Abstract

Osteoarthritis is common with radiographic features practically universal in at least some joints in people aged over 60 years. One of the main therapeutic interventions used in the management of osteoarthritis is the injection of corticosteroid and hyaluronan (Gossec 2006). However, there exist few studies that seek to explore possible factors that influence outcome following injection. This study examined the factors that may influence the outcomes following injection of either corticosteroid or hyaluronan in the management of osteoarthritis of the knee.

The study involved the use of a mixed methodology. The quantitative component consisted of a pre / post test design with subjects acting as their own control. Outcomes and correlations were assessed using the Short Form McGill Pain Questionnaire (SF-MPQ) (Melzack 1987) and the Arthritis Impact Measurement Scale 2-Short Form (AIMS2-SF) (Guillemin 1997). Additional pre-injection factors recorded included degree of radiographic degeneration and amount of aspirate obtained at injection. The qualitative component involved interviews which were undertaken at initial consultation and 3 month review. The data obtained was used to explore subject’s experience of their condition and expected outcomes.

In all 38 subjects were recruited and prospective repeated measures were recorded at initial consultation, 1 month and 3 month post injection. Statistical analysis examined perceived outcome post injection and to look for relationship between pre-injection SF-MPQ, AIMS2-SF scores, radiographic reported degeneration, degree of aspirate and age with reported change in outcome post injection. Interview data from both the initial consultation and 3 month review was explored using a thematic analysis.

Data analysis demonstrated a significant improvement in reported measures for the key domains measured (p<0.05). Correlation between pre-injection factors and reported outcomes suggested that pre-injection levels of perceived anxiety and levels of reported social interaction correlated strongly with poor outcome such that high levels of reported anxiety and low levels of social interaction correlated with poor outcome (p<0.01). X-ray reported degenerative change also correlated with poor outcome but only as measured on the AIMS2-SF symptom domain (p<0.05) and age correlated with the AIMS2-SF symptom score and lower limb function scores (p<0.05) such that older age was linked with poorer outcome.

Thematic analysis of the interview data exposed a number of issues that potentially impacted on outcome following intervention. These initial emergent themes were subsequently reduced into 4 key themes.

The findings of this study support the view that an understanding of the ‘non-physical’ factors which influence outcome has the potential to inform management strategies and allow the development of more clinically and cost-effective treatment regimes.

The study was supported with a grant from the Arthritis Research Campaign (ARC).
Declaration

I declare that the research contained in this thesis, unless otherwise formally indicated within the text, is the original work of the author. The thesis has not been previously submitted to this or any other university for a degree, and does not incorporate any material already submitted for degree.

Signed

Dated
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# Glossary of Terms

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<tr>
<td>OA</td>
<td>Osteoarthritis</td>
</tr>
<tr>
<td>AHP</td>
<td>Allied Health Professional</td>
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<tr>
<td>SF-MPQ</td>
<td>Short Form McGill Pain Questionnaire</td>
</tr>
<tr>
<td>AIMS2-SF</td>
<td>Arthritis Impact Measure Scales Short Form</td>
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<tr>
<td>CoR</td>
<td>Coefficient of Repeatability</td>
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<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
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<tr>
<td>PPI</td>
<td>Present Pain Intensity</td>
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<td>BMI</td>
<td>Body Mass Index</td>
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<tr>
<td>WOMAC</td>
<td>Western Ontario and McMaster Universities Osteoarthritis Index</td>
</tr>
<tr>
<td>NSAID’s</td>
<td>Non-Steroidal Anti-Inflammatory Drugs</td>
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<tr>
<td>KOOS</td>
<td>Knee injury and Osteoarthritis Outcome Score</td>
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<tr>
<td>mRNA</td>
<td>Messenger Ribonucleic Acid</td>
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<tr>
<td>HAD</td>
<td>Hospital Anxiety and Depression scale</td>
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<td>MPQ</td>
<td>McGill Pain Questionnaire</td>
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<tr>
<td>HAQ</td>
<td>Health Assessment Questionnaire</td>
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<tr>
<td>EQ</td>
<td>Euroqol instrument</td>
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<td>HA</td>
<td>Hyaluronan</td>
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Chapter I Background

1 Title
Injection therapy in the management of osteoarthritis of the knee.

2 Introduction
The aim of this section is to present an overview of the geographical area in which I work in so far as this has the potential to impact on any research study undertaken. In addition an overview of my clinical practice and the development of extended scope work within my profession are provided, outlining how and why this influenced my decision to develop a research question grounded within my work. There follows a discourse, examining how I arrived at a specific research question, how this question was refined, and how this was embedded within my professional practice. A background to the area of study including a review of current knowledge concerning the normal and the osteoarthritic joint in conjunction with a review of associated risk factors will proceed. Finally, there follows a review of corticosteroid and hyaluronan injection in the management of osteoarthritis together with an outline of some of the factors which may influence outcome following their use.

3 Geographical and Demographic Outline of Study Location
In outlining the geographical and demographic characteristics of the area in which my practice is based and from which this study’s subjects were recruited the aim is to provide the reader with a sense of the environment in which the study took place. This has the potential to significantly impact the findings in terms of their generalisability.
The London Borough of Hackney is one of 14 Inner London boroughs and is located in the north-east of the city. The southern tip of Hackney is just under a mile north of the River Thames. Hackney is one of the 33 boroughs making up Greater London and its direct neighbours are the City, Islington, Haringey, Waltham Forest, Newham and Tower Hamlets. It has an area of 18.98 square kilometres making it one of the smallest London boroughs.

Figure 1 Geographical location of The London Borough of Hackney

(Taken from: Hackney Council official website. www.hackney.gov.uk)

With the restructuring of the London economy during the 1970s and 1980s much of the larger firms and industries were wiped out. Much of what was left were the low intensity enterprises such as car-breakers, scrap dealers and cheap warehousing. More recently Hackney has seen a change with the development of new growth industries attracted by the position the borough occupies between Stratford, Canary Wharf and the thriving financial hub of London, the City.
Hackney’s population is recorded as 209,656 and it is estimated that around 100 languages are spoken in the borough (ODPM 2007). Unemployment rates based on the number of people in receipt of unemployment related benefits in May 2007 were 7.9%, as compared to London as a whole 4.1%, and England 3.2%. In addition Hackney is recorded as the second most deprived local authority in England (ODPM 2007). All these factors have the potential to influence outcome and effect pretreatment perceptions and expectations in regard to therapeutic intervention and should be borne in mind when the findings are finally discussed.

4 Extended Scope Physiotherapy and My Own Practice

Although not unique to Hackney the social structures outlined have bearing on my own clinical practice and suggest specific needs in terms of the development of research into this practice. In particular given the increasing medical and socioeconomic burden of osteoarthritis the need for new ways of working have become of distinct relevance, resulting in a pressing need to manage patients with non-surgical treatments, an area which was increasingly being staffed by extended scope practitioners with backgrounds in Nursing and the Allied Health Professions (AHPs).

Traditionally the extended role of AHPs has involved a substitution of traditionally doctor led services and appears to be an ever increasing area of development within the National Health Service (NHS) across all AHP and nursing professions.
The impact on the NHS of extended practice has the potential of solving a number of problems including long waiting lists, financial overspends, and impending manpower crisis prompted by the development of the New Deal European Working Time Directive (2003). Indeed the Department of Health’s Policy document ‘Ten Key Roles for AHPs’ (2003) emphasized the need for AHPs to ‘extend and develop new roles and move towards new ways of working’. In addition AHPs would seem to have a vested interest in extending their roles with perceived benefits including increased job satisfaction, a greater sense of autonomy, and enhanced career prospects. Certainly if I consider my own position there is a desire to try and deliver the best possible service that can be achieved within the available resources. However, I would be wrong if I did not concede that my own ambitions have weighed heavily on my professional development to date. The ability to work in an extended scope role and to be able ‘to do more’ from a clinically perspective, I believe has much to do with issues such as power, influence and kudos in regard to my patients and also my colleagues. I think that this needs to be exposed at the beginning because as a researcher, within my own practice, there is an inherent danger that the research serves to further my own ambitions. Moreover there is the potential for it take on my own values and beliefs rather than being able to grow independently. This issue is something that I started the doctorate with and which represented a considerable concern to me. In raising this issue now I hope to demonstrate that through a process of reflexivity I can maintain a degree of honesty that allows my research process sufficient transparency and reliability.
Returning to the issue of extended scope, there is overall a general consensus that extended practice is a good thing (Hockin and Bannister 1994, Byles and Ling 1989, Daker-White 1999). Although there do exist a number of anxieties with both physiotherapists and doctors reporting concerns with regard to litigation, lack of confidence and fear of adverse reactions when using injection skills as well as issues around variations in training and competencies (Milligan 2003, Ellis and Kersten 2002).

The Department of Health’s (DH) briefing paper ‘Evaluating Models of Service Delivery’ (2006) concluded that provided there are clear and proven benefits extended practice should be encouraged but that a number of weaknesses needed to be urgently addressed. One of the weaknesses identified was the lack of research skills within the AHP community making the evaluation of extended practice treatments and interventions difficult.

My own practice reflects this changing role being located within both City and Hackney Primary Care Trust and the Homerton University Hospital Foundation Trust. Clinics involve the assessment and treatment of both spinal and peripheral musculoskeletal pathology and in particular peripheral intra and peri-articular problems. Within the service I am one of the clinical leads who have had a primary role in the development of extended scope of practice.

Much of this development has lead to City and Hackney Primary Care Trust and the Homerton University Foundation Trust over a number of years developing a specialised
musculoskeletal service called ‘The Locomotor Service’. The Locomotor Service was initially designed in recognition of the fact that the greater part of referrals from primary care for musculoskeletal pathology were neither related to systemic inflammatory disorders or in need of surgical management. In consequence these referrals could be managed by specialist physiotherapists in the primary care setting rather than by secondary care consultants. Indeed figures have shown that of all musculoskeletal referrals to The Locomotor Service approximately 90% have been managed without referral to secondary care (Data from Internal Audit – Unpublished).

This model of service design is not completely new and has been demonstrated to work elsewhere with a number of studies backing its efficacy. Weale (1995) and Daker-White (1999) established that an appropriately trained physiotherapist is as effective as a staff grade surgeon in managing orthopaedic outpatients and incurs lower initial direct hospital costs. Hockin and Bannister (1994) concluded that a physiotherapist, with extended training in the use of local steroid injections was able to manage 85 percent of orthopaedic outpatients independently of a consultant. Importantly a study by Byles and Ling (1989) also demonstrated that as well as 60 percent of musculoskeletal referrals being managed by an appropriately trained physiotherapist the patient self-reported satisfaction rate for this service was 89 percent. In addition it has been established that injection therapy is best utilised as an adjunct to other forms of rehabilitative treatment (Nelson 1995, Kerlan 1989). This is important as in practice it means that the use of either hyaluronan or corticosteroid injection in the treatment of osteoarthritis should be
used to facilitate a patients rehabilitation program and should not be used in isolation as is often the case in secondary care clinics.

