levels were found to have a strong negative correlation ($p=0.001$) with physical limitation sub-score from the SF36, suggesting that the higher the degree of limitation to physical function the higher the concentration of salivary Substance P. There was no significant correlation found between Substance P concentration and any of the tools to measure severity of pain. Different pain measures did not even show correlations between each other. The results of the current study suggest that the indicated relationship between physical limitation and salivary Substance P concentration would be an interesting area for future studies to investigate. This may lead to the inclusion of this novel technique as an effective outcome for future trials of OA treatments.

5.9.3 Issues in Treating Osteoarthritis

OA is clearly a difficult condition to treat, regardless of the treatment approach. Conventional medications that are routinely used appear to offer little relief (Fisher et al, 2004). Results of former stages of the study (phase 1 section 3.8.2 & phase 2 section 4.4.7) indicated that OA is a condition that many homeopaths find particularly hard to treat. The age of the patient group itself increases the chances of co-morbidities, and perhaps lower "vital energy". In addition, with GPs most likely to be referring solely patients who they had utmost difficulty with on manageability of symptoms, this further enhanced the complications and difficulties of this patient group. The characteristic seasonal fluctuations in symptom severity (McAlindon, 2007) are also a factor that make the task of evaluating change due to treatment intervention very difficult.

Presence of multiple pathologies was also a consideration during treatment. As OA is a difficult problem to treat, it is possible that there is often a temptation to clear other things up first. Also, this may be a difference for medical/non-medical practitioners, as medical practitioners may be more likely to see different illnesses/symptoms separately. Treating a different condition to the one a patient sought treatment for, or was referred for, may in itself raise concerns regarding the treatment, in particular with regards to patient choice and the recent public health drives to empower patients regarding their health, lifestyle choices and health management (Department of Health, 2004). In addition, a diverted course of treatment may be something that deters GPs and other health professionals from referring their patients to a homeopath.

As musculo-skeletal condition sufferers are a patient group who reported lowest levels of satisfaction from use of conventional medicine (Fisher et al, 2004) it is clear that there is a need for more effective treatment strategies for OA patients. The evidence base for CAM therapies and novel techniques in treating OA therefore needs to be developed, in order for guidelines to be produced on the use of those which are found to be effective. This is a process that has already begun for some conditions, for example the recent inclusion of acupuncture as a treatment in the National Institute for Health and Clinical Excellence guidelines for low back pain (Savigny et al, 2009).

With respect to homeopathic treatment, results of the current study highlighted the fact that compliance was sometimes a factor that had an adverse effect on treatment. In particular, misunderstandings regarding the instructions given on taking homeopathic remedies occurred and this was not identified until the follow up appointment 6 weeks later. Methods of delivering and taking homeopathic medications differ, (see section 4.4.5) and may involve some considerations that are not relevant to conventional medicines, for example storage conditions. This can therefore be confusing for patients, especially those who are first time users. Guidelines on the use of homeopathy for OA would therefore offer practitioners support on effective remedy delivery, including how to tackle the issue of compliance. This may involve telephone follow-ups, a

method routinely used by some homeopathic practitioners (see section 3.8.1) or instruction leaflets to accompany the remedy.

5.9.3Patient Access to Homeopathy

The current study involved an atypical CAM user group, which makes for an interesting perspective. CAM use is most common with men and women who are middle class and between the ages of 25-45 (McDonough et al, 2007; Thomas & Coleman, 2004). Some participants had shown a keenness towards homeopathic treatment from the start whereas others had it suggested to them by a health professional or other person and were driven to CAM treatment out of a desperate wish to gain an improvement in the symptoms of OA. All participants reported to have suffered to a high degree from arthritis for over 5 years and this limited their actions to varying degrees, though all participants reported some limitations. Expectations of treatment were quite moderate, indicating that participants had experienced too much due to the symptoms of their condition to expect radical improvement. Expectations on ability to reduce medication usage and preventing progression of their condition plus improved manageability of symptoms were consistent with the findings of other studies on the appeal of CAM usage in private practice (Cartwright & Torr, 2005). Participants in the current study indicated that they would not be able to receive homeopathy unless it was provided on the NHS. The only negative comments from a study on experiences of the usage of CAM in private practice was cost, and participants had reported that they felt lucky to be able to afford this treatment (Cartwright & Torr, 2005). It is clear then that if homeopathy and other CAM is shown to be beneficial for particular conditions, a lack of NHS provision of such treatments could deepen inequalities in healthcare.

Several other reasons were given by participants as to why they were seeing a medical doctor rather than a non-medical homeopath. It is far more common for

NHS homeopathic treatment to be delivered by a medical homeopath and it was clear that this was felt to be preferable both in terms of credibility and safety.

It is interesting that one theme that emerged in the current study was regarding preference for a medical homeopath due to lack of prejudice towards the use of orthodox medicines in conjunction with CAM. Some participants expressed the view that they would not feel comfortable disclosing the use of these conventional treatments as they believed non-medical practitioners would be staunchly opposed to this. The issue of trust also came into this choice.

5.9.4 Limitations to the Study

Practical and clinical constraints that could not have been pre-empted were placed on the study. Some of these constraints were due to the nature of NHS practice and others were due to current changes within the NHS. These are discussed in this section.

Recruitment for the study

Recruitment largely depended on referrals to the Department of Homeopathy where the study was based. The numbers of referrals received over a period of time has varied greatly, form about 3 to 16 in a month. Unfortunately during the period of data collection for the study, the numbers of referrals were very sparse. This was partly due to reforms in the NHS allowing PCTs to hold their own budgets, resulting in many GPs being increasingly reluctant to fund referrals to services such as homeopathy. Recruitment began in February 2007 with an aim to begin homeopathic treatment and the observational study in May 2007.

The Department of Homeopathy where the study was based must allocate patients an appointment within three months of referral. It was therefore necessary to hold back from extreme forms of recruitment, e.g. a newspaper article on the clinic which was discussed as a means to increase numbers, lest the service should be overloaded. In the three month period from February to May only 9 referrals were received. Of these, two opted not to take part in the study. The recruitment period was therefore extended and a new batch of patients began treatment in July. This left a total of 11 patients. One patient was a Somali lady who spoke no English and although she had a translator with her, it was

impossible to obtain satisfactory informed consent and the patient could not be used for the study. Another patient was accepted through the exclusion criteria but upon arrival it became evident that she was in extreme pain whilst seated and so was excluded due to the researcher feeling it was unethical to continue.

Clinical Restraints to the study

In addition to the regulations set out by the NHS regarding appointment timeframes and the appointment system (whereby it is up to the patient to phone in and book an appointment), appointments would often become blocked up and so it was not always possible to make follow up appointments for the times stated in the research proposal. In addition patients often cancelled or did not attend their appointments which reflects the situation of non-attendance of appointments seen in clinics throughout the NHS (Sharp & Hamilton, 2001). This meant that the follow up time did not occur at fixed intervals and that the 6 month and 3 month follow ups were frequently merged into one, and an aim of three appointments per person was set.

Other clinical studies highlighted in the 2009 Annual Evidence Update on Homeopathy (Fisher, 2009) suffered similar limitations due to the reduced sample sizes obtained (Rostogi et al, 1999; Mousavi et al, 2009). The clinical restraints identified from this study highlight the fact that a large amount of time and effort is involved in order to ensure a sufficient sample size and allow for the usual proportion of drop out cases reducing the sample size.

5.10 Conclusion

Limited conclusions can be drawn on the effects of homeopathy on OA in participants in the current study due to the small sample sizes obtained. It is clear from the qualitative data that participants experienced some positive changes from homeopathic intervention, particularly on their perceived manageability of OA symptoms. To a greater extent, however, outcome tools did not corroborate

these findings and from the spread of results there was no indication that a larger sample size would have led to many more significant results from the outcome tools used. Therefore, in order to determine effectiveness of homeopathy for OA it is clear that future studies must first identify suitable means to measure change. Measurement of Salivary substance P showed promise as a tool for future trials, particularly due to the strong correlation seen between salivary substance P and physical limitation SF36 sub-score. It was clear that NHS provision of homeopathy allowed patients access to CAM who would otherwise not have had this opportunity and this is an important matter for the integrative health care debate.

Chapter 6

General Discussion & Conclusions

This study provided an exploration of CAM practice in the UK, with a focus on homeopathic treatment. The study is the first of its kind investigating the use of homeopathy in an NHS setting for a long-term condition that is difficult to treat. By exploring overall homeopathic as well as acupuncture practice in the UK, pertinent issues relevant to CAM were identified. A mixed methods approach was used to truly identify the essence of UK homeopathic practice, an area where there was little extant literature. Acupuncture is an area where further research is also necessary (House of Lords, 2000), however previous studies on acupuncture practice have been conducted (Dale, 1994; Wigram, 1989; Birch, 1999) and may have contributed to the advanced position of acupuncture research compared with homeopathy.

Many general and largely unsubstantiated comments have been made regarding the effectiveness of homeopathy, these comments originate primarily from a very small amount of research literature (see sections 1.3.1 and 3.1.4). Most findings to date have been inconclusive with major methodological constraints to the extant studies. One factor in this is the RCT trials that have been conducted were not considered representative of homeopathic practice, yet no literature detailing that practice was available. The current study focused on bridging the gap in this knowledge to enable more appropriate trials of homeopathy to be developed. The current study mapped out the context and methods used in UK homeopathy to build a knowledge base upon which future trials of homeopathy can draw. In addition, should homeopathy become increasingly integrated into the UK health system, it is possible that usage could reach the extent where regulations must be drawn up regarding practice. Important information on the practice methods of the two main UK homeopathic groups can inform which integration model a UK system should be based on.

In the current study, a quantitative survey ensured tapping into a large sample of UK homeopaths and a qualitative study allowed for a greater exploration of areas concerning homeopathy which cannot be deduced from the quantitative results alone. A clinically based study allows for consideration of homeopathy in its own environment and ensures that the results were not far removed from clinical practice as it occurs.

6.1 Considerations on the Integration of CAM

Regarding integration of homeopathy, there are a range of factors that may further the cause of those who are campaigning for integration. One is the potential cost savings, with predicted cost against outcome considered to be less expensive than with conventional medicine in areas where there is an effectiveness gap in mainstream medicine (Fisher et al, 2004). One factor may be due to public demand, and perhaps more important is the number of NHS practitioners, especially GPs and also physiotherapists in the case of acupuncture, who are also practising CAM. Barriers to integration include the number of practitioners who are unwilling to embrace the rules and regulations that would be imposed on their practice should the service be fully integrated. Another is the staunch opposition that CAM still receives from a large proportion of the medical profession (Colquhoun, 2007; The Lancet Editorial, 2005). At the forefront of this is the lack of evidence available on effectiveness of these treatments. A very recent inquiry into the strength of evidence behind government policy on homeopathic medicines was held in the House of Commons by the parliamentary science and technology committee, discussing issues surrounding NHS funding of homeopathy and highlighting the lack of evidence (Sample, Thursday 26th November 2009). Prominent scientists spoke against homeopathy, including Edzard Ernst who argued that it is unethical to provide homeopathic treatment as he believed it is not evidence based medicine. Others, such as Peter Fisher defended its use. It is likely that this inquiry will add to the intensity of the homeopathy integration debate. Although in reality, the lack of evidence makes it just as difficult to disprove the effectiveness of homeopathy as to prove it.

A ground breaking event for CAM was the recent inclusion of acupuncture as a mainstream treatment in the National Institute for Health and Clinical Excellence

(NICE) guidelines on care for patients with low back pain (Savigny et al, 2009). It is possible that with this may come an increased acceptance of therapies considered as CAM.

From the current study, it appeared that the question of which practitioners should provide CAM treatment in an integrated system was much more a consideration with acupuncture than homeopathy. Western "medical" acupuncturists practised an entirely different therapy in terms of philosophy, technique and diagnosis than traditional acupuncturists who were mainly non-medical. Some differences between medical and non-medical homeopaths were identified in the quantitative study (phase one), including length of consultations, potencies used, and length of treatment. In the qualitative study, however, homeopaths differed more strongly in their beliefs on the way they practised, and in the time available or deemed necessary for a consultation than they did in the actual practice methods. The differences identified in phase two of the current study were overshadowed by the overall variation in aspects of practice, including the source of remedy and tools used to identify remedies. These differences were equally apparent among members of the same affiliation, as between the members of different affiliations. However, despite the use of different methods, participants' descriptions of what they were trying to do in the consultation were mostly consistent with each other, suggesting that it was not the homeopathic philosophy that differed, but the practice methods. The strongest differences identified between medical and non-medical participants in phase two included the way that they viewed their role in the patient's health care and the differences in opinions of other medical systems and conventional medicine. Negative views regarding their homeopathic colleagues who belonged to other affiliations were commonly expressed.

From a patient's perspective, evidence suggests that many patients deliberately seek out CAM practitioners as an alternative to their GP, as they feel they will be listened to, and they want an alternative to mainstream medicine (Cartwright & Torr, 2005). However, in phase three of the current study, patients indicated several reasons for preferring a medical practitioner to a non-medical one, that extended beyond accessibility and NHS provision (see section 5.5.2(viii)).

There appears to be a lack of reporting of the level of CAM usage in mainstream medicine, and this could indicate the reluctance of medical bodies to acknowledge its practice, which may lead them to venture beyond the usual boundaries of their practice. Another possibility is an unwillingness of individual GPs and other health professionals to make this service provision publicly known. This could be due to a potential of being flooded by patient requests for CAM service provision, or individuals wishing to be able to pull back the service if it becomes too controversial, due to the unfavourable opinions of CAM among the medical profession (Colquhoun, 2007). It could, for the latter reason, be that practitioners are not altogether happy, in the current climate, to admit to professional bodies that they do offer it. The registries of the medical affiliations of acupuncture and homeopathy used in the current study indicate that there are over 9,600 doctors and other health professionals who could potentially be incorporating CAM into their NHS practice (FOH, 2009; BMAS, 2009; AACP, 2009). Results of the current study found that over 70% of medical acupuncturists, 16% of non-medical acupuncturists, and at least 30% medical homeopaths, provide treatment on the NHS. An increased number of surgeries now offer some form of CAM (Thomas & Coleman, 2004, Thomas et al, 2001), but the majority of CAM use still remains in the private sector, limiting the accessibility of treatment.

6.2 The Future of CAM and the NHS

The influence of the changes that the NHS structure is currently undergoing is a major consideration regarding the future of CAM. In particular, following the Darzi report on High Quality Care for All (Department of Health, 2008), the launch of a new vision for clinical commissioning came into effect in March 2009 (Department of Health, 2009), designed to promote the development of better local services. This has led to many mainstream health services becoming more independent from their regional healthcare trusts and operating more like social enterprises placing bids to commissioners to buy in their service. This new mode of operation may leave a situation where an independent CAM therapist's position is little different to that of a mainstream therapist, in an equal position to place bids to the commissioning bodies of NHS trusts. In this case the level of integration would depend largely on popular demand as much as on the willingness of commissioners to offer such a service. In

this event it is likely that regulations and a code of ethics may need to be imposed on homeopaths and other CAM practitioners in the same way that they are to health professionals in mainstream medicine.

6.3 Osteoarthritis Management

New approaches are needed for management of OA and chronic conditions in general. More needs to be done for this patient group, for which current medications offer little relief. Homeopaths are commonly approached to treat chronic musculo-skeletal conditions and, as demonstrated in phase one of the current study, this group is among the top 5 most commonly encountered condition groups. It is also an area that has been highlighted as an effectiveness gap of conventional medicine (Fisher et al, 2004). In phases one and two of the current study, it was indicated that in the case of OA, homeopathy can offer limited improvement to a degraded joint but it is more likely that manageability may improve. For an improvement of this kind, results suggested that it was likely to take 10-12 visits to a homeopath to achieve a significant improvement, compared with 7-9 for a non-medical acupuncturist (See section 3.8.2) and 10-12 for medical acupuncturist. There was suggestion by some participants in phase two that homeopathy worked better for OA when combined with acupuncture. The research evidence base on acupuncture for OA is more substantiated than for homeopathy, the main issue with studies on acupuncture is that some controversy remains when comparing sham and true acupuncture (see section 1.3.2), and this could be addressed in further studies. More research is necessary in order to determine the effectiveness of homeopathy for OA. However, the development of appropriate methodologies, including outcome measures that are sensitive to the changes in the aspects of health that are most likely involved, are necessary in order to bring an advance in homeopathic treatment.

It is possible in a system where CAM is fully integrated into the NHS, that certain OA patients would be more likely to see an acupuncturist than a homeopath initially, or perhaps seek the two therapies combined. It was clear however from phase two of the current study that a homeopath would not hold back from treating OA with homeopathy if they were sure the patient wanted it. Allowing for patient choice has become a high priority in the current public health agenda. Recent policy includes the freedom for patients referred to services to choose the centres where they receive the

care (Department of Health 2009b). If this right to choose services is extended, it is possible that this will lead to patients with conditions such as osteoarthritis being able to request that they see a homeopath or an acupuncturist as opposed to entering another treatment route.

The results from phase three of the current study show that no measurable improvement of osteoarthritis following homeopathic treatment can be confirmed from the study, but that many participants perceived that they had some kind of improvement. It is this kind of perceived improvement that very much needs to be the focus of improving future study designs.

6.4 Considerations for Advancement in the Evidence Base for Homeopathic Treatment

The Department of Health have demonstrated an interest in forthcoming evidence of homeopathy with the production of a recent annual report to give an evidence update on homeopathy (Department of Health, 2009c). This summary of the different types of homeopathy research that has recently been conducted shows that some newer RCTs have been conducted, though mostly with inconclusive results. In addition other studies are summarised including those of observational nature, and studies conducted on plants and animals.

In order to achieve an advanced evidence base for homeopathy and other CAM treatments, development of tools based on a biopsychosocial model incorporating the multi-dimensional aspects of chronic conditions should be a priority.

The difficulties in designing appropriate methodologies for homeopathy have been previously discussed (see section 1.3.1) and include finding ways to allow for the individualised nature of homeopathic treatment. The potential therapeutic contribution of the consultation (Milgrom, 2004) also imposes problems with use of suitable placebos in the design of RCT studies. The results from phase two of the current study indicate that many practitioners felt that health improvements began at the consultation, with the identification of the route cause. The results of the current study also indicate problems that extend beyond that reported, as practitioners were not found to use a systematic approach to review their patients. Verbal reports of

satisfaction with treatment and the intuitive sense were relied upon. The adoption of future tools that are sensitive to subtle changes in multidimensional aspects of the biopsychosocial health, in practice and in research, would allow for a more valid assessment of homeopathy, and other complex interventions. This could bridge the gap between anecdotal evidence, perceived benefits and case study examples, and actual accepted forms of hard currency evidence such as RCTs.

As discussed in section 4.1.5, perceptions of health have evolved greatly over the past century. In addition the timeline of medical treatment over the past few centuries has shown the emergence of pharmaceutical treatment only during the last 150 years, and yet has transformed the medical system to the point where many traditional methods used for centuries beforehand have almost been forgotten. If such biopsychosocial assessment tools were developed, it is possible that they could become a measure in mainstream drug trials too, which may further undermine some of the treatments currently used for certain conditions and cause a shake up to the pharmaceutical-led medical system that currently exists in favour of more holistic approaches. Traditional acupuncture may also benefit from this, as the acceptability of mechanisms proposed by TCM acupuncture could contribute to its acceptance. These fit largely within the biomedical model but results from phase one of the current study indicate that non-medical acupuncturists believed in mechanisms that extend beyond this, through the actions of "qi", and are similar to descriptions of homeopathic mechanisms on the "vital force".

The tools used in phase three of the current study, in addition to many of the other studies on interventions for OA (See sections 1.2-1.3), include the WOMAC, SF36 and MYCAW and were not sensitive to participants' reported improvements following use of homeopathy. Therefore the advances in research mentioned above are unlikely to occur until new tools are developed to better capture biopsychosocial aspects of health.

6.5 The Placebo Effect, the Biopsychosocial Model and Homeopathy

An understanding of the concept of the placebo is essential in interpreting results from large scale double blind, randomised, placebo controlled trials and smaller scale RCT

and observational studies. In addition this understanding is fundamental to the overall understanding of health and how natural healing systems operate. Homeopaths in phases one and two of the current study identified the triggering of self-healing processes in the body to be at the core of the mechanism of action of homeopathic treatment. The placebo effect describes the psychological phenomenon whereby a patient's symptoms improve because they believe they are being treated, and it is now recognised as showing some effectiveness as a "treatment" (Harrington, 1999). This indicates a role of self healing too, with the aid of a psychological stimulus. The idea that the mechanism of action of homeopathy therefore has some overlap with the mechanisms of the placebo response has been cited elsewhere (Chanda & Fulham, 2008). This potential overlap raises some issues with regard to placebo controlled trials of homeopathy. It also sheds some light on healing processes within the body. The human body is constantly undergoing homeostasis to regulate our ability to perform a large number of functions. This homeostasis includes regulating the osmotic components of intracellular and extracellular fluids, temperature and acid/base balance of the blood; the body is consistently shifting, repairing and replacing components to achieve balance in order for survival (Berne & Levy, 1993). Though there is a good level of understanding of the physiological processes of the physical state, less is known with regard to how the mental state is maintained, and to what extent the mental state influences the physical state and by what means. Neurophysiologists and psychologists have attempted to understand how the mind functions, however much of this is still unknown. Neuromodulator concentrations and neuroreceptor function are also kept in balance by physiological processes for which we have a limited understanding, but pharmaceutical attempts to interfere with this process and increase manageability of symptoms rather than creating extra side effects have rendered a majority of these agents unusable for many sufferers. This suggests that other factors and more complex systems are at work in all of these processes.

Osteoarthritis pain is thought to have both mental and physical aspects (Odding, 1998), adding to the difficulty in treating it successfully. The multiple dimensions of OA pain were highlighted by the lack of correlation seen in phase three of the current study between the scores from different pain measurement tools. The reported improvements in the qualitative results from phase three were also not reflected in the

scores of these tools. Substance P, believed to be involved in neuropathic and inflammatory pain (Nichols et al, 1999), showed a close correlation with functional limitation rather than with pain. This is an example of an area where our understanding of physiological processes is limited.

With an increased understanding of how the body's own regulatory and self healing systems operate, that will hopefully unfold as biomedical and biopsychosocial science progresses, perhaps the concept of a therapy that starts with focusing a patient on events at the time the symptom first appeared and then a gentle reminder by way of a "frequency" that is in some way reminiscent of the illness as it first appeared, will not seem so absurd to scientists. The biopsychosocial and biomedical models may turn out to converge to meet each other. Perhaps some discovery of how different CAM therapies may influence the body's healing mechanisms will allow us to develop a better understanding of how the healing processes themselves function and how best to manipulate these processes during healthcare pathways. In any event, within the current evidence base it is not yet possible to draw any firm conclusions on the interaction of homeopathy and other CAM on the body's healing mechanisms.

Limitations to the study

The explorational nature of the study has allowed a broad outlook on aspects relating to homeopathy and other CAM. The author felt that this was necessary due to the lack of information available and the aim was to collect information on a range of topics that can then be used in the design of future studies. One consequence of this is that individual topics could not always be given the level of attention that might have been necessary to draw firm conclusions and as a result a number of future research suggestions have resulted from the current study.

Limitations to individual phases of the study are discussed in sections 2.5.4., 3.4.3 and 4.4.5. To some extent the limitations identified in phase one were elucidated in phase two and vice versa. Phase three had a number of limiting factors that largely revolved around a drop in referral numbers of OA patients to the Homeopathic Department and the influence of this on recruitment. In addition the use of novel techniques, the

protocols for which have not previously been thoroughly devised, makes it hard to draw conclusions from the results. Perhaps most importantly, the lack of sensitivity of the assessment tools used in phase three may have limited the strength of the results, primarily because these validated tools have not yet been superseded by ones sensitive to more complex processes.