Although the efficacy of such an extended scope service has been demonstrated many of these studies have examined the role of the physiotherapist working in conjunction with medical colleagues (Weale 1995, Daker-White 1999, Byles and Ling 1989). There are no studies that have looked at outcomes of injection therapy in physiotherapist led clinics. In an attempt to address this and provide both justification for my practice and to increase my own self confidence a study was carried out in my clinic to establish if an appropriately trained physiotherapist was able to manage patients requiring injection therapy and achieve good outcomes as well as a high level of patient satisfaction with the service provided (Resteghini 2003).

Although this pilot study demonstrated a significant improvement in outcome with a good level of perceived patient satisfaction it was limited in scope, being only concerned in exploring outcome and not attempting to explain how these outcomes may have arisen. This was in part due to available time but also reflected a personal lack of knowledge in regard to research methods. It is surprising given the growing medical burden of an increasing elderly population that a search of the literature produces few studies that have specifically examined the factors that may influence outcome in the management of osteoarthritis with injection therapy. The ability to predict outcome and target treatment, with particular regard to the specific population needs of Hackney has the potential to allow the development of more clinically and cost-effective treatment regimes. This need
to develop an enhanced capacity to accurately target treatment formed the basis of this research study and was the starting point for the development of a specific research question.

5 Developing a Research Question

There have been many changes to practice implemented in the NHS throughout its history a situation which seems to have exponentially increased in recent years. Additionally it would be a fair assumption to say not all of these changes have resulted in a perceived improvement in service delivery. My own practice is no exception and has witnessed a rapid change in terms of the need to develop new professional competencies and new ways of delivering services within an increasingly financially astute NHS.

In particular the development of extended scope practice within my own profession provides an example of how scientific knowledge, rather than increasing by a logical and ordered accumulation of demonstrated facts based on hypothesis, that have survived rigorous testing has in reality much more to do with revolutionary developments (Kuhn 1970, 1972). These developments seem to be particularly motivated through political need and financial pressures as opposed to best clinical practice and occur in such a rapid and responsive way that time for reflection and evaluation has been minimal.

This problem is not an isolated phenomenon and has been identified at a national level. The Department of Health’s (DH) briefing paper ‘Evaluating Models of Service Delivery’ (2006) outlined a clear need for research to evaluate the role of extended
practice within physiotherapy. In addition my own professional body the Chartered Society of Physiotherapy (CSP) had in its ‘Priorities for Physiotherapy Research in the UK’ (2002) identified as an area of concern physiotherapy management of osteoarthritis of peripheral joints. It stated that the research trials that were conducted were generally poorly designed and of low methodological quality and that future studies should be both pragmatic and clinically applicable.

The development of a research question needed to include recognition of these issues but also be designed in such a way that it satisfied the various stakeholders who had a potential interest in the area of my research. These stakeholders included the NHS Trust for which I work, my patients, derived from the general population of Hackney, my colleagues, and my profession. The design of an appropriate question also needed to be mindful of potential obstacles in regard to time scales, financial issues, ethics approval, and the political and professional implications of the results.

Initial focus was gained by examining what extended scope of practice meant with in my own practice. With regard to the treatment of peripheral osteoarthritis this entailed the injection of either corticosteroid or a hyaluronan based drug. Although evaluation of the use of corticosteroids has been undertaken in traditional medical clinics there was still little work focusing on outcomes with regard to their use in musculoskeletal clinics staffed by extended scope practitioners (Hockin and Bannister 1994, Resteghini 2003). With reference to hyaluronan based drugs there was evidence to support their use in the management of osteoarthritis of the knee (Gossec & Dougados 2006, Clinical
Evidence Concise 2005) but again this did not extend to their use in musculoskeletal clinics staffed by extended scope practitioners. Additionally the cost effectiveness of hyaluronan based drugs in the management of osteoarthritis in peripheral joints became the subject of the National Institute of Clinical Excellence (NICE) which questioned their value in the NHS given their cost, although also suggested they may have a place in private medicine (NICE www.nice.org.uk/CG59).

With the publication of the NICE paper (NICE www.nice.org.uk/CG59) there was a clearly recognizable need to address the use of Hyaluronan in my clinic which linked in with my own issue with extended scope of professional practice. At this early stage I still did not want to risk becoming too specific in my description of the problem and succumb to the possibility of asking the incorrect question. To this end I found it useful to summarise some of the key words that I thought were at the heart of my problem. This took the form of a brain storming session, an exploration of issues within the action learning set of the course. A summary of what was produced is outlined in figure 2.
The next step was to rework these keywords in such a way as to be able to further articulate my disturbance in a focused manner, this took the form of writing a broad and inclusive description of the problem rooted in the keyword summary, something from which a question could emerge,

‘The Locomotor service within Hackney seeks to manage peripheral osteoarthritis with injection of both corticosteroid and hyaluronan through the use of Extended Scope Physiotherapy Practitioners. Little evidence exists to support this position and it is unknown which patients are most likely to benefit. Additionally there is little evidence for the use of hyaluronan in the management of peripheral osteoarthritis in joints other than the knee joint’.
Both the list of keywords and the description outlined above contain many potential researchable questions which could be addressed with a variety of methodologies. Some of which would have been possible to do, some not either as a result of specific time scales involved, finances, likely success of an ethics application or various other work related issues.

In an attempt to extract a researchable question form this broad description, one that was both feasible and which satisfied my disturbance I drew on the approach described by Clough and Nutbrown (2006). The next section outlines this approach and how it was utilized in focusing on a defined research question.

6 Refining the Research Question

Clough and Nutbrown (2006) developed two simple tools to enable the construction of clearly defined and focused research questions. These tools they named the ‘Russian Doll’ principle and the ‘Goldilocks’ test. Making use of the Russian Doll principle involved stating a specific research question and then breaking it down in such a way that its very heart is exposed and subject to critical review. The question can then be reformulated until it becomes focused and more clearly defined. This reformulated question can then be subject to the Goldilocks test which seeks to ask the researcher the suitability of that question for the environment and time in which it is positioned. Figure 3 outlines this process for my study.
Figure 3 The ‘Russian Doll’ principle and the ‘Goldilocks’ test

<table>
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<tr>
<th>Question</th>
<th>Goldilocks Test</th>
<th>Russian Doll Test</th>
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<tbody>
<tr>
<td>1. Is a Physiotherapy led service more cost effective than a traditional medically run clinic in managing musculoskeletal pathology?</td>
<td>Too big / Too hot</td>
<td>This contains many smaller studies (eg which conditions? which medical clinic?). In addition little will be gained to the patients or participants benefit from a head to head confrontation.</td>
</tr>
<tr>
<td>3. Does injection therapy effectively treat (a specific condition) eg the knee or hip?</td>
<td>Too big/Too small</td>
<td>What drug? A lot of work already done on the knee. Numbers recruited might be small for other joints and time scales an issue with a doctorate.</td>
</tr>
<tr>
<td>4. How effective is injectable Hyaluronan in the treatment of osteoarthritis of the basal joint of the thumb?</td>
<td>Too big/Too small</td>
<td>RCT? Problems with ethics and time scales. In addition there would be potential problems with numbers recruited.</td>
</tr>
<tr>
<td>5. Is the use of injectable Hyaluronan effective in the treatment of osteoarthritis?</td>
<td>Too Big?</td>
<td>More specific with regard to drug but includes all peripheral joints therefore greater numbers. Little previous work carried out beyond the knee. RCT? Would an evaluation be too small on its own?</td>
</tr>
<tr>
<td>6. Is it possible to predict which patients with osteoarthritis will benefit from injection therapy with in a physiotherapy led musculoskeletal clinic?</td>
<td>Just right? (Too small?)</td>
<td>Specific to a profession and pathology. Not so specific however that there would be a problem with numbers. Unlikely to have a problem with ethics? Too small on its own?</td>
</tr>
<tr>
<td>7. How effective is the use of injection therapy in the management of osteoarthritis in a Physiotherapy led musculoskeletal clinic?</td>
<td>Just right?</td>
<td>Assesses the role of Physiotherapy in an extended role (a professional and service need). Covers a number of conditions therefore greater numbers could be recruited.</td>
</tr>
</tbody>
</table>

In light of the environment in which the question was to be asked and taking into account who will ask the question and the expectations of the stakeholders involved numbers 6 to 7 seemed the most meaningful and achievable. Additionally these questions seemed to be
appropriate as they fit with the nationally recognised need for research into extended scope practice (Department of Health’s briefing paper ‘Evaluating Models of Service Delivery’ March 2006) and recognized the need for research to investigate the conservative management of peripheral osteoarthritis (Chartered Society of Physiotherapy in its ‘Priorities for Physiotherapy Research in the UK’ 2002).

Question 7 (In figure 3) ‘How effective is the use of injection therapy in the management of peripheral osteoarthritis in a Physiotherapy led musculoskeletal clinic?’ seemed to offer a good starting point with regard to outcomes and effectiveness. Question 6 provided additional focus and depth within this broader context seeking to answer specific issues which may present in terms of a geographical population based in Hackney and had particular relevance with regard to cost-effectiveness.

By combining both these questions it was possible to include elements which explored both outcome and prediction of outcome. This promised to address my disturbance and attempted to explore an area of real interest to both my profession and the Health Service. The question that was constructed is outlined below.

Can the outcome of intra-articular injection of corticosteroid and hyaluronan in the management of osteoarthritis of the knee be predicted?

Reflecting on this question suggested that it was derived from not only current professional trends and the available or lack of available evidence but also from my own
epistemological perspective. If research is considered to be grounded in either a naturalistic or a positivist viewpoint I had taken a fairly positivistic stand. I was looking at a level of questioning which looked for relationship and cause and effect between different concepts and constructs, one which is interested in exploring the nature and direction of these relationships. This is explored in more depth in the section outlining my methodological choices.

Having arrived at a specific research question there now follows a review of the background to this area of study. This includes an outline of both normal and osteoarthritic joints, the management of osteoarthritis with corticosteroid and hyaluronan injection, and a review of the factors which may influence outcome following treatment with these two drugs.

7 Background Information

7.1 The Normal Synovial Joint

Most joints in the human body are classified as synovial or diarthrodial joints the remainder being either cartilaginous joints or fibrous joints. Synovial joints generally have the ability to move through large ranges of movement in addition to being able to sustain considerable axial loading (Schuenke et al 2006). These two distinct features of the synovial joint are facilitated by cartilage, synovial membrane and synovial fluid. It is the altered ability of these structures to sustain load that leads to the degeneration of the joint and subsequent osteoarthritic change. The articular cartilage, synovial membrane
and synovial fluid of the normal joint will now each be considered before a review of the pathological process involved in the osteoarthritis joint is considered.

7.1.1 Articular Cartilage

Articular cartilage is hyaline cartilage and serves two distinct functions. It acts as a gliding surface to facilitate smooth movement and it serves as a shock absorber during joint loading. It is made up of an extracellular matrix which consists of up to 80% water, collagen fibres and proteoglycans in addition to a sparse number of chondrocytes (Bland 1984). Articular cartilage can be divided into four zones characterised by the arrangement of collagen fibres, the superficial tangential zone, the intermediate zone, the deep zone and the zone of calcified cartilage adjacent to the subchondral bone. Water content is highest in the superficial zone, while the deep zone has the highest proteoglycan content.