6.6 Concluding remarks

In the current study it was found that homeopathy is, broadly speaking, practised in a similar way by medical and non-medical practitioners alike, differing mainly in opinions on their role in patient care, the degree to which they felt that homeopathy was effective for certain conditions, opinions on other medicinal models, and the time allocated to consultations and follow up intervals. In some cases the length and frequency of consultations were a result of limitations associated with NHS provision. Methods of undertaking a consultation were similar, though practitioners would use different material medica or online repertories and relied on these to a varying degree. However, a large amount of variability did occur in certain aspects of practise, irrespective of medical status, in terms of the method of obtaining, directions on taking and the source of homeopathic remedies. Each of these factors indicates potential discrepancies in effective treatment delivery.

Medical acupuncturists, in contrast, practise a therapy with an entirely different theoretical background to their non-medical colleagues, treat a limited range of conditions relating to pain management and reported being neutral on the effectiveness of acupuncture for other conditions. Non-medical acupuncturists, in contrast, treated a spectrum of conditions that was very similar to that seen by homeopaths and corresponds with the effectiveness gap reported by GPs in conventional medicine (Fisher et al, 2004).

OA is an extremely difficult problem to treat. Of the different therapeutic approaches that have been identified, none offer a straightforward treatment to improve quality of

life for sufferers in any immediacy. Results from the current study indicate that acupuncturists and homeopaths believed that their treatment would be effective for OA management but that it would take a large number of visits before a significant improvement was seen. Limited acupuncture and homeopathy are provided on the NHS, restricting access to those who are able to afford private treatment. In order for UK healthcare policy to include further integration of acupuncture and homeopathy for this patient group, more research is needed to enhance the evidence base for these therapies in the management of OA. Perhaps acupuncture and homeopathy should be researched as a combined package to improve manageability of OA. If this care package was shown to be successful then it is possible that in future it may be provided within mainstream healthcare to improve the quality of life of the large numbers of sufferers of OA.

Future Research Recommendations

Moving away from the RCT model is a popular idea among CAM therapists as phase two of this study, and other articles have highlighted (Walach, 2006; Milgrom, 2007). As homeopathic texts are filled with illustrative case studies and CAM therapists feel comfortable with these, perhaps it would be beneficial to provide training in formal case study research models to CAM therapists as part of their training. This could help practitioners to add structure to their practice by further recognising treatment patterns. It may also build upon the evidence base of these treatments, which may help to reduce the scepticism that many among the scientific community hold towards homeopathy and similar treatments, or at least increase their understanding of what is involved in treatment.

A future study extending the model used in phase 3 of the current study, ensuring large sample sizes, may yield firmer conclusions. The findings of the current study indicate that if more sensitive outcome tools were developed, these may have been able to identify changes linked to those reported by patients in the qualitative results and therefore strengthen these findings. In addition, if more was learned on the salivary concentrations of Substance P, and the correct treatment of saliva samples were to be known, then the assay of salivary Substance P may prove to be an

important biochemical tool for future studies. An additional line of research comparing homeopathy and acupuncture combined for OA management to other treatments could also provide useful information.

Provings, conducted to identify new remedies (see section 1.4.2), are also carried out routinely in the development of homeopathic remedies. It would be useful if these could be conducted in a way that includes firm scientific rigour so that they could be used as evidence in themselves. Again, this is likely to require the development of new tools in order to measure symptoms in provings, rather than relying on informal reports on effects by participants.

There are a vast number of grey areas and knowledge gaps concerning the physiology of the body. As biomedical science advances, new modulators, messengers and other bioactive substances are identified, each having a relevant role in the body. Equipment used is becoming increasingly sophisticated, and increasingly low concentrations of the bioactive messengers and compounds within the body can be detected. It is therefore possible that future biomedical research will reach a stage where can observe the modulations involved in body processes from compounds that work at homeopathic concentrations. If the knowledge base develops in this way then it is possible that the biomedical model itself may evolve in a way that does not conflict with the homeopathic theory or that of other CAM.

Homeopathic science could also benefit from advancement though more studies such as the ultra high dilution (UHD) research on the memory of water to enhance research in this area that has already begun (Elia et al 2004, Schulte & Christi, 1998) in order to get the backing of the scientific community.

It would perhaps be advisable that these different approaches to homeopathy research, to build the evidence base for homeopathy were all adopted in order to combine the results and obtain a more true representation of what, if anything, is behind this most mysterious and highly controversial treatment.

It is clear that in order to understand what interventions work more effectively for patients with long standing OA, more research is needed and particularly more research into the CAM therapies that may offer help to this patient group, who have so far been offered little that can improve their quality of life in mainstream healthcare.

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Appendices

Appendix 1

Liverpool Paediatric Research Ethics Committee – Confirmation letter of ethical approval

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Appendix 2

Liverpool PCT –Honorary Contract Letter

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Appendix 3

Liverpool John Moores University – Ethical Approval letter

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Appendix 4

Recruitment letter sent to the homeopathic sample for the homeopathy questionnaire in phase 1

Faculty of **Health and**
Applied Social Sciences

Dear

Re. Homeopathy Questionnaire

I am a PhD student studying at Liverpool John Moores University and am carrying out a research project in homeopathy.

As I'm sure you are aware, research into homeopathy to date has generally led to inconclusive results and this has been largely put down to the methodological constraints of existing published work. This project involves investigating the modes of practice and views of homeopathic practitioners in the UK.

I hope that this study will provide information that will assist development of research in homeopathy and allow for more effective trials. By participating you will be helping this process. I would be very grateful if you could complete the enclosed questionnaire and return it to me in the prepaid envelope provided at your earliest convenience.

The study is anonymous and you will not be identified.

If you have any further queries, please contact me on 0151 231 4056 or email NRSAMAJU@livjm.ac.uk

Many thanks for your time.

Yours sincerely

Anne J Majumdar

Dr. Nikki Adams BSc(Hons) PhD MCSP CPsychol
Head of Centre for Research In Health Care
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Appendix 5

Homeopathy Questionnaire, for phase 1

HOMEOPATHY QUESTIONNAIRE

ALL RESPONSES ARE STRICTLY CONFIDENTIAL AND YOU WILL NOT BE IDENTIFIED.

THANK YOU FOR YOUR PARTICIPATION.

HOMEOPATHY QUESTIONNAIRE

GENERAL

1 About you

A Status (please tick the most appropriate)

Medically qualified Homeopath (FFHom)	Medically qualified Homeopath (MFHom)	Member of the Society of Homeopaths	Other
❑ 1	❑ 2	❑ 3	❑ 4

B Location

Manchester	Merseyside	London	Yorkshire	Other (please state county)
❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

C How long have you practised as a homeopath?

Less than a year	1-5 years	6-10 years	11 years or more
❑ 1	❑ 2	❑ 3	❑ 4

D What initially led to your interest in homeopathy?

2 Do you practice any other forms of medicine / therapy?

	Yes, currently	Yes, previously	No	If yes, please specify
Conventional Medicine Within the NHS:	❑ 1	❑ 2	❑ 3	
Conventional Medicine in Private Practice:	❑ 1	❑ 2	❑ 3	
Complementary & Alternative Medicine (Other than homeopathy):				

HOMEOPATHY QUESTIONNAIRE

❑1 ❑2 ❑3 _____

YOUR PRACTICE

3 On average how many consultations do you hold 310 k?

		0 to 5	6 to 10	11 to 15	16 to 20	More than 20
i)	New Patients	❑1	❑2	❑3	❑4	❑5
ii)	Existing patients	❑1	❑2	❑3	❑4	❑5

4 Please list the 5 health conditions you most frequently encounter, 1 being the most frequent:

1 _____

2 _____

3 _____

4 _____

5 _____

5 A How long would an initial consultation last (for a chronic illness)? _____

B Following the initial consultation , how long after would you arrange the next appointment for:

i Acute ear infection (with a history of recurrent infections) _____

ii Eczema _____

iii Osteoarthritis _____

C In your experience approximately how many times have you needed to see a patient for the following conditions before obtaining significant improvement (i.e. greater than 80% improvement) or complete cure

		1 to 4	5 to 8	9 to 12	More than 12
i	Acute Ear Infection (with a history or recurrent infections)	❑4	❑3	❑2	❑1
ii	Eczema	❑4	❑3	❑2	❑1
iii	Osteoarthritis	❑4	❑3	❑2	❑1

HOMEOPATHY QUESTIONNAIRE

6 When taking a patient's case history, which of the following do you ask for? (Please tick any that apply): -

Emotional state	❑ 1	Constitutional Temperament	❑ 2	Food Preferences	❑ 3
Environmental stress (Allergies, smoke e.t.c.)	❑ 4	Stress levels (family relations/ work pressures)	❑ 5	Feel hot / cold	❑ 6
Dreams	❑ 7	Sleep patterns	❑ 8	Weather influences -feel better in hot/cold	❑ 9
Medical History	❑ 10	Feels thirsty / not thirsty	❑ 11	Vaccination history	❑ 12
Daytime influences	❑ 13	Other symptoms	❑ 14	Frequency of passing urine	❑ 15
Frequency of stools	❑ 16	Work environment	❑ 17	Details of patients' birth (e.g. caesarean)	❑ 18
Family medical history – previous generation	❑ 19	Family medical history- previous 2-3 generations	❑ 20	Details of patients' Mothers' pregnancy	❑ 21

Others_____

7 The following includes assessments that are sometimes used as tools in clinical trials of homeopathy. Do you use the following methods of assessment in your practice?

		Always	Often	Sometimes	Rarely	Never
A	Ask patients to fill in a questionnaire prior to appointment	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1
B	The Glasgow Homeopathic Hospital Outcomes Score	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1
C	The SF36 Questionnaire	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1
D	MYCAW (Measure yourself concerns and well-being) Questionnaire	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1

E Other (please specify)_____

8 **Prescribing:** -Please indicate your usage of the following methods:

		Always	Often	Sometimes	Rarely	Never
A	I prescribe one single remedy at a time:	❑5	❑4	❑3	❑2	❑1
B	I tend to prescribe multiple remedies:	❑5	❑4	❑3	❑2	❑1
C	I try to start off with a low potency and work upwards:	❑5	❑4	❑3	❑2	❑1
D	I start with a high potency and work downwards:	❑5	❑4	❑3	❑2	❑1
E	I give homeopathic remedies for the shortest time possible (i.e. a few days or a few weeks maximum):	❑5	❑4	❑3	❑2	❑1
F	I would advise my patient to continue taking their usual medicine (e.g. anti-inflammatories/painkillers) at the beginning of homeopathic treatment:	❑5	❑4	❑3	❑2	❑1
G	I follow a course of homeopathic medicine with a placebo to allow the medicine time to work through:	❑5	❑4	❑3	❑2	❑1
H	I identify the constitutional type of the person, e.g. Sulphur, Calcerea Carbonica, Lachesis and this influences my prescribing:	❑5	❑4	❑3	❑2	❑1
I	I use the decimal scale:	❑5	❑4	❑3	❑2	❑1
J	I use the centesimal scale:	❑5	❑4	❑3	❑2	❑1
K	I use LM Doses:	❑5	❑4	❑3	❑2	❑1

9 **Homeopathic Theory** - Please indicate your agreement or disagreement with the following statements.

HOMEOPATHY QUESTIONNAIRE

		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
A	A treatment will only work if the patient has faith in it:	❑5	❑4	❑3	❑2	❑1
B	I consider myself to be a classical homeopath:	❑5	❑4	❑3	❑2	❑1
C	A miasm is the underlying cause of chronic disease:	❑5	❑4	❑3	❑2	❑1
D	Miasm is a person's inherited predisposition to disease:	❑5	❑4	❑3	❑2	❑1
E	A chronic disease is initiated by the inherited or acquired miasm e.g. psora, gonorrhea, syphilitic:	❑5	❑4	❑3	❑2	❑1
F	The placebo effect plays a big role in the effectiveness of homeopathic treatment:	❑5	❑4	❑3	❑2	❑1
G	Homeopathic medicines work on the vital energy of the body:	❑5	❑4	❑3	❑2	❑1
H	Homeopathy works on electrodynamic fields in the body:	❑5	❑4	❑3	❑2	❑1
I	The energy of the medicine must match that of the disease. This must be taken into account when prescribing:	❑5	❑4	❑3	❑2	❑1
J	Homeopathy is a form of energy medicine. Acupuncture is also a form of energy medicine but manipulates the body's energy using different methodologies:	❑5	❑4	❑3	❑2	❑1
K	The way in which homeopathic medicine works is not important to me:	❑5	❑4	❑3	❑2	❑1

10 **Research:** - Please indicate your agreement c 314 eement with the following statements.