Chondrocytes are essentially secretory cells that produce the extracellular matrix consisting of the proteoglycans, collagen and other proteins. Chondrocytes also control cartilage maintenance through the secretion of degrading enzymes, the metalloproteinases (collagenase, gelatinase, cathepsin) their inhibitors, and repair through the mediation of growth factors (TGF-β, IGF-1, FGF, PDGF and others). Importantly chondrocytes also contribute to the production of pro-inflammatory cytokines that play a role in cartilage degradation in arthritis. They do this predominantly through the production of interleukin-1 beta and tumour necrosis factor-alpha. In normal cartilage a chondrocyte should last a person’s lifetime (Mankin 2000).
The extracellular matrix consists of two structurally interwoven components, collagen fibres and proteoglycans (Fig 4.). In cartilage the collagen is predominantly type II collagen, this resembles the type I collagen of bone but does not support the deposition of minerals. In the superficial tangential zone these collagen fibres run parallel to the joint surface, in the intermediate zone they curve downwards toward the deep zone, and in the deep zone they are arranged vertically. Proteoglycans and water fill and distend the space between the fibres holding the fibres taught and preventing them from damage.

A large part of the shock absorbing quality of cartilage is due to the ability of proteoglycans to sustain load. These proteoglycans are macromolecules consisting of a protein core carrying approximately 150 side chains of glycosaminoglycans. The glycosaminoglycans consisting of approximately 100 long side chains of chondroitin sulphate with 50 shorter side chains of keratin sulphate. These protein cores are in turn ‘aggregated’ with approximately 300 being assembled along a hyaluronate chain, thus forming a very large proteoglycan macromolecule complex. It is the ability of these complex macromolecules to retain water which gives cartilage its shock-absorbing quality, indeed the retained water is under five times the pressure of a standard motor vehicle tyre. The proteoglycan molecule retains water by two distinct mechanisms. Firstly the chondroitin and keratin sulphate side chains carry a negative charge creating strong mutually repulsive forces between adjacent molecules opening up the space between them allowing water to be ‘soaked up’. Secondly, this negative charge attracts the positive ions sodium and calcium which in turn increases osmotic pressure and attract water (Schnitzler 2005).
Figure 4 The extracellular cartilage matrix

The extracellular matrix of cartilage is composed of proteoglycans attached to a backbone of hyaluronic acid that is intertwined among collagen fibrils. Proteoglycans have both chondroitin sulphate and keratin sulphate regions with link proteins binding the aggrecan to hyaluronic acid.


A factor of normal aging is that the chondroitin and keratin sulphate side chains become shorter, a process which also occurs in the development of osteoarthritis. This shortening results in a reduction in the negative repulsive charges and therefore reduction in overall water content of the cartilage. This decrease in water content results in loss of turgor which means that collagen fibres become less supported and vulnerable to distortion and damage. Ultimately the result is a reduction in the ability of the cartilage to bear load with subsequent osteoarthritis development.

7.1.2 Synovial Membrane and Synovial Fluid

Paracelsus writing in the early 16th century described joint fluid as ‘synovia’ which means ‘like egg’ because like egg white it is slippery. The synovial membrane lines the
The entire interior of the joint, with the exception of the cartilage and menisci. It consists of two layers, the synovial lining cell layer and the sub-lining. The lining cell layer, 1-3 cells deep, contains macrophages, the type A cells, and the secretory fibroblast-like cells, the type B-cells. It is these type-B cells that produce synovial fluid. The sub-lining consists of fibrous tissue, capillaries, arterioles, venules, and lymphatics. The synovial lining cells lack a basement membrane permitting a rapid exchange of plasma dialysate, nutrients and waste products as well as the migration of leucocytes from blood vessels into the joint cavity. In part it is these features that also facilitate the development of arthritis (Schnitzler 2005).

### 7.1.3 Synovial Fluid & Joint Lubrication

The lubrication of the synovial joint is dependent upon the rheological function of synovial fluid which facilitates low friction gliding between articular surfaces and reduces articular cartilage wear during joint motion. Synovial fluid is produced by the synovial membrane as a plasma dialysate. Synovial cells also secrete hyaluronan, a large glycosaminoglycan, as a lubricating agent. The amount of synovial fluid in a normal joint is small, amounting to no more than 1-5ml even in larger joints such as the knee. The synovial fluid forms a film covering the interior of the joint including the cartilage, the synovial membrane, and the menisci, if present (Mankin 2000, Schnitzler 2005). As joint motion commences, movement takes place within this fluid film by what is termed ‘fluid film lubrication’, which means that the cartilage surfaces themselves do not actually come into direct contact. As load increases, the fluid film is slowly squeezed out from between the areas of direct load on the cartilage surfaces. However, a thin layer of
glycoprotein molecules called ‘lubricin’ remains on the articular cartilage surface, this boundary layer continues to provide low friction gliding against abrasion and also cushioning against the increasing pressures within the joint. With decreasing pressure within the joint the fluid film returns to the joint space and fluid film lubrication resumes. Both fluid film and boundary lubrication are usually present within the joint at the same time providing a degree of mixed lubrication dependent upon the joint surface congruity; prominent regions moving with boundary lubrication and receding regions taking advantage of fluid lubrication. In addition the joint surfaces themselves may slightly alter their shape temporarily during loading as under load the collagen-proteoglycan network undergoes elastic deformation, and a small amount of water is displaced, returning again on unloading (Mankin 2000, Schnitzler 2005).

7.2 The Osteoarthritic Joint

The pathological process by which the normal synovial joint undergoes degeneration is termed osteoarthritis. Usually defined as being either primary (idiopathic) or secondary when it follows some clearly defined predisposing factor such as injury. In the broadest terms the structural failure of articular cartilage and bone witnessed in the development of osteoarthritis may be seen as either the result of abnormal mechanical stresses causing damage to normal tissues, or failure of pathologically impaired tissue (such as those following injury) being subject to normal mechanical forces. Osteoarthritis is characterized by focal areas of damage to the cartilage surfaces of synovial joints, associated with remodelling of the underlying bone and mild synovitis. When severe,
there is associated joint space narrowing and osteophyte formation, with visible subchondral bone changes on radiography.

Osteoarthritis is a heterogeneous condition for which the prevalence, risk factors, clinical manifestations, and prognosis vary according to the joints affected. It most commonly affects hands, knees, hips, and apophyseal joints. It is usually defined by pathological or radiological criteria rather than clinical features despite the fact that there appears little direct correlation between the degree of reported change as seen on x-ray and perceived pain (Hannan 2000). This lack of correlation was the prime factor that prompted the use of a mixed methodology in this study so as to incorporate qualitative data to gain insight into other potential factors that may correlate with more significance and be of particular relevance to a patient population located in Hackney.

Osteoarthritis is common and an important cause of pain and disability in older adults. Radiographic features are practically universal in at least some joints in people aged over 60 years, but significant clinical disease probably affects 10-20% of people. Knee disease is about twice as prevalent as hip disease in people over 60 years (about 10% v. 5%) (Clinical Evidence 2005). Although many patients with osteoarthritis do not seek medical attention and seem able to function well without treatment (Hadler 1992) the medical and socioeconomic burden of osteoarthritis is likely to increase further in coming years, with the continued growth of the elderly population who often have a concomitant increase in quality of life expectations (March 1997). Indeed estimates suggest that total costs for arthritis, including osteoarthritis, may exceed 2% of the gross domestic product in the United States (Yelin 1998). In addition raising levels of obesity seen in ever increasing
numbers in younger sections of the population will have the potential to raise the number of people with osteoarthritis in weight bearing joints in coming years. This trend for younger patients seeking help for symptomatic osteoarthritis is certainly one I have witnessed increasingly in my own clinics and represented a further factor in the justification of this study. There now follows a review of some of the commonly held beliefs concerning osteoarthritis with an examination of the pathological process involved in the onset and development of osteoarthritis including some of the associated risk factors.

### 7.2.1 Myths and Misconceptions

There exist a number of misconceptions regarding osteoarthritis held by the general public and also by many medical professionals which may lead to both poor management of the condition and to poor outcomes following treatment as perceived expectations are not addressed. This is surprising as differences between normal ageing processes at a joint and the pathological changes at a joint affected by osteoarthritis have been known about for some time.

A clear summary of these differences was given by Meacham as long ago as 1969 who described how osteoarthritis is not solely a consequence of chronological age, something that should be considered ‘normal’ wear and tear. In osteoarthritis there is an increased rate of synthesis of collagen and proteoglycans, there is enzymatic destruction of hard tissue, with remodelling of all tissues around the joint, both articular and periarticular. Chondrocytes undergo mitosis subchondral bone becomes eburnated and marginal osteophytes develop, a progressive fibrillation of cartilage occurs at weight bearing sites.
There is often an associated, intermittent and re-occurring inflammation. By contrast normal joint aging exhibits no increased synthesis of collagen or proteoglycans, and there is no enzymatic destruction of hard tissue above what would be considered normal rate. No remodelling of articular and periarticular tissue occurs other than changes at the cartilage and chondrocytes do not undergo mitosis. There is no eburnation of subchondral bone and marginal osteophytes only develop as a result of excessive use. Fibrillation of cartilage is non progressive and occurs at non weight bearing sites as well as those that are weight bearing. In addition there is no associated inflammation (Wiltrud 2007, Angel 2003).

In addition to this is the commonly held belief is that cartilage damage as a result of osteoarthritis cannot be arrested or reversed and that the condition will inevitably progress steadily resulting in a concurrent increase in disability and morbidity. This is not the case and although hyaline cartilage cannot regenerate itself in the form of normal hyaline cartilage it can to a degree regenerate with chondrocytes demonstrating the ability to replicate themselves and therefore basing the idea of wearing on a theory that they cannot is not tenable (Jasin 1981, Wiltrud 2007, Angel 2003).

Many of the erroneous beliefs in regard to the cause of osteoarthritis may be considered in terms of the need to make sense of illness in a way that is understandable. This need for understanding is similar to what one might expect in reaction to any other unusual or disturbing life event. A patient will attempt to make sense of their painful knee in terms of their own past life experiences and on the information that is available to them. Turner (2005) explored these lay perceptions in regard to osteoarthritis using interviews and an
interpretative phenomenological analysis. The results of this study demonstrated that the participants attributed the cause of their osteoarthritis to a number of factors including past trauma, genetic predisposition, and temperature (eg: cold and damp weather). However, the most commonly reported cause of osteoarthritis was overload of the joint throughout their life related to either work or sport. The idea of physical ‘overload’ of the joint being the root cause of their problems allowed a level of understanding that could be attributed to a cause and effect model (Turner 2005). This idea of activity being responsible for osteoarthritis may explain the difficulty in gaining compliance with some patients when weight bearing exercises are prescribed as a form of treatment despite there being a significant amount of evidence in support of exercise for osteoarthritis (Clinical Evidence Concise 2005). This link between inappropriate beliefs and compliance with exercise is an area that would be explored within the interviews of this study providing further insights into the factors that influence outcome with the aim of being able to target these areas in future clinical practice.