HOMEOPATHY QUESTIONNAIRE

		Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
A	More research into the effectiveness of homeopathy is necessary	❑5	❑4	❑3	❑2	❑1
B	More research into the mode of action of homeopathy in the body is necessary	❑5	❑4	❑3	❑2	❑1
C	More research into the physics of the synthesis of homeopathic remedies is necessary	❑5	❑4	❑3	❑2	❑1
D	I consistently keep myself up to date with advances in homeopathy research	❑5	❑4	❑3	❑2	❑1

11 Please indicate your agreement or disagreement with the following statements:

		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	Homeopathy is an effective treatment for: -					
A	Musculoskeletal conditions	❑5	❑4	❑3	❑2	❑1
B	Skin conditions	❑5	❑4	❑3	❑2	❑1
C	Asthma	❑5	❑4	❑3	❑2	❑1
D	Menopausal / PMT symptoms	❑5	❑4	❑3	❑2	❑1
E	Acute illness	❑5	❑4	❑3	❑2	❑1
F	Mental illness	❑5	❑4	❑3	❑2	❑1
G	All illnesses	❑5	❑4	❑3	❑2	❑1

12 Please indicate your level of belief in the following medical

HOMEOPATHY QUESTIONNAIRE

	Strongly believe	Have some faith	Neutral	Disbelieve	Strongly disbelieve
Traditional Chinese Medicine	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Ayurvedic Medicine	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Conventional Medicine (UK)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

13 Any other comments?

____

____

____

____

____

____

HOMEOPATHY QUESTIONNAIRE

PLEASE RETURN TO:

ANNE MAJUMDAR
LIVERPOOL JOHN MOORES UNIVERSITY
FREEPOST LV6587
JMU TOWER, 24 NORTON STREET
LIVERPOOL L3 5YE

IN THE REPLY-PAID ENVELOPE PROVIDED.

THANK YOU FOR YOUR PARTICIPATION.

Appendix 6

Recruitment letter sent to the acupuncture sample for the acupuncture questionnaire in phase 1

Liverpool John Moores
University
70 Great Crosshall Street
Liverpool L3 2AB
Telephone: 0151 231 4056

27 July 2005

«Title» «FirstName» «LastName»
«Address_1»
«Address_2»
«Address_3»
«Town_» «PostalCode»

Faculty of **Health and**
Applied Social Sciences

Dear «Title» «LastName»

Re. Acupuncture Questionnaire

I am a PhD student studying at Liverpool John Moores University and am carrying out a research project in acupuncture.

As I'm sure you are aware, the integration of acupuncture into the health system in this country is a heavily debated topic and more research into acupuncture would be very beneficial. This project involves investigating the modes of practice and views of acupuncture practitioners in the UK.

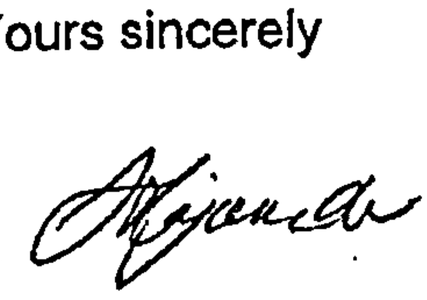
I hope that this study will provide information that will assist development of research in acupuncture and inform the integration debate. By participating you will be helping this process. I would be very grateful if you could complete the enclosed questionnaire and return it to me in the prepaid envelope provided at your earliest convenience.

The study is anonymous and you will not be identified.

If you have any further queries, please contact me on 0151 231 4056 or email NRSAMAJU@livjm.ac.uk

Many thanks for your time.

Yours sincerely



Anne J Majumdar

Dr. Nikki Adams BSc(Hons) PhD MCSP CPsychol
Reader In Health & Social Care

Head of Centre for Research In Health Care

Appendix 7

Acupuncture Questionnaire, for phase 1

ACUPUNCTURE QUESTIONNAIRE

ALL RESPONSES ARE STRICTLY CONFIDENTIAL AND YOU WILL NOT BE IDENTIFIED.

THANK YOU FOR YOUR PARTICIPATION.

ACUPUNCTURE QUESTIONNAIRE

GENERAL

1 About you

A Status (please tick the most appropriate)

Member of the British Medical Acupuncture Society	Member of the British Acupuncture Council	Member of the Acupuncture Association of Chartered Physiotherapists	Other
❑ 1	❑ 2	❑ 3	❑ 4

B Location

Manchester	Merseyside	London	Yorkshire	Other (please state county) _____
❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

C How long have you practised acupuncture?

Less than a year	1-5 years	6-10 years	11 years or more
❑ 1	❑ 2	❑ 3	❑ 4

D What initially led to your interest in acupuncture?

_____

_____

_____

_____

_____

_____

E Do you offer acupuncture treatment on the NHS?

Yes, always	Some provided on NHS	No
❑ 1	❑ 2	❑ 3

2 Do you practice any other forms of medicine / therapy?

	Yes, currently	Yes, previously	No	If yes, please specify
Conventional Medicine Within the NHS:	❑ 1	❑ 2	❑ 3	_____ _____ _____
Conventional Medicine in Private Practice:	❑ 1	❑ 2	❑ 3	_____ _____ _____
Complementary & Alternative Medicine (Other than acupuncture):	❑ 1	❑ 2	❑ 3	_____ _____ _____

ACUPUNCTURE QUESTIONNAIRE

YOUR PRACTICE

3 On average how many acupuncture consultations 321 hold per week?

		0 to 5	6 to 10	11 to 15	16 to 20	More than 20
i)	New Patients	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5
ii)	Existing patients	❑ 1	❑ 2	❑ 3	❑ 4	❑ 5

4 Please list the 5 health conditions you most frequently encounter, 1 being the most frequent:

1 _____

2 _____

3 _____

4 _____

5 _____

5 A How long would an initial consultation last (for a chronic illness)? _____

What would be the interval before a follow-up appointment? _____

B For the following conditions, what would be the average length of needling time?:

i Acute ear infection (with a history of recurrent infections) _____

ii Eczema _____

iii Osteoarthritis _____

C In your experience approximately how many times have you needed to see a patient for the following conditions before obtaining significant improvement (i.e. greater than 80% improvement) or complete cure

		1 to 3	4 to 6	7 to 9	10 to 12	More than 12
i	Acute Ear Infection (with a history or recurrent infections)	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1
ii	Eczema	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1
iii	Osteoarthritis	❑ 5	❑ 4	❑ 3	❑ 2	❑ 1

6 **In Practice:** -Please indicate your usage of the following methods:

	Always	Often	Sometimes	Rarely	Never
A	I use physical diagnostic measures such as pulse diagnosis as the most significant indicators to identify the source of the illness	❑5	❑4	❑3	❑2	❑1
B	Before treatment I inquire in depth details of the personal life and emotional state of the patient	❑5	❑4	❑3	❑2	❑1
C	I ask the patient to fill in a questionnaire prior to the initial consultation	❑5	❑4	❑3	❑2	❑1

Please state which one:

_____

D	I ensure that a conventional western medical diagnosis is conducted prior to acupuncture treatment	❑5	❑4	❑3	❑2	❑1
E	I would advise my patient to continue taking their usual medicine (e.g. anti-inflammatories/painkillers) at the beginning of acupuncture treatment	❑5	❑4	❑3	❑2	❑1
F	I practice TCM acupuncture	❑	❑	❑	❑	❑
G	I practice Western acupuncture	❑5	❑4	❑3	❑2	❑1
H	I practice Japanese acupuncture	❑5	❑4	❑3	❑2	❑1
I	I practice five elements acupuncture	❑5	❑4	❑3	❑2	❑1

Any Comments

_____

_____

_____

ACUPUNCTURE QUESTIONNAIRE

7 **Acupuncture Theory** - Please indicate your agreement or disagreement with the following statements.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
A	Acupuncture treatment works via the meridians and collaterals in the body				
	❑5	❑4	❑3	❑2	❑1
B	Meridians and collaterals are subtle physiological pathways in the body				
	❑5	❑4	❑3	❑2	❑1
C	Acupuncture works by causing the release of endorphins in the body				
	❑5	❑4	❑3	❑2	❑1
D	The effects of acupuncture are largely due to nerve stimulation				
	❑5	❑4	❑3	❑2	❑1
E	The effects of acupuncture are mainly due to its effects on blood circulation				
	❑5	❑4	❑3	❑2	❑1
F	Acupuncture also has some "non-local" effects which are essential to it's effectiveness				
	❑5	❑4	❑3	❑2	❑1
G	The placebo effect plays a big role in the effectiveness of acupuncture treatment				
	❑5	❑4	❑3	❑2	❑1
H	Acupuncture works on the Qi of the body:				
	❑5	❑4	❑3	❑2	❑1
I	Acupuncture works on electrodynamic fields in the body:				
	❑5	❑4	❑3	❑2	❑1
J	Acupuncture is a form of energy medicine. Homeopathy is also a form of energy medicine but manipulates the body's energy using different methodologies:				
	❑5	❑4	❑3	❑2	❑1
K	The way in which acupuncture works is not important to me:				
	❑5	❑4	❑3	❑2	❑1

ACUPUNCTURE QUESTIONNAIRE

8 **Research:** - Please indicate your agreement or disagreement with the following statements:

		Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
A	More research into the effectiveness of acupuncture is necessary	❑5	❑4	❑3	❑2	❑1
B	More research into the mode of action of acupuncture in the body is necessary	❑5	❑4	❑3	❑2	❑1
C	More research into the physiology behind the meridian pathways is necessary	❑5	❑4	❑3	❑2	❑1
D	I consistently keep myself up to date with advances in acupuncture research	❑5	❑4	❑3	❑2	❑1

9 Please indicate your agreement or disagreement with the following statements:

		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
	Acupuncture is an effective treatment for: -					
A	Musculo-skeletal conditions	❑5	❑4	❑3	❑2	❑1
B	Skin conditions	❑5	❑4	❑3	❑2	❑1
C	Asthma	❑5	❑4	❑3	❑2	❑1
D	Menopausal / PMT symptoms	❑5	❑4	❑3	❑2	❑1
E	Anxiety / depression	❑5	❑4	❑3	❑2	❑1
F	Digestive disorders	❑5	❑4	❑3	❑2	❑1
G	Chronic Fatigue Syndrome	❑5	❑4	❑3	❑2	❑1
H	Acute illness	❑5	❑4	❑3	❑2	❑1
I	All illnesses	❑5	❑4	❑3	❑2	❑1

ACUPUNCTURE QUESTIONNAIRE

10 Please indicate your level of belief in the following medical systems as effective:

	Strongly believe	Have some faith	Neutral	Disbelieve	Strongly disbelieve
Traditional Chinese Medicine	☐5	☐4	☐3	☐2	☐1
Ayurvedic Medicine	☐5	☐4	☐3	☐2	☐1
Homeopathy	☐5	☐4	☐3	☐2	☐1
Conventional Medicine (UK)	☐5	☐4	☐3	☐2	☐1

13 Any other comments?

____

____

____

____

____

____

ACUPUNCTURE QUESTIONNAIRE

PLEASE RETURN TO:

ANNE MAJUMDAR
LIVERPOOL JOHN MOORES UNIVERSITY
FREEPOST LV6587
JMU TOWER, 24 NORTON STREET
LIVERPOOL L3 5YE

IN THE REPLY-PAID ENVELOPE PROVIDED.

THANK YOU FOR YOUR PARTICIPATION.

Appendix 8

Information sheet for prospective patients to participate in phase 3

Department of Homoeopathic Medicine
Telephone: 0151 285 3707 * Fax 0151285 3755
Consultant: Dr W R Richardson MB BS FRCS MRCGP FFHom

Old Swan Health Centre
Crystal Close
St. Oswald's Street
Liverpool
L13 2GA

Information for Patients

Study Title: An investigation into the use of homeopathy for the management of osteoarthritis within a primary care setting

What is the purpose of the study?
The aim of this study is to evaluate the effects of homeopathy for osteoarthritis by collecting certain information from patients before and after they receive treatment. With your permission, a saliva sample will also be taken for analysis. The notes that your GP makes on matters that concern to study regarding your arthritis would also be available to me for research. The study will take place over 6 months. We hope that from this study we will be able to make recommendations on how homeopathy can be delivered most effectively and improve the treatment available for osteoarthritis.

Why Have I been chosen?
You have been chosen for the study as a patient who is due to begin homeopathic treatment for osteoarthritis at the Old Swan Medical Practice. We are hoping that around 14 patients will participate in the study.

Do I have to take part?
No. It is up to you to decide whether you would like to take part or not. If you do decide to take part you will be given this information sheet to keep and asked to complete a consent form. If you do decide to take part you are free to withdraw from the study at any time without giving a reason. If you decide not to take part this will in no way affect the treatment that you will receive.

What will happen to me if I take part?
If you do take part in the study you will be given a short interview by a researcher who will assist you to complete a questionnaire. If you agree, the interview will be taped and will take place on each of 4 of your routine visits to the clinic. The interview will last 10 minutes and will be conducted whilst you are waiting to see the doctor. You will also be asked to give a saliva sample to the researcher on each occasion, this will involve the placement of a small amount of spittle into a vessel. This sample will undergo biochemical analysis to assess any change due to treatment. The interview and saliva sample collection will take place during your normal scheduled appointments and you will not need to attend the surgery any more often than you would normally do.

What will I have to do?
The days when you will receive the interviews will be on your first visit to the clinic, at a 6 week follow – up, 3 months after you have begun your treatment and then at a 6-month follow-up. The completion of the questionnaire and providing a saliva sample will be the only things required of you. If you agree to the use of a tape recorder during the session it will be transcribed and the tapes

will be destroyed within 6 weeks of the interview. The study will finish there and you will not be asked for anything further.

The study will not affect your treatment at the clinic in any way. Your homeopath and other staff at the clinic will explain the procedure for your homeopathic treatment to you when you attend.

Will my participation be confidential?
Your GP will be informed that you are participating in the study. All information collected about you during the study will be kept strictly confidential. Should any results or information leave the Medical practice your name and details will be removed so that you cannot be recognised and the results remain anonymous.

What will happen to the results of the research?
The results will be used in a student research project for a postgraduate degree. The results of the study will be used to determine any factors of treatment that influence the outcome of homeopathic treatment for osteoarthritis.

What are the risks to me if I take part in the study?
None

What are the benefits of the study for me?
None. The study will not affect your treatment, however we hope that the information we gather in this study will enable us to make recommendations for improved treatment for patients with osteoarthritis in the future.

Who is funding the research?
The research is being funded by Liverpool John Moores University.

Who has reviewed the study?
Liverpool Research Ethics Committee and Liverpool John Moores University Ethics Committee have reviewed the study.

If during the study you are not happy or have a complaint you can formally raise this to an independent source: D. Leighton, tel no. o151 231 4551

Who can I contact for further information?
If you would like more information on the study, please feel free to call Anne Majumdar on **0151 231 4056**. You can also speak to the staff at the Old Swan Medical practice for further advice.

Thank you for reading this

Version 2 Last updated 14 June 2006

Appendix 9

Invitation to participate in the study letter for patients attending the Department of Homeopathy in phase 3

Department of Homoeopathic Medicine
Telephone: 0151 285 3707 * Fax 0151285 3755
Consultant: Dr W R Richardson MB BS FRCS MRCGP FFHom

Old Swan Health Centre
Crystal Close
St. Oswald's Street
Liverpool
L13 2GA

Date

Dear Mr X

Research Study: An investigation into the use of homeopathy for the management of osteoarthritis within a primary care setting

I would like to invite you to take part in the research study that is detailed in the attached Information Sheet, last updated 14 January 2006.

The study would take place at the Old Swan Medical Centre during your treatment here. Participation in the study is entirely voluntary.

To help you decide whether or not you wish to take part in the study, I would be grateful if you could read the information about the project the attached sheet. Please feel free to discuss it with family, friends or your GP and if you have any questions about it please feel free to contact the staff at Old Swan on the above number or contact the researcher on **0151 231 4056.**

Thank you for your time.

Yours sincerely

Dr H Nielsen

Appendix 10

GP recruitment letter to refer patients to the Department of Homeopathy

Department of Homoeopathic Medicine
Telephone: 0151 285 3707 * Fax 0151285 3755
Consultant: Dr H Nielsen BM BCH MRCP FFHom

Old Swan Health Centre
Crystal Close
St. Oswald's Street
Liverpool
L13 2GA

Date

Dear Dr X

Do you have any patients with osteoarthritis who are intolerant of / not responding to NSAIDS?

We are planning to carry out a clinical research project at the Department of Homeopathic Medicine here at Old Swan in order to evaluate the effectiveness of our treatment of osteoarthritis. The title of the study is as follows: -

An Investigation into the outcome of Homeopathic treatment of Osteoarthritis in patients attending the Department of Homeopathic Medicine, Old Swan Health Centre.

The study itself is in collaboration with Liverpool John Moores University. It will involve the usual homeopathic consultation as well as an interview with a research assistant. Patients will be seen at the clinic for their initial assessment, then at 6 weeks 12 weeks and 6 months after commencing treatment. The department will supply all Homeopathic remedies. Patients who have benefited from Homeopathic treatment after 6 months will be offered further follow up appointments. Saliva samples will also be taken from patients to assess for biochemical markers of pain. Please see the enclosed patient information sheet, last updated 14 June 2006 for more details.

Many patients have been treated with homeopathy at the centre for osteoarthritis and patients continue to be referred to us with osteoarthritis for treatment. In order for the study to be accurate we would like to be able to use a larger sample size than are currently referred to us. Therefore I am writing to inquire whether you currently have any patients with osteoarthritis who you feel may benefit from homeopathic treatment (eg patients who are intolerant of or don't respond to NSAIDs). Should you have any suitable patients I would be extremely grateful if you could refer them to me at the Homeopathy Department, providing x-ray evidence of osteoarthritis.

If you have any queries, please feel free to contact me on 285 3707 Or the research team at LJMU on 0151 231 4056.

Thank you for your time.

Yours sincerely

Dr H Nielsen

Version 2 - Last updated 14 July 2006

Appendix 11

Letter to participants' GP to inform them of participant's involvement in the study

Department of Homoeopathic Medicine
Telephone: 0151 285 3707 * Fax 0151285 3755
Consultant: Dr W R Richardson MB BS FRCS MRCGP FFHom

Old Swan Health Centre
Crystal Close
St. Oswald's Street
Liverpool
L13 2GA

Dear Dr Smith

Re. Study

Thank you for your recent referral of Mrs X for homeopathic treatment of osteoarthritis here at Old Swan. I would like to inform you that the patient has consented to participate in a research study to be conducted at the centre. The study is of an observational nature and the patient will only be required to meet with the researcher for 10 minutes, on 4 separate occasions, to complete a questionnaire prior to her homeopathic appointment at the centre. She will also be asked to give a saliva sample for analysis of biomarkers of pain. Please see the attached Patient Information Sheet, last updated 14 June 2006 for more details.

If you require any further information regarding the study or the patient's involvement please feel free to contact me on 0151 231 4056 or to contact the staff at Old Swan on the above number.

Thank you for your time.

Yours sincerely

A Majumdar

Appendix 12

Patient consent form to participate in the phase 3 study

Department of Homoeopathic Medicine
Telephone: 0151 285 3707 * Fax 0151285 3755
Consultant: Dr H Nielsen BM BCH MRCP FFHom

Old Swan Health Centre
Crystal Close
St. Oswald's Street
Liverpool
L13 2GA

Centre Name: Old Swan Health Centre

Study Number : 1

Patient Information Number for this Trial:

CONSENT FORM

Title of Project: An investigation into the use of homeopathy for the management of osteoarthritis within a primary care setting: a preliminary study

Name of Reseracher: Anne Majumdar
Contact Number of Reseracher: 0151 231 4056

Please Initial box:

1. I confirm that I have read and understood the information sheet, last updated 14 June, 2006 for the above study. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. ☐
3. I understand that sections of any of my medical notes may be looked at by the researchers involved in the study. I give permission for these individuals to have access to my records. ☐
4. I agree to the interview being taped by the researcher. ☐
5. I give consent for my GP to be informed that I am participating in the study. ☐

Name of Patient	Date	Signiture
Name of Person Taking Consent (At the Old Swan Health Centre)	Date	Signiture
Researcher	Date	Signiture

Appendix 13

Interview Schedule for homeopathy interviews, phase 2

Interview Schedule - Homeopathy:

The interviews aim to derive the following information, though a semi-structured approach is used and the topics discussed may move freely from the schedule in order to further probe matters that arise. A description of information sought is presented along with the question itself, which is presented in bold.

Time Available: 45 Minutes

Q1 This question is a warmer and obtains information on the level of experience and training participants had. Also their background in terms of other therapies practised and conventional medicine is confirmed in this question.

1. How long have you practiced as a homeopath?
   - Initial interest?
   - Where did you Train?
   - Any other therapies practised?
   - How does your practice work?
   - Any NHS provision of homeopathy?

Q2 This is to tap into details of the preferred prescribing styles of practitioners (See phase 1(section 3.8). Phase one results showed that prescribing styles did vary and some significant differences were seen between medical and non-medical homeopaths. This question is to explore this further as many respondents to the survey commented that it was hard to answer the questions on prescribing in such a structured way

2. Do you consider your style to have changed since you first started out?
   - consulting style
   - prescribing - scale, liquid/tablets

Q3 There is a distinct pattern in commonly treated conditions for homeopaths (See phase one results, section 3.8) (Colin ,2000), (Thompson, 2004)) but as questions on treatment are included in this schedule it seems appropriate to first ask which they commonly treat to check that those mentioned in the survey are commonly encountered.

3. What conditions you most commonly treat?

Q4 This is to get some detail on matters during the consultation process through to prescribing. A lot of work has been carried out on the consultation process itself (Wetherly-Jones, 2005), (Ewes, 2006). Phase one results showed that non-medical

practitioners give longer consultations than medical practitioners in general (See section 3.8) and non-medical practitioners agreed more strongly that homeopathy was successful for treating certain conditions, so the main purpose of this question is to highlight any difference in method that might explain the difference in confidence in the treatment. Part b also explores some of the theory behind homeopathy and how this relates to treatment in practice, for example the movement of disturbance from most internal to the extremities described in Hering's Law, and the matter of aggravations, or side effects from homeopathic remedies.

4. a) I would like to now look more in-depth at matters during a consultation. I have an example of a lady who is suffering from osteoarthritis, is that ok? (Full case study ready) If treating osteoarthritis what questions would you want to ask the patient in order to help you to select a remedy?

- Then how do you go about selecting the remedy?

- What information would you use to decide what potency to prescribe?

- Which version of the Materia Medica do use?

b) Once the patient had begun homeopathic treatment for osteoarthritis what are the first changes that you would expect to see / would you be looking for to check if remedy is working?

- Herings law
- Aggravation?

Q5 This question highlights the number of attempts that a practitioner may take to get the correct remedy. It also is relevant to theories on the role of the placebo effect in homeopathic treatment since from a placebo point of view the specific remedy itself is not important.

5. Under what circumstances would you consider changing the remedy you prescribed?

- Does this happen regularly?