In summary osteoarthritis seems to have a strong genetic component and people with a parent or sibling with the condition are two to three times more likely to develop osteoarthritis than those who have not (Lanyon 2000). In addition to this genetic component rendering some people more susceptible to osteoarthritis there are environmental factors which can exacerbate the condition including obesity, injury, and heavy manual occupation. There also exist a number of erroneous beliefs that are held by both lay people and medical professionals that may be unduly influencing treatment, treatment compliance and subsequent outcome (Turner 2005).
7.2.2 Pathophysiology of the Osteoarthritic Joint

In the healthy synovial joint there exists a balance between cartilage degradation and repair. This balance is regulated by several factors produced in the synovium and chondrocytes, with cytokines mediating cartilage degradation and growth factors mediating repair (Fig 5).

Figure 5 Schematic demonstrating normal balance between cartilage degradation and repair

<table>
<thead>
<tr>
<th>Degradation</th>
<th>Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pro-inflammatory Cytokines (IL-β, TNF-α, also IL-6, IL-8, IL-11, IL-17, IL-18)</td>
<td>Anti-inflammatory Cytokines (IL-4, IL-10, IL-13)</td>
</tr>
<tr>
<td>Metalloproteinases (collagenase, stromelysin, gelatinase)</td>
<td>Tissue inhibitor of Metalloproteinase (TIMPs)</td>
</tr>
<tr>
<td>Aggrecanases</td>
<td>Growth Factors</td>
</tr>
<tr>
<td>Prostaglandins</td>
<td>Collagen synthesis</td>
</tr>
<tr>
<td>Nitric Oxide</td>
<td>Proteoglycan synthesis</td>
</tr>
</tbody>
</table>


In osteoarthritis this equilibrium is disturbed and the predominant force is degradation. The exact mechanism that tips the balance and results in a net destructive process remains unclear. There is some evidence that an autoimmune response triggered by circulating cartilage molecules may be responsible but this has not been proven (Nishioka 2004). The process of the development of osteoarthritis may be divided into three stages: stage I, a proteolytic degradation of cartilage matrix; stage II, a fibrillation of the cartilage
surface; stage III, a chronic synovitis in response to the process of cartilage breakdown and the release of by products into the synovial cavity. The initial process of degradation which occurs in stage I is outlined in fig 6.

**Figure 6 Schematic representation of cartilage degradation in osteoarthritis**

Schematic representation of degradation process of cartilage in osteoarthritis. Proteoglycans are degraded by aggrecanase, stromelysins and plasmin. Collagen is broken up by collagenase and gelatinase.
**Stage I** is initiated when synovial cells and chondrocytes produce an increasing number of metalloproteinases, including collagenase, stromelysin, and gelatinase which can be found in both chondrocytes and on the articular surface of the cartilage (Sandell 2001, Aigner 2007). This increase in metalloproteinase activity is due to both an increase in synthesis and an increase in activation of pro-enzymes with a concurrent decrease in activity of their inhibitors (Sandell 2001). Increased production of cytokines, particularly IL-1 and TNF-α occurs in both the synovium and chondrocytes in addition to IL-1β which has been shown to be present only in the osteoarthritic joint (Abramson 2001). As well as exhibiting an enhanced expression of metalloproteinases chondrocyte receptors also become sensitized to cytokines. In addition both IL-1β and TNF-α are able to stimulate their own production and that of other cytokines such as proteases and prostaglandins enhancing the overall degradative state (Pelletier 2001).

Aggrecans, consisting of a protein core and their side chains of glycosaminoglcans are the first component of cartilage to be degraded. This is done by aggrecanase, stromelysin, plasmin and other enzymes (Tortorella 2001, Belcher 1997). The glycosaminoglcans side chains consisting of long side chains of chondroitin sulphate and shorter chains of keratin sulphate thus become shorter this results in diminished negative repulsive electrical charges with a concurrent decrease in osmotic pressure. This results in an overall decrease in the ability to retain water with the consequence of diminished tissue turgor and an overall softening of the cartilage (Fig 6). Collagen fibres are next cleaved by collagenase, gelatinase, and other enzymes. This results in a loosening of the tightly woven network which forms the cartilage matrix resulting in further fracture of collagen fibres and breakdown of the cartilage surface.
Stage II proceeds with the initial small, superficial collagen splits beginning to run parallel with the surface of the cartilage a process known as fibrillation. As degeneration continues fibrillation reaches deeper into the cartilage with vertical splits extending as far as the subchondral bone. An attempt is made to repair the damage and chondrocytes increase their output of new matrix materials such as proteoglycans. This repair occurs predominantly in the deeper layers of the cartilage and so a net loss still results particularly in the more superficial layers (Sandell 2001). The rate of destruction eventually overwhelms the ability of the chondrocyte to make repairs and they succumb to a process of programmed cell death known as apoptosis (Aigner 2007). Death of chondrocytes may lead to further decrease in matrix production as they are not renewed. Additionally the cellular products of apoptosis may contribute to the degradative state as they are not effectively removed due to their avascular nature which does not seem to elicit the normal inflammatory response associated with necrosis; the reason for this remains unclear (Sandell 2001). The extent at which apoptosis is present has been demonstrated to correlate with the degree of osteoarthritic change (Hashimoto 1998).

Another inflammatory mediator synthesised in osteoarthritic cartilage is Nitric Oxide which is stimulated by IL-1 and TNF-α. Nitric oxide may be involved in cartilage metabolism by inhibiting synthesis of collagen and proteoglycans as well as increasing the activity of the metalloproteinases and contributing to chondrocyte apoptosis (Sandell 2001, Pelletier 2001, and Abramson 2001, Aigner 2007).

Stage III is associated with continuing fibrillation and cartilage breakdown as described for stage II, with the products of this process being released into the synovial fluid. Here
synovial phagocytes engulf these products with subsequent rupture and release of degradative enzymes resulting in a chronic synovitis. Synovitis further increases the production of cytokines which results in additional cartilage breakdown and synovitis. If the synovitis proceeds unchecked then secondary thickening and fibrous of the capsule will take place leading to further joint deformity and restriction (Sandell 2001). This may be why the control of an active synovitis in osteoarthritis is important and would both explain the use of corticosteroid in the treatment of osteoarthritis and how benefits seem to be limited to only certain patients. Certainly from my own clinical view point it is normal practice to only inject corticosteroid if there appears to be an active synovitis as evidenced by the presence of a joint effusion. If none exists it is practice to consider the use of a hyaluronan injection as an alternative therapeutic intervention.

In addition to changes within the articular cartilage changes also occur within synovial fluid in particular to hyaluronic acid which coats the surface of the cartilage as well as being an essential component of the cartilage matrix itself. Hyaluronic acid is responsible for the viscoelastic quality of synovial fluid as it acts as both lubricant and shock absorber. In osteoarthritis there is a decrease in the elastic and viscous properties of synovial fluid (Balazs 1982). Specifically in osteoarthritis it is the molecular weight and concentration of hyaluronic acid in synovial fluid which decreases (McCarty 1998, Dahl 1985). Tanimoto (2001) demonstrated using in vitro experiments that in rabbit synovial cells the cytokines IL-1 and TNF-α stimulated expression of hyaluronic synthetase which may cause the fragmentation of the hyaluronic acid molecule and in so doing decrease its molecular weight and subsequently its rheological characteristics. The degradation of
hyaluronan forms the basis of the use of supplementation of synovial fluid with hyaluronan injection therapy.

7.2.3 Associated Risk Factors in the Development of Osteoarthritis

It would seem likely that in the majority of patients with both primary and secondary osteoarthritis there exist a number of factors which contribute to the pathogenesis and progression of joint change including both genetic predisposition and subsequent environmental influences. The perception of any such change may have relevance as to whether patients seek help for their condition and furthermore this perception may well influence any subsequent treatment outcome, a factor of particular relevance to this study.

With regard to gender women appear to be more susceptible to the development of osteoarthritis then men at many although perhaps not all joints. Huang (2000) reported a correlation with gender and the severity of knee osteoarthritis with women having more severe osteoarthritis in addition to the disease being more prevalent in women than men. Additionally there seems to be a sharp increase in the incidence of osteoarthritis of the knee in women over the age of 50 years which may suggest changes are in part due to an association with the menopause and a deficiency in available oestrogen (Reginster 1999).

The fact that women seem to have a greater degree of degenerative change in weight bearing joints is interesting if the commonly held perception that osteoarthritis is associated with an increased physical activity is considered. It would be reasonable to assume that men would be more likely to take part in heavy manual work then women and therefore presuming osteoarthritic change is due to increased work load does not
seem tenable. This study plans to explore some of these beliefs through the course of the interviews carried out.

Of relevance to the issue of increasing levels of obesity within society is the accumulation of evidence demonstrating that increased body mass index is a particular risk factor in developing osteoarthritis, and not surprisingly this is particularly noticeable in the weight bearing joints such as the knee (Felson 1997). Sturmer (2000) defined normal body weight as being a body mass index (BMI) of less than 25kg/m², overweight as being over 25kg/m², and obesity as being a BMI of over 30kg/m². There appear two theories in the literature which attempt to explain the effect of obesity on lower limb arthritis. The first theory, a biomechanical one, suggests a direct relationship in that obesity leads to repetitive increased loading of the knee with a subsequent increase in degeneration of articular cartilage (Sharma 2000). The second theory proposes a metabolic, indirect relationship with a metabolic change associated with being obese affecting the joint cartilage and surrounding structures. Such possible metabolic factors are suggested as being related to hypertension, hyperuricemia, diabetes, and hypercholesterolemia (Sharma 2000). Certainly subjects with knee osteoarthritis are generally heavier than subjects with little or no osteoarthritis, and evidence exists to suggest that being overweight increases the risk of developing knee osteoarthritis (Felson 2004). In addition Shiozaki (1999) demonstrated that as BMI increased in women so did the degree of osteoarthritis.

Furthermore being overweight seems to negatively influence the progression of osteoarthritis of the knee in those who already have the disease. Several studies found
that BMI was a strong predictor of knee osteoarthritis (Felson 2004, Toda 2001, Sturmer 2000, Huang 2000). These studies also suggested a positive association between BMI and the severity of osteoarthritis in the knee. Additionally Gelber (1999) in a longitudinal study found that subjects with high BMI and aged between 20 and 29 had increased potential to develop osteoarthritis of the knee in the future. Anderson (1988) demonstrated that in both men and women with a body mass of 30 -35 there was an approximate 4 fold increase in the incidence of osteoarthritis of the knee compared to normal weight controls.

Although these findings would suggest that the link between obesity and osteoarthritis of weight bearing joints is causal and due to an increased mechanical strain placed through these joints a certain degree of caution needs to be employed. It may well be that other mechanisms such as the level of function and activity in people with excessively high BMI play an important factor. It may be reasonable to assume that people with very high BMI are not as physically active as those within their ideal weight range and that osteoarthritic change has more to do with physical activity and function rather than weight alone. Indeed it may also be that the factors which lead to someone becoming obese have an influence over the way in which pain from osteoarthritis is perceived and managed. Certainly few studies seem to explore these specific issue in what would require a more qualitative approach.
This cautionary approach is supported by Cicuttini (1996) who demonstrated a significant increase in the risk of developing osteoarthritis of the basal joint of the thumb in obese subjects despite this joint clearly not being directly influenced by increased body mass.