Q6 The amount of time to continue to deliver treatment and obtain an 80% improvement in symptoms was also different from different practitioner groups in survey in phase one and practitioners' views on what factors affect speed of treatment are an important part of understanding the therapeutics of homeopathy.

6. How long would you expect to treat someone similar to this lady, with osteoarthritis? What factors would influence the speed of improvement of symptoms?

Q7 This question is designed to gage practitioners' views on other medical systems. There were significant differences highlighted in these views by the phase one survey and it would be interesting to explore these further. Part b is to explore this on a personal level.

7. a) What is your opinion on other CAM?
   - TCM -Acupuncture / Herbalism
   - Ayurveda
   - Reiki/Reflexology/Chiropractics etc.
   - Conventional Medicine

   b) If a family member who lived elsewhere in the country had osteoarthritis and you not there would you advisor them to a Homeopath, Acupuncturist, GP, Herbalist or other?

Q8 is to further explore the differences seen in the perceived effectiveness of homeopathy seen in phase one of the study and also to explore the reasons why homeopathic treatment may be more effective for some illnesses than others.

8. a) What particular conditions have you noticed homeopathy to be most successful for?
   - Which least successful for?

8. b) Why more/less successful for these conditions?
   - More provings / remedies available?
   - Easier to recognise and match remedy?
   - Nature of the disease itself?

Q9 This question explores practitioners' views on the role of different aspects of treatment on therapeutics. Previous studies have explored the therapeutic role of the consultation process (Wetherley-Jones, 2005), (Ewes, 2006) and theorised the reasons for this with quantum physics and entanglement theory (Milgrom, 2004), (Walach, 2002). Practitioners opinion on this would be interesting.

9. How much of a successful homeopathic treatment would you say is due to the remedy itself and how much whole effect of treatment including the consultation and the patient's attitude?

Q10. Is to give participants a chance to comment further on homeopathic theory. The three statements used in Q10 are statements from leading theorists in homeopathy explaining the interaction of the remedy and the body/illness (See section 1.4 of thesis) and were placed down as prompts. Practitioners' views on the theories behind homeopathy were explored briefly in the practitioner survey in phase one of the current study, but a more open discussion on these would give a deeper insight into practitioners' views.

10. Do you have any further comments on the actions of homeopathy and on health and healing?

- Which of the following ideas to you believe to be relevant to homeopathy or what is your opinion on them? (Three statements on homeopathy will be written on pieces of card which will be displayed to homeopath)

A network of energy channels exist in the body that are quite separate from those identified by conventional physiology (Vithoulkas

Electro Dynamic fields exist in the body, partly determined by physiochemical properties, and maintains a pattern in the midst of a physio-chemicl flux. (Burr)

A treatment must be of the same essence as the disease and must be of the same frequency in order to extinguish the disease (Hahnmann)

Appendix 14

Letter of invitation to interview for phase 2 of the study

Dr. Nikki Adams BSc(Hons) PhD MCSP CPsychol

Reader In Health & Social Care

Liverpool John Moores University
70 Great Crosshall Street
Liverpool L3 2AB
Telephone: 0151 231 4056

Centre for Public Health

«TITLE» «FIRST_NAME» «SURNAME»
«M_1ST_ADDRESS»
«M_2ND_ADDRESS»
«M_3RD_ADDRESS»
«CITY_AND_POSTCODE»

6 June 2006

Dear «TITLE» «SURNAME»

Re. Interviews for Homeopathy Study

Many thanks for all your responses to the questionnaire on homeopathic practice that I sent out previously. These have been extremely useful. Analysis is still on-going and the results of the study will be made available by the completion date of my PhD study. Initial findings can be found in FACT, Volume 10, supplement 1 p 45.

I am now planning the second phase of the study. This involves interviews with practitioners on issues that arose during questionnaire analysis and other matters that require further attention.

As you may remember, I am a PhD student at Liverpool John Moores University and the aim of the study is to explore the mechanism of action of homeopathy and identify factors that determine the effectiveness of treatment. It is hoped that the information gained will be useful to practitioners and researchers and will assist the development of future homeopathy studies. Your opinions are extremely important to the study.

The interviews will take place at a location and time convenient to the practitioner. Each interview will last no longer than 45 minutes.

If you are willing to be interviewed for the study, I would be most grateful if you would provide your details on the attached sheet and return them to me in the prepaid envelope enclosed. Alternatively, Please feel free to contact me by email to: A.J.Majumdar@2003.ljmu.ac.uk

Please note that it is possible that not everyone who replies will be contacted for interview due to the limited time available for the study. If you have any queries please do not hesitate to contact me on 0151 231 4056 or on the email address above.

I look forwards to hearing your views. Many thanks for your time.

Yours sincerely

A J Majumdar
Research Student

Appendix 15

Form for registration of interest in participating in phase 2 of the study

Liverpool JMU
Centre for Public Health

Interview Phase of The Homeopathy Study

Please complete the following form if you are willing to be interviewed for the study and enclose it in the prepaid envelope provided: -

Name _____

Address _____

_____

_____

Email address _____

Contact number _____

Any additional information / availability:

Appendix 16

Sample transcript homeopathy transcript from phase 2

Sample Interview 20/09/07

Q So to start with, how long have you practised as a homeopath?

A Since 1982

Q What initial interest?

A I qualified as a doctor in 1977, in Dublin, and I also started meditating in my first year as a medical student, so I'd been meditating for 7 years when I qualified. So when I started working as a doctor I was horrified by the drugs, I felt like I was poisoning people, I was horrified by the side effect of drugs, and felt that the romantic notion of the doctor curing the patient and was very deflated by the reality of everyday medical practise and I just felt that I wasn't helping people or helping them to help themselves and that the whole drug industry was slightly skewed. And so I was prepared to give it all up, until someone told me about homeopathy and I came to London in 1981 to study at the Royal London Homeopathic Hospital, full time. And that has been my major source of therapeutic medicine ever since.

Q Do you also practice conventional medicine or any other therapies?

A I would say that I always work as a conventional practitioner who chooses to use homeopathy rather than conventional drugs. I'm also a trained Psychotherapist. I've also done some training in Acupuncture and diet (pause) Ayurvedic, traditional Indian Medicine. So the conventional medical training is at the core of what I do.

Q So when a patient comes to you for a consultation, would they come to you sometimes as an acupuncturist, sometimes as a conventional practitioner or do you have the same hat on each time?

A Yes, I tend to wear the same hat. I call myself a holistic doctor using non-drug approaches to help people, and mainly people would know that I do homeopathy. I don't call myself an acupuncturist I just use it in a rather Western way for Musculo-Skeletal things. I don't treat holistically with acupuncture, I use it in a symptomatic kind of way.

Q So how does your practise work, do you sometimes get referrals from GPs or do patients come directly to you?

A I am referred patients from various GPs who feel that either there patients are unsuitable to take drugs or do not wish to take drugs, Um by and large most patients are probably self-referred or referred by word of mouth.

Q And with the ones who are referred does the NHS cover the cost or is it always a private practice

A No, always privately, unless they have medical insurance

Q You've obviously practised as a homeopath for some time. Would you say that your style of practise has changed at all in that time?

A Yes I would, I think the change has gone more from being the expert trying to find a magic wand, to being much more relaxed. So instead of being the expert trying to find the magic bullet to deal with your problem, I have come more to see that we create an alliance together, doctor and patient. Which is part educational, part emotional attitude

and part physical, changing like diet and exercise and homeopathic medication. And this has been deepened by my journey into psychotherapy, and realising that...waiting to be drawn upon.

Q And in terms of the potencies and remedies you use, has there been any change?

A No I would say over the last 25 years of practise I probably follow the pattern that most of my colleagues share with me which is using low potencies for distinctly physical problems and using high potencies where there are more psychological and mental factors and using middle potencies where there is some mixture of both

Q And what form would you give the remedy in, would it be in liquid form or as a tablet?

A It tends to be a mixture of powders that I give in 3 or 6 doses. I use tablets for more long term medication and occasionally I would give that in alcohol if a patient is lactose intolerant and I would say that that has not changed. Oh and granules for babies of course.

Q And would you tend to use single remedies or multiple remedies?

A I'm classically trained and tend to use single remedies.

Q And that's always been the case as well?

A Yes

Q And what conditions do you usually come across?

A Well I call them conditions of men rather than conditions of medicine. People come to me for so many different reasons and so I don't have a huge database of eczema

cases and blood pressure cases etc. You know, people come to me with their own symptomatology.

Q But obviously practise a number of therapies, which therapies would you tend to say that you would focus on homeopathic treatment most?

A You mean what are the medical diagnoses that they come in the door with?

Q Yes.

A Um, Asthma, migraine, eczema, gastro, intestinal disturbances like digestive problems, thrush, Chronic fatigue syndrome, recurrent urinary cystitis, depression, stress, insomnia, lack of confidence, phobias, occasionally, joint musculo-skeletal problems, arthritis. That's just what comes into my mind, I'm sure there are more.

Q Just to get a better idea of what goes on in a consultation Can I talk you through a case study?

A Yes

Q If a 60 year old lady has come in to you with OA and she is fed up with conventional treatment what would happen first?

A Well I'd want to know the history of her arthritis, what joints were and how badly affected. What her symptoms she has and whether they are better worse, whether it runs in the family. I would want to know where she's at the moment in terms of her life. And I would want to know what medication had she been put on, for how long, had she felt on them and if she said they're not really helping I'd want to know what that means. Does it mean she is pain free but the arthritis is still there or does it mean that it's not even helping her symptoms at all. And having ascertained all of that I would discuss the options that I could offer her with would tend to fall into the dietary, the

homeopathy and the acupuncture treatment. In other words I have no doubt that eliminating toxins from the body and eliminating food intolerances helps to restore fuller vitality, better immune capacity, better digestion. And when all that's going well a lot of joint pains automatically either disappear or get better. That's number 1. And reducing food intolerances like wheat for example or dairy, which would show up on the blood test on the dietary side. On the homeopathic side I would take a full homeopathic case history, and then prescribe accordingly and ask, if she had had it for a eight years that we give it a 3 to 4 month trial before making a decision either way in whether it was helping on not. The body takes some time to respond. And thirdly if the symptoms were recent and in one joint only, I might do some local pain relief directly into the joint or around the joint, in addition to the other treatment. For example, I've had people coming here, looking like they need a hip replacement, and on anti-inflammatory medication, when using the right needle in the right place allowed them to be symptom free for 8 months, even though I'm not changing the joint disease I am reducing the need for anti-imflammatories and improved sleep etc.

Q So supposing you'd taking a full homeopathic history, how do you then transfer that knowledge into choosing a remedy? Do you already have an idea in your head by the end of the consultation?

A Homeopathy, and reading the material medica I would say... In taking a case study from the patient I would take a full standard homeopathic case history and would detail all of not only the bodily symptoms but the psychological state, the mode of life, the diet, the exacerbating and alleviating factors and the personality characteristics that gives us a picture of the sort of metabolic and physiological type we are dealing with and choose the remedy based on some of the physical, emotional and mental symptoms

Q Do you think that you can specifically notice modalities and types in people?

A Yes there does seem to be a general trend in that

Q So once you've got the picture and have an idea, what materials do you use to help you choose a remedy?

A I have Mac repertory on my computer but I don't sit down and repetorise every patient now, I'd have done that more years ago. I might use it to look up lists, o if I had an unusual symptom that had come up I might put it in to see if any interesting little known remedies come up but basically from my learned store I have a good sense and I would usually, while you're sitting there I would be picking up my material medica and I'd be doing a differential thing and say this and that and what about this and that and I'd be thumbing through, leafing through, just to keep my knowledge reality based rather than a fantasy of my own, um, so that's Remoons concordance or my other favourite book is Berica's material medica, it's well thumbed.

Q So once you have selected the remedy, what happens next, would the patient get the remedy from you yourself?

A No. Love to be a magic shaman that gives a magic pill. Time wise I'm single handed, it doesn't work for me. And also I'm lucky in my location, Ainsworths Homeopathic Pharmacy is round the corner. So I would discuss with the patient our plan of action, what remedy I would suggest, get their consent and Agreement, I'd like to precede in that way, I'd write out a prescription, hand it to the patient, draw them a map of how to get to Ainswoths round the corner and they would fill it out.

Q Ok, And so once she has gone home with her remedy, what would be the next contact between the two of you?

A Um, I would say to her I would like to see you within a month for a follow up appointment and if you have any questions or problems in the meantime, call me.

Q Ok, And once she's back what kind of thing are you looking for?

A If there were a lot of emotional factors in the case and I felt that were weighing her down and going into the pain of her arthritis as a target, I might have to invite her back, interesting I say her, it might be a him in fact, then I might invite her or him back within a week, sometimes two weeks, if they were very heavily loaded. It may be that the OA is quite manageable but appears to be unmanageable do to her present stress levels and that might present a different scenario, if I am to see people sooner. To answer your question for the person who comes back after the month for the first time we would rectify what we had done with her diet, we could check on the progress of her symptoms and how they got on after the homeopathy and then take a decision to change the dose, repeat it stop it, change the remedy.

Q If you wanted to check if the patient had been given the correct remedy what sot of things would you look for?

A Well, I often say to the patient, that the story that you told me, gave me an idea of what kind of person you are and seemed to fit in very nicely with one of our remedies "shall I read it to you?" And I would read out the salient features, and they often say " Oh Gosh, that sounds just like me" or " Gosh yes, did I say all that?" So I am already hyping up the sympathetic resonance and the expectations of helping themselves in taking this remedy, and let us know where we are.

Q And what kind of improvements would you be looking for?

A Any, that's what I'm looking for, What has changed, what hasn't changes, what's better, what's worse, what's new.

Q In particular with this lady, are there an specific changes in her symptoms that you would be looking for already? Are there any specific improvements that you would expect at this time?

A No, Absolutely not. That's not true, you might get an inflammation in swelling or inflammation but that's all. And changes in their vitality.

Q And under what circumstances might you consider changing the remedy?

A I try not to, I try to interfere as little as possible. I tell them it's like a ball rolling down a hill, slowly getting better and better. Getting better is natural to us, it's written into our system. We're always getting better. And all we are doing is stopping the arthtocraf that is stopping the natural process. And I would say homeopathy is just for when the ball stops rolling, the remedy is just like giving it another kick to keep it moving. The only reasons for changing it apart from nothing happening, is it could be that a lots has happened and it has revealed a deeper layer that is ready for the next remedy. It could be that I decide that this patient needs that remedy and a nosode, a miasmatic remedy which I would not like to prescribe at the same time but would make notes to give it next time. So in that case I would probably change the remedy 25 to 30% of the time.

Q And after you have started to give a remedy that has brought about improvements how long would you expect them to be on the remedy?

A Usually with a combination of diet and remedy, many patients would come to a place where they are seriously reducing the amount of pain medication or where the symptoms have gone altogether or are no longer a problem. Even though they know that their joint is compromised, it doesn't bother them they find they can live with it. They may be able to stop homeopathy all together and only resurrect it on an as need basis, should their circumstances change.

Q Ok. You've obviously practise other therapies too so it appears that you are quite open to them.

A Yes

Q So how about your views on conventional Western medicine.

A I have greatest respect for western medicine. But it is limited as a model of health and disease. And I believe a lots of medicine distortions come from the pharmaceutical industry, as they're only interested in expensive drugs, rather than what is good for patients.

Q You're quite unique really in that you are able to offer a number of different therapies to patients. Supposing someone, say a close friend or relative called you to ask your advice. They had a medical problem but for some reason, maybe you were on holiday or too far away, you were unable to treat them. Who would you refer them to?

A For diagnosis I would advise them to see a GP, but for treatment of OA I would suggest to them to go to a holistic practitioner, either an acupuncturist or a homeopath.

Q And would you recommend that they see a holistic practitioner who is medically trained?

A By and large I have colleagues around the country and I always like to refer to people I know, but I have on occasion approached non medical practitioners with regard to acupuncture, usually colleagues, and with regard to homeopathy if there aren't Drs available I would not hesitate to recommend a good lay homeopath, or should I say a non-medically qualified homeopath, because some of the non-medically qualified practitioners are very good.

Q Are there some conditions that are easier to treat with homeopathy than others?

A I am not sure I could narrow it down just like that because again that is going down the non-medical path of classifying everything by its lowest common denominator and

holistic practitioners are interested in the person, removing the obstacles and supporting them.

Q how about certain types of people, are some easier to treat than others?

A Yes, if you get a person with a family history of homeopathy all there lives and are used to it, more than anything else. If you get people who are sent along by there mother and don't want to be there then that's difficult.

Q Are there any physical or personality characteristics that affect it

A Yes lots affect it but will they make it useless, that's different. People who have multiple pathologies, these are the heavy end cases of all medicines no matte what you practise and have been messed about by different people for a long time are obviously don't respond as well as people who are fresh.

Q How much of the effectiveness of homeopathy would you put down to the remedy itself and how much to the whole process

A I can't answer that, I don't know. For the past 25 years of my practise, I have walked either side of that line, and I still don't know. And I have taught with vetinary practitioners and seen treatments work in animals with the most obscure conditions, cycstitis in cats, mastitis, eczema in dogs, horse diseases, and I see pictoral evidence from my vetinary colleagues that astonishes me.

Extracts:

A network of energy channels exist in the body that are quite separate from those identified by conventional physiology:

As much as I understand this statement I would say yes.

A treatment must be of the same essence as the disease and must be of the same frequency in order to extinguish the disease:

I'd say most similar not the same, and same frequency or higher in order to extinguish the disease.

I would say that all of us are already self healing. I would take this to mean that homeopathy does not interfere with the self healing processed capacity of the body which conventional medicine does. And that homeopathy actively supports that capacity

Q What do you say to sceptical medical colleagues, how would you describe where HP interacts with the body?

A It's an alternative that does not poison the body, that is safer than drugs, supports the body in active terms to heal itself and works with nature instead of trying to biologically override nature, and has a proven track record of over 200 years and is a useful tool for any GP for any non-serious non-surgical cases.

Q Thank you very much, any comments you would like to make?

A Only that you are a very good researcher, completely bland, and give nothing away, and I wish you luck with your study.

Appendix 17

WOMAC tool used in phase 3 of the study

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Appendix 19

MYCAW Tool for phase 3 of the study

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Appendix 19

SF36 Tool used in phase 3 of the study

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Appendix 20

Permission form for audio-recordings of homeopathy interviews in phase 2 of the study

Faculty of Health

An investigation into the views and practices of homeopathic practitioners in the UK

I give permission for Anne Majumdar to audio record and transcribe my interview conducted as part of her PhD study at Liverpool John Moores University. I understand that the transcript will be confidential and only used for the purposes of the study and that I will not be identified in anyway in the findings of the study. I understand that the audio recordings will be destroyed 6 weeks following transcription.

Signed _____ Date _____

Print Name _____

Appendix 21

Complete table of correlations of outcome tools in phase 3

Correlations

			m1ycaw1	m1ycaw2	SubsP1	p1ainvasflat	p1ainvasstairs	p1ainvasbed	p1ainvassit
Spearman's rho	m1ycaw1	Correlation Coefficient	1.000	.173	.179	.692*	.341	.098	.311
		Sig. (2-tailed)	.	.610	.620	.018	.304	.775	.352
		N	11	11	10	11	11	11	11
	m1ycaw2	Correlation Coefficient	.173	1.000	-.199	.117	.366	.105	.222
		Sig. (2-tailed)	.610	.	.582	.733	.268	.759	.512
		N	11	11	10	11	11	11	11
	SubsP1	Correlation Coefficient	.179	-.199	1.000	.518	.103	-.091	-.530
		Sig. (2-tailed)	.620	.582	.	.125	.776	.802	.115
		N	10	10	20	10	10	10	10
	p1ainvasflat	Correlation Coefficient	.692*	.117	.518	1.000	.594	-.123	.311
		Sig. (2-tailed)	.018	.733	.125	.	.054	.719	.353
		N	11	11	10	11	11	11	11
	p1ainvasstairs	Correlation Coefficient	.341	.366	.103	.594	1.000	.046	.205
		Sig. (2-tailed)	.304	.268	.776	.054	.	.894	.544
		N	11	11	10	11	11	11	11
	p1ainvasbed	Correlation Coefficient	.098	.105	-.091	-.123	.046	1.000	-.036
		Sig. (2-tailed)	.775	.759	.802	.719	.894	.	.915
		N	11	11	10	11	11	11	11
	p1ainvassit	Correlation Coefficient	.311	.222	-.530	.311	.205	-.036	1.000
		Sig. (2-tailed)	.352	.512	.115	.353	.544	.915	.
		N	11	11	10	11	11	11	11
	p1ainvasup	Correlation Coefficient	.040	.466	-.401	.053	.442	-.027	.066
		Sig. (2-tailed)	.907	.149	.251	.878	.174	.936	.846
		N	11	11	10	11	11	11	11
	s1lffmom	Correlation Coefficient	.460	.618*	-.293	.116	.224	.278	-.030
		Sig. (2-tailed)	.154	.043	.412	.733	.508	.408	.931
		N	11	11	10	11	11	11	11
	m1ycawwb	Correlation Coefficient	-.012	.890**	.061	.002	.161	.238	-.007
		Sig. (2-tailed)	.973	.000	.868	.995	.637	.481	.984
		N	11	11	10	11	11	11	11
	SFLimphy1	Correlation Coefficient	-.023	-.128	-.767**	-.475	-.245	.085	.320
		Sig. (2-tailed)	946	.708	.010	.140	.468	.804	.338
		N	11	11	10	11	11	11	11

Correlations

			m1ycaw1	m1ycaw2	SubsP1	p1ainvasflat	p1ainvasstairs	p1ainvasbed	p1ainvassit
Spearman's rho	SFphysica1	Correlation Coefficient	-.104	-.317	.123	-.088	-.552	-.286	.157
		Sig. (2-tailed)	.761	.342	.734	.797	.078	.394	.645
		N	11	11	10	11	11	11	11
	SFLimemo1	Correlation Coefficient	.136	-.607	-.176	.147	-.049	.273	.359
		Sig. (2-tailed)	.709	.063	.651	.685	.893	.445	.308
		N	10	10	9	10	10	10	10
	SFsocial1	Correlation Coefficient	-.155	-.916**	-.066	-.261	-.477	-.260	-.163
		Sig. (2-tailed)	.650	.000	.857	.439	.138	.440	.632
		N	11	11	10	11	11	11	11
	SFMental1	Correlation Coefficient	.424	-.393	-.210	.123	.283	-.086	.173
		Sig. (2-tailed)	.222	.261	.561	.734	.428	.813	.633
		N	10	10	10	10	10	10	10
	SFPain1	Correlation Coefficient	.447	.466	.473	.592	.634*	.380	.035
		Sig. (2-tailed)	.168	.149	.167	.055	.036	.250	.918
		N	11	11	10	11	11	11	11
	SFghp1	Correlation Coefficient	-.456	.289	-.313	-.583	-.370	.257	-.084
		Sig. (2-tailed)	.159	.389	.379	.060	.262	.445	.805
		N	11	11	10	11	11	11	11
	SFVitener1	Correlation Coefficient	.317	-.560	-.426	-.095	-.086	.324	.239
		Sig. (2-tailed)	.373	.092	.219	.794	.814	.361	.506
		N	10	10	10	10	10	10	10