In terms of occupational factors Schouten (2002) carried out a systematic review reporting on four studies in regard to the development of osteoarthritis of the knee. All were retrospective in design but demonstrated a positive relationship between exposure to excessive joint loading of the knee and osteoarthritis. In a further systematic review Maetzel (1997) demonstrated that there existed a positive association between work involving knee bending and osteoarthritis of the knee in men, interestingly this appeared to be less strongly correlated in women.

Bernard (2010) in a study examining the influence of occupational exposures on the development of osteoarthritis in the knee, foot, hand and cervical spine found association between the degree of osteoarthritis in the knee and those occupations involving repetitive stair climbing, jolting of the legs and standing on rigid surfaces. These findings were supported by Anderson (1998) who found a 3 fold increase in radiographic appearances of osteoarthritis of the knee in those undertaking heavy work which involved repeated knee bending. However, other occupational activities such as climbing stairs, walking on uneven ground and standing for long periods have been inconsistent in demonstrating any specific link to the degree of risk of developing osteoarthritis (Coggon 1998). This is important as it would suggest that these normal activities of daily living do not lead to osteoarthritic change even though the perception is often that they do. This
fact would suggest that education may have a significant part to play in any management strategy when confronted with a patient complaining of an osteoarthritic joint.

In regard to activity levels outside of occupation there is some evidence to suggest that regular sporting activity may lead to increased risk of osteoarthritis. Kujala (1994) found that the incidence of admission to hospital for osteoarthritis of the knee, hip or ankle was up to 2.17 times higher in athletes than in a control population. Although it was noted that in athletes practicing mixed and power sports there was a higher rate of admission for premature osteoarthritis these admissions were generally at an older age for endurance athletes. Spector (1996) found that the weight bearing sports activity in former elite women runners and tennis players produced a 2 to 3 fold increased risk of radiologic osteoarthritis of knees and hips compared to matched controls although it should be noted this was predominantly the identification of osteophytes and did not represent loss of articular cartilage.

The increased risk of osteoarthritis in those participating in sporting activity is not however supported by all. Kujala (1995) found little increase in knee osteoarthritis in high level long distance runners. Lane and colleagues reporting on a series of prospective studies found no clinical or radiographic difference in osteoarthritis of the knee or lumbar spine between recreational runners (averaging 25 miles per week) and controls matched for age, sex, and occupation (Lane 1986). In addition follow up at 5 and 9 years showed similar rates of progression of radiographic osteoarthritis of the knee in both the runners and controls with no significant difference between the groups (Lane 1993, 1998).
This conflicting data may have arisen for a number of reasons. Injury is known to be a major factor in the development of osteoarthritis (Honkonen 1995, Maxian 1995) with Felson (1998) describing a 3 fold increase in osteoarthritis of the knee following major knee injury. It would therefore seem a reasonable assumption that the increased incidence of osteoarthritis due to sporting activity may largely be attributable to the higher incidence of associated injury leading to meniscectomy and ligament injuries. Any study investigating links between osteoarthritis and sport would therefore need to take into account any concomitant injury to avoid confounding results. However, this appears to be missing in most studies.

In addition the beneficial or detrimental effects of activity may have been over shadowed by the failure of studies to adjust for individual and environmental factors, such as BMI, which may mediate the effects of exercise and activity on the development of osteoarthritis at the knee joint. Indeed the lack of inclusion of other such factors should extend to take account of more profound and inherent individual factors which may only be investigated with a more qualitative exploration.

Studies examining patterns and incidence of osteoarthritis in different racial and ethnic groups support the role of ethnicity in the development of osteoarthritis. For example hip osteoarthritis is rare in China and in those of Chinese descent in the United States when compared to a Caucasian population (Nevitt 2002). Felson (1998) reported on 29 epidemiological studies from 14 countries finding that the prevalence of radiologically reported osteoarthritis of the hip to be higher in Caucasian populations than non-
Caucasian populations although interestingly no differences in the prevalence of radiographic osteoarthritis of the knee.

Having outlined the normal and osteoarthritic joint and discussed some of the possible risk factors in the development of osteoarthritis there now follows a review of the management of osteoarthritis in regard to the use of injectable corticosteroid and hyaluronan.

8 Management of Osteoarthritis with intra-articular injection

Although surgical treatments will continue to improve and the number of procedures carried out will increase, only a small fraction of patients with osteoarthritis require surgery (Buckwalter 2001). Most can be managed in a primary care setting with advice on activity modification, exercise, analgesia and non-steroidal anti-inflammatory medication and injection when needed.

One of the main treatment modalities used in the management of both intra-articular and peri-articular lesions are corticosteroid and hyaluronan injections. Data concerning their short and long term efficacy and their potential side effects have recently been reviewed in best practice guidelines (Gossec & Dougados 2006) and also in Clinical Evidence Concise (2005).
8.1 Corticosteroid and its use in the Management of OA

Intra-articular corticosteroids seem to be effective for reducing short term pain having a rapid onset with effect being noticed within 24-48 hours, maximum efficacy occurring by 1-week, and with a benefit lasting for up to 4-weeks (Gossec & Dougados 2006, Bellamy 2005). They may be more efficacious in patients with joint effusion and/or symptom flares and as a management approach to facilitate rehabilitation (Gossec & Dougados 2006, Clinical Evidence Concise 2005). However, assessment of any true physiological affect is difficult for as might be expected with an interventional procedure there appears to be a strong placebo. This was supported by Friedman (1980) who using a double blind trial to assess corticosteroid injection on osteoarthritis of the knee demonstrated that both placebo and treatment groups showed a significant decrease in pain from 1-week to final assessment at 8-weeks.

Further exploration of the literature demonstrates that despite corticosteroid injections having been in frequent use for 50 years, with a wealth of anecdotal evidence for their efficacy, there are few definitive studies of their application in joint and soft tissue lesions (Drugs and Therapeutics Bulletin 1995, Assendelft 1996, Van der Hijden 1996), and few studies comparing injection therapy with other modalities (Winters 1997, Van der Windt 1998, Dando 1997, Hay 1999). Towheed (1997) carried out a systematic review on the evidence from five controlled trials examining intra-articular injection of corticosteroid in patients with osteoarthritis of the knee. Using a quality rating system to critically analyse the methodology no study achieved more than three out of eight for design. The conclusion must therefore be that our knowledge base concerning the efficacy of intra-
Articular corticosteroid in the management of osteoarthritis remains inadequate with many trials being of poor methodological quality. In addition to this poor methodological quality the majority of trials focus on outcome and seem rarely to look beyond this concluding point to investigate why the intervention may have or have not worked. This would seem essential if we are to fully understand the mechanisms at work and direct future treatment appropriately.

The problem seems to rest with the fact that there exist few facts and lots of opinions about which lesions to treat, optimal steroid dosages, and injection intervals. This variability in the methodological approach taken makes any direct comparison between different studies difficult and of questionable use. Given that intra-articular corticosteroid injections for the knee form part of the American College of Rheumatology treatment guidelines for knee arthritis (Altman 2000) and that steroid injection is the single commonest therapeutic intervention in rheumatological practice (Haslock 1995) this is quite surprising.

It may be that the lack of in vivo evidence for the use of corticosteroid in the management of osteoarthritis reflects the phasic nature of the disease process itself with damage and inflammation occurring in a series of exacerbations rather than in a linear progression. Certainly anecdotal evidence from clinic strongly supports this phasic progression of exacerbation and remission. This would presumably suggest that corticosteroid would be more useful as a modality at certain times when the joint concerned is exhibiting an exacerbation indicating a more active disease process and would be less efficacious when the joint is in remission. Unfortunately and importantly most studies do not seem to
identify this phasic process within their methodology and results may therefore represent an unduly negative bias.

Although the efficacy of corticosteroids in the management of osteoarthritis is difficult to substantiate from the available literature their mode of action has been well described and would lend weight to the idea that they should be used at particular times in the osteoarthritic process. Corticosteroids show complex anti-inflammatory and immunomodulatory effects acting directly on nuclear steroid receptors to control the rate of synthesis of mRNA and various proteins. They inhibit migration of leucocytes to sites of inflammation and interfere with the function of leucocytes, endothelial cells and fibroblasts. They also suppress production and release of factors involved in the inflammatory response, such as cytokines, prostaglandins and leukotrienes as well as the inhibition of phospholipase A2 which results in a reduction of the pro-inflammatory derivates of arachidonic acid (Stitik 2006, Klint 2005).

Although osteoarthritis is not traditionally considered as primarily an inflammatory condition it does exhibit an inflammatory component at various times throughout its natural progression (Klint 2005) and it is presumably this aspect of the osteoarthritic process that corticosteroids are able to influence. The cause of this transient inflammation in osteoarthritis is unclear but may be secondary to the release of various substances from cartilage degradation which subsequently results in further activation of synovium and the release of cytokines and other inflammatory mediators (Evans 1981, Sandell 2001). More recent studies have demonstrated that such changes in the pericellular matrix in which the chondrocytes are situated and to which they are adapted can have significant
effects on the chondrocytes in terms of gene expression with subsequent affect on the anabolic / catabolic homeostatic balance (Hayman 2006). This alteration in normal chondrocyte function may tip the balance from an anabolic to catabolic state with subsequent degenerative change seen in osteoarthritis.

When inflammation is present it may also contribute to the osteoarthritic process through the production of inflammatory cytokines such as IL-1 which in turn facilitates the release of collagenases, stromelysin, and other degradative enzymes which are responsible for cartilage breakdown (Belcher 1996, Sandell 2001, Abramson 2001, Tortorella 2001). Additionally inflammatory products such as bradykinin and histamine are able to directly stimulate primary afferent nociceptors as well as other mediators such as prostaglandins, IL-1, and IL-6 which sensitize the same primary afferent nociceptors to mechanical stimuli all of which feeds into the symptoms of pain associated with osteoarthritis.

In addition to the anti-inflammatory effects of corticosteroid in the management of osteoarthritis there also exists some evidence to suggest that corticosteroid may have a disease modifying role to play. Butler (1983) demonstrated that intra-articular corticosteroid (triamcinolone hexacetonide) given prior to the onset of osteoarthritis resulted in reduced osteophyte formation and cartilage fibrillation in rabbit knee cartilage. In a similar animal study examining dog knees Pelletier (1995) found a comparable chondro-protective effect from corticosteroid even when the joints had established osteoarthritis.
A possible mechanism for the disease modifying effect of corticosteroid injection may be their effect on the synthesis of metalloproteinases. Pelletier (1987, 1995) demonstrated a reduction in the synthesis of metalloproteinases in a human model post introduction of corticosteroid. These findings would run contrary to the popularly held belief that corticosteroid can cause joint damage. It may be that a balance is to be found and that the judicious use of corticosteroid is wholly appropriate.

Whatever the mechanism that intra-articular corticosteroid plays in the management of the osteoarthritic joint the effect seems to be short lived. Jones (1996) in a double blind placebo controlled crossover study found significantly greater reduction in pain with corticosteroid injection over placebo at three weeks but failed to demonstrate an effect beyond this time. The inability to detect significant effect in the longer term may reflect the outcome measures being utilised. Frequently these measures include some form of subjective measurement of pain, such as the visual analogue scale, as well as an inclusion of a measure of functionality however little more in depth subject assessment is routinely conducted. In addition subjects tend to be grouped together with no consideration being given to either the phasic nature of the condition or the factors which may affect the outcome such as subject expectation or knowledge of condition.

From a clinical perspective even this short lived effect may be of significant use. The ability to control pain even in the short-term enables a facilitation of the patient in being compliant in a course of prescribed rehabilitation, and although the literature suggests
that injection therapy is primarily used for pain relief it may be best utilised as an adjunct to other forms of rehabilitative treatment (Grillet 1990, Nelson 1995, Kerlan 1989).

In terms of long-term safety there appears to be little recent evidence to support a deleterious effect of corticosteroid injection on cartilage metabolism. Indeed as mentioned previously a limited number of animal studies examining cartilage metabolism and progression of osteoarthritis appear to support a chondroprotective mechanism (Butler 1983, Pelletier 1995). With regard to human models a placebo controlled trial of repeated intra-articular corticosteroid injections in the knee given every 3-months for up to 2-years demonstrated no difference in loss of joint space between control or experimental groups (Raynauld 2003). Despite this evidence there still appears to be a belief with some clinicians that corticosteroid injection may cause joint damage. In part this belief may be based on old research. A review of the available literature identified 2 studies which demonstrated that the number of intra-articular corticosteroid injections received in human subjects appeared to correlate both with more severe disease at the time of surgery (Salter 1967) and with radiographic acceleration in joint destruction (Chandler 1958). However, such correlation should not be considered proof of causation. Instead it is possible that the underlying pathology which first prompted treatment was such that deterioration was going to happen regardless of the injection carried out and reflects natural progression of the disease itself rather than a reaction to treatment. There appears to be little evidence which suggests an overall incidence of possible cartilage damage following corticosteroid injection other than an old study by Hollander (1961)
which estimated an incidence of steroid arthropathy of being <1% based on a retrospective follow up of patients’ medical records over a 7-year time period.

In summary intra-articular corticosteroids are effective for reducing short term pain and appear to have no long term deleterious effects on the cartilage; they may be more efficacious in patients with joint effusion and/or symptom flares and as a management approach to facilitate rehabilitation Clinical Evidence Concise (2005).

8.2 Hyaluronan and its use in the Management of OA

In contrast to corticosteroids intra-articular injections of hyaluronan have been shown to have a modest but long lived symptomatic effect on pain as measured on a Visual Analogue Scale (VAS) and functional outcome measured with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in knee osteoarthritis (Clinical Evidence Concise 2005). They seem to have a delayed onset as compared to corticosteroid injection with effect being noted at 2-5 weeks following injection, maximum effect occurring by 1-2 months, but with efficacy extending from between 4 months to 1 year. A systematic review by Kirwan (1997) looked at 10 RCT’s comparing hyaluronan with placebo in the treatment of osteoarthritis of the knee and was able to demonstrate a slightly greater benefit then placebo at both 1 and 6 month post injection. In another systematic review of 9 RCT’s again comparing hyaluronan with injection of placebo Towheed (1997) demonstrated that hyaluronan was better than placebo at a mean follow up of 4 months and was also well tolerated with few adverse reactions. The
differences in efficacy related to the molecular weight of the hyaluronan are a subject of debate Clinical Evidence Concise (2005).

Of particular interest to this study are the recently published guidelines for the management of osteoarthritis produced by the National Institute for Clinical Evidence (NICE 2009 www.nice.org.uk/CG59). NICE concluded that in regard to the use of intra-articular hyaluronan that there was not sufficient evidence to support their use on the NHS based on their cost effectiveness. This would seem to go against current clinical practice and much of the evidence that has been produced examining their efficacy. It may be that the use of intra-articular hyaluronan in the NHS is not as selective as it could be and therefore results are mixed. Although only anecdotal my own experience suggests that intra-articular injections of hyaluronan are often given with little thought to the level of degeneration present or function of the patient treated in a similar way to the use of corticosteroid in joints which demonstrate no signs of an active inflammation. The ability to predict those who may benefit is of course one of the primary aims of this study.

The history of the use of hyaluronan stems from 1934 when Mayer and Palmer isolated a polysaccharide from bovine vitreous humour. They found a substance which contained two sugar moieties, one of which was uronic acid and gave it the name hyaluronic acid. This term is derived from the Greek word ‘hyalos’ meaning ‘glass like’ with the addition of uronic denoting the acid component. Balzas (1986) proposed the name hyaluronan instead of hyaluronic acid. There now exists some confusion in the literature as the terms hyaluronic acid, hyaluronan, sodium hyaluronate, and HA are used interchangeably.
Hyaluronan is a large glycosaminoglycan composed of repeating units of glucuronic acid and N-acetylglucosamine. Numerous cells including synoviocytes, chondroblasts and fibroblasts synthesize hyaluronan (Balazs 1982). In synovial fluid hyaluronan is primarily secreted by group A synoviocytes (Balazs 1993). The normal molecular weight of hyaluronan in synovial fluid is $6-7 \times 10^6$ (6-7MDa). The only variation in endogenous or exogenous hyaluronan is the length and therefore the size of the individual molecules, the repeating units themselves do not change. The length and subsequent molecular weight of the hyaluronan molecule varies between different tissues and species but in particular this variation is dependent on the condition of the tissue. In synovial hyaluronan molecules bend and twist and adopt the conformation of an expanded random coil. The molecules are sufficiently large that at even relatively low concentrations of 0.1% (1mg/ml) they are capable of filling up the entire solution that contains them. At higher concentrations the molecules intertwine and become entangled which helps to retain relatively large quantities of water while still allowing the passage of cellular metabolites (Balazs 1982, 1993).

Hyaluronan is not only found in cartilage and synovial fluid but is an essential component of the extracellular matrix of all tissue. The average concentration of hyaluronan throughout all tissue in the human body is 200mg/kg; thus a human body weighing 60kg contains about 12mg of hyaluronan (Science of Hyaluronan Today. www.glycoforum.gr.jp/science/hyaluronan/ hyaluronanE.html. Editors Hascall and Yanagishita 2008).
The normal state of hyaluronan in tissues is as a free polymer. However, as previously described in some tissue including cartilage hyaluronan is bound to proteoglycans.

The overall turnover of hyaluronan is very fast compared to other cellular components such as collagen (Science of Hyaluronan Today. www.glycoforum.gr.jp/science/hyaluronan/ hyaluronanE.html. Editors Hascall and Yanagishita 2008). This synthesis of hyaluronan does not take place within the cell but is maintained in the cell membrane with the two basic glucuronic acid and N- acetylglucosamine units being added onto the growing hyaluronan chain to form the polysaccharide macromolecule. These units are added to the growing chain on the interior of the cell membrane which is then released into the surrounding extracellular medium. Of particular relevance to the use of hyaluronan in the therapeutic management of osteoarthritis is its very short half-life which in most tissues in the human body is never more than a few days. Indeed in the skin it is no more than 24 hours. This very fast catabolism takes place in a series of steps which firstly involves the hyaluronan molecules disentangling and moving out of the molecular network in which they are situated and entwined. The molecules then bind to receptors on the cell membrane which subsequently engulfs them so that intracellular lysosomes can degrade the molecules into their basic constituents for reuse or elimination (Science of Hyaluronan Today. www.glycoforum.gr.jp/science/hyaluronan/ hyaluronanE.html. Editors Hascall and Yanagishita 2008). The half-life is partly dependent upon the molecular weight of the hyaluronan molecule with greater weights having increased residency times. In addition the inflammatory process will significantly reduce the half-life of hyaluronan. This has a significant impact on timing with regard to the optimal moment for injection and may mean that any inflammatory component to the
patient’s pain may initially need to be dealt with prior to injection of hyaluronan. This is reflected in the choice of drug used in this study with corticosteroid being used if a joint was effused. From a clinical perspective the assumption is that effusion is related to an active inflammatory process, one in which hyaluronan is less likely to be effective due to decreased residency (Fraser 1993).

The principle of injection of hyaluronan in the management of osteoarthritis referred to as viscosupplementation is based on the changes which are found in the synovial fluid of arthritic joints. With osteoarthritis, there is a decrease in the elastic and viscous properties of synovial fluid (Balazs 1968, 1982). This is due to both a decrease in the molecular weight and in the concentration of the hyaluronan present in the synovial fluid of the joint (McCarty 1998, Dahl 1985).

As the viscoelastic properties of synovial fluid are dependent upon the presence of hyaluronan any change in either its concentration or ability to act as a lubricant will significantly reduce the function of the joint. These viscoelastic properties are important to the normal functioning of a joint. They allow synovial fluid to act as a viscous liquid and decrease friction at low shear rates. At high shear states synovial fluid acts as an elastic solid and absorbs shock.

Intraarticular hyaluronan therapy was introduced in an attempt to enhance the viscoelastic properties of synovial fluid and the cartilage matrix in osteoarthritic joints (Balazs 1993, Rosier 2000).
Synthetic hyaluronans were initially derived from chicken combs (Ayral 2001) however; most commonly used preparations are now produced by a process of bacterial fermentation which enables a highly purified form of hyaluronan to be manufactured. In addition this has the effect of decreasing any possible allergenic reaction. The molecular weight of the early hyaluronan preparations was lower than hyaluronan found naturally in synovial fluid (Balazs 1993). More recent preparations have higher molecular weights.

There are a number of reasons why molecular weight may be important in viscosupplementation. Increased molecular weight leads to increased elastic properties of the synovial fluid (Balazs 1993, Wobig 1999). In addition the half-life of hyaluronan in synovial fluid may be lengthened by a higher molecular weight (Weiss 1995). To increase the molecular weight, synthetic cross-linking of the molecules was introduced. These cross-linked hyaluronans are known as hylans.

While in theory viscosupplementation with hyaluronan enhances the rheologic properties of synovial fluid, its exact mechanism remains unknown. The half-life of injected hyaluronan, like its naturally occurring counterpart, is very short and cannot account for its long-term effect (Rosier 2000). Indeed in sheep studies the mean metabolic half-life of exogenous hyaluronan in healthy knee joints was demonstrated to be about 20 hours and only 12 hours in joints which were inflamed (Fraser 1993).

The short half-life of hyaluronan cannot explain the increases in synovial fluid concentrations of hyaluronan long after therapeutic administration. Bagga (2006) investigated the effect of injection of hyaluronans (Hylan GF-20) on the concentration, viscosity, and elasticity of synovial fluid over a 6-month period in patients considered to
have mild to moderate osteoarthritis of the knees. Using uronic acid assay to determine hyaluronic acid concentration at 6-month post injection the hyaluronic acid concentration still demonstrated an increase of 10% (p<0.05) over pre-injection levels.

A number of mechanisms have been proposed to explain the affect that hyaluronan exerts other than that of a short lived lubricant. Exogenous hyaluronan administration to human synoviocytes in vitro has been shown to enhance endogenous production of hyaluronan (McCarty 1998, Smith 1987). This may be one way in which lasting effects are obtained. Hyaluronan has also been shown to stimulate proteoglycan synthesis (Fukuda 1996, Schiavinato 1989).

Hyaluronan also seems to protect cartilage from damage by the metalloproteinases responsible for the degradation of cartilage in osteoarthritis (Yasui 1992, Williams 1997, Comer 1996). Keratin sulfate concentration, a marker for cartilage breakdown, was decreased in synovial fluid from osteoarthritic knees after administration of hyaluronan (Creamer 1994).