Correlations

			p1ainvasup	s1iffmom	m1ycawwb	SFLimphy1	SFphysica1	SFLimemo1	SFsocial1
Spearman's rho	m1ycaw1	Correlation Coefficient	.040	.460	-.012	-.023	-.104	.136	-.155
		Sig. (2-tailed)	.907	.154	.973	.946	.761	.709	.650
		N	11	11	11	11	11	10	11
	m1ycaw2	Correlation Coefficient	.466	.618*	.890**	-.128	-.317	-.607	-.916**
		Sig. (2-tailed)	.149	.043	.000	.708	.342	.063	.000
		N	11	11	11	11	11	10	11
	SubsP1	Correlation Coefficient	-.401	-.293	.061	-.767**	.123	-.176	-.066
		Sig. (2-tailed)	.251	.412	.866	.010	.734	.651	.857
		N	10	10	10	10	10	9	10
	p1ainvasflat	Correlation Coefficient	.053	.116	.002	-.475	-.088	.147	-.261
		Sig. (2-tailed)	.878	.733	.995	.140	.797	.685	.439
		N	11	11	11	11	11	10	11
	p1ainvasstairs	Correlation Coefficient	.442	.224	.161	-.245	-.552	-.049	-.477
		Sig. (2-tailed)	.174	.508	.637	.468	.078	.893	.138
		N	11	11	11	11	11	10	11
	p1ainvasbed	Correlation Coefficient	-.027	.278	.238	.085	-.286	.273	-.260
		Sig. (2-tailed)	.936	.408	.481	.804	.394	.445	.440
		N	11	11	11	11	11	10	11
	p1ainvassit	Correlation Coefficient	.066	-.030	-.007	.320	.157	.359	-.163
		Sig. (2-tailed)	.846	.931	.984	.338	.645	.308	.632
		N	11	11	11	11	11	10	11
	p1ainvasup	Correlation Coefficient	1.000	.723*	.285	.273	-.729*	.016	-.382
		Sig. (2-tailed)	.	.012	.396	.417	.011	.964	.246
		N	11	11	11	11	11	10	11
	s1iffmom	Correlation Coefficient	.723*	1.000	.484	.165	-.617*	-.147	-.507
		Sig. (2-tailed)	.012	.	.131	.628	.043	.685	.111
		N	11	11	11	11	11	10	11
	m1ycawwb	Correlation Coefficient	.285	.484	1.000	-.218	-.216	-.642*	-.909**
		Sig. (2-tailed)	.396	.131	.	.519	.524	.045	.000
		N	11	11	11	11	11	10	11
	SFLimphy1	Correlation Coefficient	.273	.165	-.218	1.000	.096	.384	.354
		Sig. (2-tailed)	.417	.628	.519	.	.779	.273	.286
		N	11	11	11	11	11	10	11

Correlations

			p1ainvasup	s1iffmom	m1ycawwb	SFLimphy1	SFphysica1	SFLimemo1	SFsocial1
Spearman's rho	SFphysica1	Correlation Coefficient	-.729*	-.617*	-.216	.096	1.000	-.136	.433
		Sig. (2-tailed)	.011	.043	.524	.779	.	.708	.183
		N	11	11	11	11	11	10	11
	SFLimemo1	Correlation Coefficient	.016	-.147	-.642*	.384	-.136	1.000	.527
		Sig. (2-tailed)	.964	.685	.045	.273	.708	.	.117
		N	10	10	10	10	10	10	10
	SFsocial1	Correlation Coefficient	-.382	-.507	-.909**	.354	.433	.527	1.000
		Sig. (2-tailed)	.246	.111	.000	.286	.183	.117	.
		N	11	11	11	11	11	10	11
	SFMental1	Correlation Coefficient	-.022	-.034	-.550	.337	-.038	.128	.462
		Sig. (2-tailed)	.953	.926	.100	.341	.918	.742	.179
		N	10	10	10	10	10	9	10
	SFPain1	Correlation Coefficient	.028	.261	.467	-.655*	-.470	-.152	-.718*
		Sig. (2-tailed)	.934	.439	.147	.029	.144	.675	.013
		N	11	11	11	11	11	10	11
	SFghp1	Correlation Coefficient	.223	.197	.515	.500	.118	-.307	-.196
		Sig. (2-tailed)	.510	.562	.105	.118	.729	.389	.564
		N	11	11	11	11	11	10	11
	SFVitener1	Correlation Coefficient	.022	.135	-.738*	.374	-.270	.818**	.554
		Sig. (2-tailed)	.953	.710	.015	.286	.450	.007	.097
		N	10	10	10	10	10	9	10

Correlations

			SFMental1	SFPain1	SFghp1	SFVitener1
Spearman's rho	m1ycaw1	Correlation Coefficient	.424	.447	-.456	.317
		Sig. (2-tailed)	.22[illegible]	.168	.159	.373
		N	10	11	11	10
	m1ycaw2	Correlation Coefficient	-.393	.466	.289	-.560
		Sig. (2-tailed)	.26[illegible]	.149	.389	.092
		N	10	11	11	10
	SubsP1	Correlation Coefficient	-.210	.473	-.313	-.426
		Sig. (2-tailed)	.56[illegible]	.167	.379	.219
		N	10	10	10	10
	p1ainvasflat	Correlation Coefficient	.123	.592	-.583	-.095
		Sig. (2-tailed)	.734	.055	.060	.794
		N	10	11	11	10
	p1ainvasstairs	Correlation Coefficient	.283	.634*	-.370	-.086
		Sig. (2-tailed)	.428	.036	.262	.814
		N	10	11	11	10
	p1ainvasbed	Correlation Coefficient	-.086	380	.257	.324
		Sig. (2-tailed)	.813	.250	.445	.361
		N	10	11	11	10
	p1ainvassit	Correlation Coefficient	.173	.035	-.084	.239
		Sig. (2-tailed)	.633	.918	.805	.506
		N	10	11	11	10
	p1ainvasup	Correlation Coefficient	-.022	.028	.223	.022
		Sig. (2-tailed)	.953	.934	.510	.953
		N	10	11	11	10
	s1iffmom	Correlation Coefficient	-.034	.261	.197	.135
		Sig. (2-tailed)	.926	.439	.562	.710
		N	10	11	11	10
	m1ycawwb	Correlation Coefficient	-.550	.467	.515	-.738*
		Sig. (2-tailed)	.100	.147	.105	.015
		N	10	11	11	10
	SFLimphy1	Correlation Coefficient	.337	-.655*	.500	.374
		Sig. (2-tailed)	.341	.029	.118	.286
		N	10	11	11	10

Correlations

			SFMental1	SFPain1	SFghp1	SFVitener1
Spearman's rho	SFphysica1	Correlation Coefficient	-.038	-.470	.118	-.270
		Sig. (2-tailed)	.918	.144	.729	.450
		N	10	11	11	10
	SFLimemo1	Correlation Coefficient	.128	-.152	-.307	.818**
		Sig. (2-tailed)	.742	.675	.389	.007
		N	9	10	10	9
	SFsocial1	Correlation Coefficient	.462	-.718*	-.196	.554
		Sig. (2-tailed)	.179	.013	.564	.097
		N	10	11	11	10
	SFMental1	Correlation Coefficient	1.000	-.131	-.273	.422
		Sig. (2-tailed)	.	.718	.446	.224
		N	10	10	10	10
	SFPain1	Correlation Coefficient	-.131	1.000	-.383	-.156
		Sig. (2-tailed)	.718	.	.245	.668
		N	10	11	11	10
	SFghp1	Correlation Coefficient	-.273	-.383	1.000	-.396
		Sig. (2-tailed)	.446	.245	.	.258
		N	10	11	11	10
	SFVitener1	Correlation Coefficient	.422	-.156	-.396	1.000
		Sig. (2-tailed)	.224	.668	.258	.
		N	10	10	10	10

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Appendix 22

Sample transcript phase three

Q So how've you been since last time?

A Not too bad. This wrist is troubling me a bit but it's not as bad as it could be. It's just a little bit worse than it was last time that's all but it's not bad at all really.

Q So it does actually feel worse than last time?

A No I feel that the tablets are doing something because since I've been taking them they've never woken me up in the night. It's never woken me up the arthritis so that's a good thing. Because sometimes it used to wake me up you know, the pain in me fingers because it's mostly in me hands. So I think it must be doing something.

Q That's good. Are you still on the same, is it the same tablets that your taking. So basically I'm going to go through the same questions as last time. This is for the saliva sample. So basically there are these MYCAW scales and you'd mentioned the pain in your fingers and thumbs and wrist as your main concern which would you say.

A Well the wrist is bothering me this time. It's the thumbs really though. I mean that on (left thumb) is ok really now but I couldn't say that it wasn't bad.

Q And the grip strength was your other previous main complaint

A That's pretty much the same actually the grip. But it's not that bad, I mean I can do pretty much what I need to, so it's not bad. I'd say it's 4, no 3.

Q Ok, and you're overall well being?

A No it's alright, 2.

Q And during the time between your last appointment and this one are there any other things that might have influenced your health, any changes or events or holiday?A I don't think so no. It's been quite typical really.

Q And looking at your experiences of coming here, what kind of things have you found compared to what you were expecting?

A Um, I don't know what I was expecting really, ermyou know, I knew it'd be in tablet form. I really didn't believe it would do anything to be honest but you know I thought I'd give it a go and I think I proved myself wrong in that sense although the winter's not here yet so that's the test. The doctor says she could give me a stronger one if it starts to feel worse but at the moment it feels fine you know. And I don't think I have been struggling so much but then like I say the winter's not here yet but I do take my rings off and they used to get stuck on and I'd get worried you know that I'd have to have them cut off. So I tend now to take them off in the house anyway and I don't sleep in them any more which I used to so erm so I do take the rings off because my fingers did swell up and I couldn't get the rings off but they don't seem to have done that. But as I say the winter's not here yet.

Qis that the usual pattern that it gets worse in winter?

A Well I think it does. Well I say that but I haven't really looked at it till I've been on this programme if you like so I'm just going to look at it when it gets a lot worse.

Q And have you been taking many painkillers this past couple of months?

A No I only take one of a night

Q Ok, And which ones do you take?

A I take, well the other day I took one paracetamol and another one a couple of days later. I think that was for me wrist.

Q And how often does that happen?

A No that's quite rare really. And I take halopidole over night yeah. I tend to take paracetamol in the day if I need it but that doesn't happen much. You can get too used to painkillers.

Q Yeah, that's the problem as well. So do you remember these visual scales of pain? They are more for the knees, but I believe you also had some trouble with your knees?

A Yeah, I mean the knees aren't bad until I'm walking up the stairs or down the stairs. It's only when they bend really. They don't bother me normally unless I'm, at the moment I mean I have had pain in my knees but since I've been on these tablets, because sometimes in would wake me up in the night the pain in my legs and it's really, I haven't had any pain in my legs since.

Q So if you're walking on flat ground?

A Very little pain, quite low down. There.

Q And when you're walking up stairs?

A Yeah, it is a bit, I'd put it there.

Q And during the night?

A That's not bothered me for a while, there.

Q And when you're sitting like you are now?

A That's fine. Here.

Q And when you get in the morning, the pain.

A Not too bad really, I'd put it here. It's just getting going really in the morning.

Q Yeah, so is really stiffness in the morning rather than pain?

A Yeah, I do have a bit of stiffness, I'd put it here.

Q So it's the SF36 now:

(Pretty straight forward, only notes that are not encaptured on the questionnaire are documented here: -)

A I don't lift things anyway so it doesn't get in the way really.

Bending and kneeling does bother me a bit, I can't get up again.

"My Health is Excellent" :-
Well as far as I know it is yeah coz I mean I don't often go to the doctors, I mean I have thyroxine but that's because I've got low thyroids so that's all really. So mostly true.

Q So was it the Doctor that suggested you had homeopathy in the first place or was it just something you'd thought of?

A Well I went to them because they were getting worse you see. I don't go periodically. I had just been using that Ibruprofen gel as it's called, to be honest it's more me husbands that gel, but I want and I had had one off one of the doctors and he gave me another one, and that's why I went and he said something about the homeopathic and he said would you like to try some and I said why not and I'd say I haven't used the gel much since I started coming here. I only had the one tube and I've still got that tube or some of it. It didn't really do much good to be honest but you know.

Q That's great well I've followed you for 6 months and it's only a six month study so next time you won't have to see me.

A The Dr said it should be in 2 months but she didn't say when

Q Yes, just tell them that at the desk and they'll sort it out for you. Many thanks and take care.

Appendix 23

Conference presentations and published abstracts

Conference Attendances

The posters or published abstracts used for some of the conference presentations related to this PhD study are displayed in the following pages:

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