Anti-inflammatory properties have also been described including effects on leukocytes, inhibition of arachidonic acid release, and prostaglandin E2 synthesis (Dougados 2000, Hochberg 2000). Hyaluronan may also protect cartilage from damage by free radicals (Balazs 1993, Takahashi 2000).

In practice there exist a number of different hyaluronan preparations with both Durolane and Ostenil routinely being used. Durolane has been licensed for the hip and knee and requires only one injection while Ostenil is licensed for all synovial joints but requires
three to five injections for any one episode of symptomatic osteoarthritis. The essential
difference between these being the molecular weight of the hyaluronan molecule
contained within each. Three of the commonest preparations used in the UK are detailed
below (Fig. 7).

**Figure 7 Common preparations of hyaluronan**

<table>
<thead>
<tr>
<th>Name</th>
<th>Dosage per Injection</th>
<th>Number of injections</th>
<th>Molecular Weight</th>
<th>Half-Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Durolane</td>
<td>60mg</td>
<td>1</td>
<td>10MDa (10x10⁶)</td>
<td>20 Days</td>
</tr>
<tr>
<td>Synvisc</td>
<td>16mg</td>
<td>3</td>
<td>6MDa (6x10⁶)</td>
<td>7 Days</td>
</tr>
<tr>
<td>Ostenil</td>
<td>20mg</td>
<td>3-5</td>
<td>1-2MDa (1-2x10⁶)</td>
<td>4 Days</td>
</tr>
</tbody>
</table>

With regard to the molecular weight of the hyaluronan molecule a number of *in vitro*
studies suggest that this is an important factor in the ability of the administered
hyaluronan to affect its target tissue. Smith (1987) demonstrated that the amount of newly
synthesized endogenous hyaluronan in response to exogenous hyaluronan as administered
to synovial fibroblasts from osteoarthritic knees was both concentration and molecular
weight dependent (molecular weights of between 3.4x10⁵ and 4.7x10⁶ were used) with
higher molecular weights stimulating more synthesis than lower weights. Gotoh (1993) in
a study exploring a bradykinin induced analgesic effect in rats noted that the analgesic
action was molecular weight dependent with higher weights having a greater effect than
those with lower weights. High molecular weight hyaluronan has also been demonstrated
to exert a greater inhibitory affect on the production of arachidonic acid than lower
weights, certain metabolites of which such as prostaglandins mediate the inflammatory
response (Tobetto 1992).
Immunological effects of hyaluronan may also be reliant on its molecular weight with higher weights demonstrating a dose dependent inhibition of macrophage phagocytic activity. Such macrophage inhibition was not noted with lower molecular weights (Forrester 1980). In osteoarthritis in rabbits the extent of the observable beneficial effects on cartilage were seen to be dependent upon the molecular weight of the preparation with the histology of the articular cartilage and synovial tissue being significantly better with hyaluronan of molecular weight $2.02\times10^6$ than with weight of $9.8\times10^5$ (Sakakibara 1994).

In summary intra-articular administration of hyaluronan has a modest but long lived symptomatic effect on pain as measured on a Visual Analogue Scale (VAS) and functional outcome measured with the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in knee osteoarthritis (Clinical Evidence Concise 2005). The differences in efficacy related to the molecular weight of hyaluronan are a subject of debate as little in vivo clinical evidence exists to support one particular weight over another (Clinical Evidence Concise 2005), however there does appear to be in vitro evidence to suggest that higher molecular weights may be more beneficial (Smith 1987, Gotoh 1993, Tobetto 1992, Forrester 1980, Sakakibara 1994).

Having explored the normal and osteoarthritic joint and the basis for the use of corticosteroid and hyaluronan injection the next section reviews some of the possible factors which may influence the outcome of treatment of the osteoarthritic joint following injection with either of these drugs and in so doing provides justification for the implementation of this study.
9 Factors Influencing Outcome

To find relevant studies concerning the possible factors that influence outcome following injection in subjects with osteoarthritis of the knee a literature review was carried out. This search included MEDLINE, CINHAL and PROQUEST databases over the years 1980 - 2008. Keywords used were osteoarthritis, osteoarthrosis, arthrosis, knee, injection, x-ray change, effusion, occupation, job, obesity, anxiety, social function and depression. Little work was identified that explored the possible influencing factors on outcome other than physical variables such as degree of x-ray change and effusion. In particular there appeared to be a dearth of work exploring the possible influence of social and physical function or degrees of anxiety and depression on outcome. There now follows a review of this literature.

9.1 Degree of Osteoarthritic Change

The most commonly studied factor in relation to prognosis and outcome was degree of osteoarthritic change as evidenced on x-ray. Certainly radiographic investigation forms the most universal assessment of the degree of osteoarthritis in most clinics. An assumption seems to exist that the degree of change is both linear and constant during the course of the disease progression in regard to radiographic features in addition to a progression of disease which correlates with an equal progression in impairment and reported pain levels.

However, in the axial skeleton there exists little correlation between the degree of osteoarthritic change and degree of impairment or reported pain (Waddell 1996). In the
appendicular skeleton there is general acceptance within clinical practice that more of a
correlation does occur with greater change being associated with more impairment and
pain. However, this correlation does not seem to be a simple ‘cause and effect’ model.
Hannan (2000) examined 3 indicators of osteoarthritis, x-ray evidence of structural
damage, self-reported knee pain and self-reported diagnosis of osteoarthritis by a
physician in a large study sample (n=6880) in the United States. Hannan (2000) was able
to demonstrate considerable discordance between the 3 factors examined concluding that
this may have considerable bearing on the design of clinical trials in regard to what we
examine.

In another study Birrel (2005) investigated the link between pain and radiographic change
in the hip. In this study responders to a postal questionnaire (n=1071) were stratified into
hip pain positive and negative groups. Samples from each were then x-rayed and a
correlation looked for. The conclusion was that although mild to moderate radiographic
change was frequently noted it was not related to pain, whereas severe change although
rare was strongly linked to pain except in younger males who even in the presence of
severe radiographic change do not complain of pain. A point not noted in regard to these
studies is the degree of self-selection that takes place, such that subjects included in trials
have had to complain about knee pain to be included and therefore an automatic
exclusion takes place in regard to any subject who may have osteoarthritis but has never
reported being symptomatic.
If any conclusion may be drawn it would seem that the degree of radiographic change may represent an underlying anatomical change but not the disease state, or perceived disease state as described by the patient. Within my own clinic, x-ray is often requested to assess the degree of osteoarthritic change but increasingly my own feeling is this approach is based on tradition rather than necessity and that of more use would be the incorporation of other factors such as expectation of treatment and knowledge of condition. At the very least these potential factors should be given an equal weighting during initial assessment.

With regard to injection the presence of more significant radiological defined osteoarthritis in the knee or moderate to severe patellofemoral arthritis has been shown to be a negative prognostic factor to successful injection of hyaluronan (Vad 2003). This large study was further supported by Toh (2002) who concluded that patients with minimal to mild osteoarthritis as assessed by radiological examination formed the group most likely to benefit from hyaluronan injection as assessed using the WOMAC. At variance with the idea of hyaluronan only being beneficial in less severe osteoarthritis Lohmander (1996) in a large randomised double-blind placebo controlled trial found no significant differences at 20 weeks between injection of hyaluronan or placebo compared to baseline evaluation. However, once stratified according to age and degree of severity of osteoarthritic change hyaluronan proved to be more efficacious in patients over 60 years of age who demonstrated the most severe osteoarthritis.
9.2 Presence of Effusion

Clinically a commonly described prognostic factor is the degree of knee effusion present at the time of examination. Despite this there appear to be few current and relevant studies exploring the influence of effusion of outcome following injection. Gaffney (1995) examined the efficacy of a single intra-articular injection of triamcinolone hexacetonide in osteoarthritis of the knee and looked for possible factors which may have influenced outcome. In this study 84 subjects were randomly allocated to either corticosteroid or placebo injection (0.9% normal saline 1ml). The results supported the efficacy of corticosteroids in short term relief of symptoms with 78% of subjects in the experimental group reporting overall improvement at 1 week but only 49% reporting a similar improvement in the placebo group. This difference was however lost at 6 weeks with 57% and 55% reporting overall improvement respectively. Although subgroup analysis of the experimental group demonstrated greater improvement in those subjects with clinical evidence of effusion (p<0.05) and those who had synovial fluid successfully aspirated (P<0.01) no other predictors of outcome were noted. It should be noted that although Gaffney’s study included a modified Health Assessment Questionnaire this was used as a primary outcome measure and not a possible tool to explore the possible factors that may have influenced this outcome. No other psychosocial aspect of well being was examined for possible impact on outcome.

Contrary to the findings of Gaffney (1995) with respect to the relevance of effusion a study by Friedman (1980) using a double blind approach to examine the efficacy of
corticosteroid in the treatment of osteoarthritis of the knee found that the outcome was not related to the presence or absence of an effusion.

With regard to hyaluronan a retrospective Canadian study of 336 subjects with radiological confirmed osteoarthritis of the knee, found that the efficacy of intra-articular injection of hyaluronan (Hylan GF-20) was reduced in subjects who presented with effusion prior to injection. The percentage that improved was the same (70%) but more subjects reported being ‘much worse’ after injection if they had an effusion present (7.3%) as opposed to those that had no effusion (1.1%) (Lussier 1996).

A point to consider here is that the importance of an effusion being present may be related to the accuracy of the injection and not the effusion itself. An effused knee joint that can be aspirated confirms accurate needle placement whereas no effusion makes aspiration difficult and subsequently accurate needle placement cannot be easily confirmed. The accuracy of needle placement in the knee was examined by Jones (1993) who found that up to a third of injections for knee osteoarthritis were either placed extra-articularly or were of uncertain position as assessed by contrast radiography. Additionally from a clinical view point effusion of a joint would suggest an active synovitis a true ‘osteoarthritis’ rather than an osteoarthrosis and would therefore be considered more likely to respond to corticosteroid injection than a joint which had no active synovitis present.
9.3 Psychosocial Factors

No studies were found investigating the specific impact on outcome following injection for osteoarthritis of the knee or other joint in regard to psychosocial factors such as anxiety, depression or social function, although a number of studies have explored these factors in more general terms.

In regard to this study the definition of anxiety was considered to be a psychological and physiological state which may be characterised by cognitive, somatic, emotional and behavioural components. These components may combine to create an unpleasant feeling that the subject associates with uneasiness, worry and a general sense of poor self worth. In this regard anxiety is a generalised mood condition that can occur with or without any specific identifiable trigger. In the context of this study it should be distinguished from fear which may occur in the presence of an observed threat and which may be related to behaviours of escape and avoidance, whereas anxiety may be the result of threats that are perceived to be uncontrolled. However, it may be considered to be similar to mild forms of depression in that the subject may also exhibit a state of low mood and aversion to activity (Ohman 2000).

Psychosocial factors have been reported as having a significant influence for several chronic disorders (Booth-Kewley 1987). Many studies have focused on cardiovascular diseases (Mark 1992) and within the management of musculoskeletal disorders most of the attention has focused on low back and neck/shoulder pain with a number
demonstrating a link between psychological factors and disability in these pain syndromes (Leino 1989, Leino 1993, Bongers 1993).

In regard to chronic low back pain there remains little doubt that it is not solely attributable to physical pathology. The accepted belief being that psychosocial factors play an important role in the production of low back pain and associated reported disability (Waddell 1996). Indeed a patient’s report of the degree of pain they experience does not always appear to match the objective findings found during clinical examination. Those reporting severe pain and disability can have little to find in the way of objective signs (Fordyce 1995).

Sullivan (1992) found that depression is the most common psychological disturbance in patients suffering from chronic pain. Other studies support this finding showing that 30-80% of patients at a pain clinic have some depressive symptoms, and up to 20% meet the criteria for a major depressive disorder. A degree of caution needs to be exercised here as these are selected groups of patients, but lesser degrees of depression do appear to be important in most patients with chronic pain (Romano and Turner 1985, von Korff 1993).

Butt (2005) demonstrated a prevalence of clinically significant anxiety and / or depression in an outpatient population with x-ray confirmed osteoarthritis of the lower limb of 40.7%. In addition this study found that the presence of a depressive disorder was a better predictor of pain than the reported degree of anxiety, although both were related to the reported level of pain. Although indicating depression may predict levels of reported pain it is not possible to say whether outcome following injection may also be...
predicted in a similar fashion. In addition although utilising subject interview the
interviews in Butt’s study were focused on assessing the degree of depressive symptoms
present and did not endeavour to take a more inductive approach which may have
enabled the identification of other equally or more important factors to be explored.

The lack of evidence linking psychosocial factors and the ability to predict outcomes of
specific treatments may not be surprising. Rosemann (2006) looked at 220 primary care
patients with hip or knee osteoarthritis and concluded that assessment relied on physical
measures (plain radiograph and pain) to diagnose and tended to underestimate the
significance of socioeconomic and psychological aspects of the patients problem. Given
the limited time frame available to assess patients in most clinical settings this should not
be considered too unexpected.

A study by Pirjo (1997) assessed psychological distress and its impact on disability in a
number of conditions including osteoarthritis of the hip, knee, and hand. In a large study
(n=8655) with long term follow up (10-years) they observed a statistically significant link
in low back and neck pain syndromes but no such link in the peripheral system. However,
it should be noted that this study was aimed at establishing links between psychological
distress and disability rather than being interested in predicting outcomes following an
intervention. In addition although inclusive of a large cohort sample and long term follow
up the cohort was limited to a rural community in Finland which makes any direct
comparison difficult.
In a study specifically looking at osteoarthritis in knees, Jones (1996) used a double blind, placebo controlled crossover study to investigate whether it was possible to determine factors that may influence the outcome to intra-articular injection of corticosteroid in the treatment of osteoarthritis. The results concluded that there were no clinical predictors of response that were identifiable. Although this study investigated clinical measures such as range, stiffness, strength, tenderness, and effusion it also included subject’s perceived health status and levels of reported depression and anxiety using the Stanford health assessment questionnaire and the Hospital anxiety and depression score. However, these measures still represent a rather deductive, quantitative approach. Perhaps given the lack of available research a more inductive approach would be more appropriate. Such an approach would allow for the emergence of new areas of interest to become apparent which could subsequently be explored in more detail.

In a further study Creamer (1999) used a RCT to study the effects of acupuncture on osteoarthritis of the knee in 62 subjects. Each subject received 2 sessions of acupuncture per week for 8 weeks with response to treatment being measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Data was recorded at 4, 8, and 12 weeks. There were two points of interest that this study demonstrated firstly response to acupuncture was significantly related to duration of symptom (p=0.03) with subjects who experienced a longer duration of symptoms responding slightly better than those with more recent onset. A trend was also found (non-significant) which suggested that older and more educated subjects experienced a better response although
no indication for this trend is suggested this does point to an avenue of exploration on which the interview data of my study may shed some light.

In addition 1 year following final review at 12 weeks Creamer (1999) recalled subjects and asked them to complete a number of questionnaires to measure psychosocial variables that may have impacted on their original outcome following treatment. In all 37 subjects were contacted and assessed for levels of depression, anxiety, fatigue, helplessness, self efficacy, and quality of life. The only correlation found between reduction in pain and psychosocial variables measured was an inversely related response to anxiety (p=0.07) and fatigue (p=0.09) neither statistically significant. The problem with this study is the long gap between the original treatment which took place and the retrospective analysis of psychosocial factors 1 year latter. A point commented on by Silverman (1998) when discussing the potential problems with semi-structured interviews one of which being that data is often collected in a retrospective manner, after the event has taken place which allows for more of a reflective aspect to the data, one which may risk losing some of the ‘raw’ quality being searched for. The collection of my data was carried out at the point of clinical assessment in an attempt to gain insight into subject’s issues and perceptions as they occurred.

In a further attempt to investigate factors that may influence pain and physical function in patients with osteoarthritis Thumboo (2002) recruited 126 subjects of predominantly Chinese ethnicity with diagnosis of osteoarthritis of the knee (n=118) and hip (n=8). This difference in numbers between patients complaining of osteoarthritis of the knee and hip
reflects a ratio familiar to most clinics in the UK and certainly my own and was the
reason for concentrating on the knee only for this study as relatively few patients
presenting with hip pain would have made recruitment of numbers within the time frame
of the doctorate course difficult. Subjects were assessed using the Short-Form 36 and also
had data recorded describing socioeconomic and other demographic domains. A multiple
regression model was then used to identify those factors which influenced reported levels
of pain and function.

The results of Thumboo’s (2002) study demonstrated that less reported pain was
associated with a younger age, shorter duration of symptoms and similarly to the study by
Creamer (1999) better education as well as being in employment. Better physical function
was also associated with better education, less pain and less learned helplessness. The
term ‘learned helplessness’ was defined as a state whereby the subject, as a result of past
experiences holds beliefs that any current efforts directed at their problem will be
ineffective. This is of particular interest to my own study as it would seem reasonable that
a high degree of learned helplessness would lead to poorer outcome. This is an area that I
planned to explore through interview of subjects post injection. In addition Thumboo
demonstrated a strong positive correlation with reported pain and physical function
(correlation coefficient 0.44 p<0.001) as might be expected and as both were subscales of
the Short-form 36 support the internal consistency of this tool. A strong negative
correlation was found with the degree of helplessness and reported function (correlation
coefficient -0.29 p<0.001) while no significant correlation was demonstrated for
helplessness and reported pain only a negatively directed trend (correlation coefficient - 0.16) (Thumboo 2002).

10 Summary

In summary I grounded my research question in a self perceived disturbance within my professional practice. This in turn was rooted in a lack of confidence in my own professional effectiveness with regard to extended practice and in particular in the management of osteoarthritis of the knee and the ability to accurately target treatment. By means of the use of the approach advocated by Clough and Nutbrown (2006) I was able to construct the following clearly defined and focused research question.

Can the outcome of intra-articular injection of corticosteroid and hyaluronan in the management of osteoarthritis of the knee be predicted?

This question allowed for both the assessment of outcome and perhaps more importantly an exploration of the factors which may predict this outcome. Significantly this question also seemed in alignment with a number of other agencies’ current recommendations including The Department of Health’s (DH) briefing paper ‘Evaluating Models of Service Delivery’ (2006), The Chartered Society of Physiotherapy (‘Priorities for Physiotherapy Research in the UK’ 2002), and recent published NICE guidelines (NICE 2009 www.nice.org.uk/CG59).
Current concepts concerning the normal and osteoarthritic joint were then reviewed which included the use of injected hyaluronan and corticosteroid. A further review of the literature in regard to osteoarthritis and influencing factors concerning prognosis and outcome suggested that clinical decisions on how to treat osteoarthritis of the knee joint seem to be frequently based on reported levels of pain and radiographic change despite poor correlation seeming to exist between these factors and reported levels of pain and disability. This indicates the involvement other factors. Research has attempted to look at various psychosocial factors but this has tended to be quantitative in nature.

There would appear to be the need for research utilising an inductive approach through the use of qualitative work and directed at generating new theories through an exploration of possible influencing factors. This is important given the considerable resource implications for continued treatment of osteoarthritis in the NHS and it would seem prudent to fully understand all the processes involved to be able to best target treatment interventions.

All this must be considered in light of the fact that current demographic trends are for a continued growth of the elderly population with concomitant increases in quality of life expectations and an increase in population obesity throughout all ages mean that the potential burden of osteoarthritis in terms of both medical and socioeconomic cost will increase significantly over the coming years. As such the ability to predict outcomes in patients with osteoarthritis of the knee would seem to be of obvious benefit allowing for the correct intervention at the right time for best outcomes. In addition providing the right intervention in the right patients at the right time has major cost implications a particular
consideration in today’s climate of fiscal accountability. The following section will explore the methodology and methods which aim to outline the procedural aspects of this study together with the underpinning methodological foundations.
Chapter II Methodology and Methods

1 Introduction

This section will illustrate the position and role of the researcher within the setting of a research study in terms of their own unique theoretical background and identification of self within this background. There then follows a review of the outcome measures appropriate for this study’s aims to assess outcome in subjects who have had injection for osteoarthritis of the knee and explore the factors that may influence this outcome (the research question is defined in Chapter I, section 6, page 20). Next an outline of the methods used including sample size, subjects, procedure and the ethics and clinical governance issues associated with the study. Finally, the process of planned data collection and analysis will be outlined.

The research question needed to be both achievable and relevant to my clinical practice while at the same time having the potential to answer my own disturbance. The task was therefore look at possible methodological approaches and methods that would serve as appropriate tools. I had originally wanted to consider a tool that would provide data that was numerical in nature and which could subsequently be the subject of statistical analysis. The analysis would then inform whether treatment was or was not successful and identify those factors that may influence outcome, this in turn would provide data that would form the basis of a treatment algorithm from which clinicians could make more informed decisions concerning which patient received treatment and which should receive alternative treatment.
The confidence in being able to identify the factors which could predict treatment outcome would essentially seem to be based on the positivist cause and effect model that would seek to reduce patients into two categories, those who will do well and those who will not. However, during the course of reviewing the available literature it became clear to me that this approach, although having the potential to furnish some useful data, would run the risk of only ‘scratching the surface’. It seemed that the literature lacked a truly inductive approach, an approach which would work from the ground upward in an attempt to uncover new knowledge and data. Factors that influence outcome may exist that would not be uncovered if the data collected were too superficial in nature. This led me to explore the possible use of more of a qualitative approach and ultimately the use of a mixed methodology. To be able to do this I had to carefully think about my own perspective in terms of methodological approaches and how these perspectives may subsequently influence my choices and guide my research.

2 Position and Role of Researcher

2.1 Theoretical Background

At a basic level the choice of methodological approach would seem to come down to a philosophical belief focusing on my own assumptions relating to the most general features of the world, features which would encompass such aspects as the mind, matter, reason and proofs for knowledge (Clarke 1998). Essentially the researcher either has a belief in a naturalistic or a positivist philosophy. This philosophical stance cannot fail to influence at both conscious and subconscious levels whether there exists a bias towards a more qualitative or quantitative approach to investigation. As already outlined my own
initial bias was clearly positivist in nature, a view that may have been tempered somewhat by completing the doctorate programme but not wholly changed. Although this need not necessarily be problematic the bias that it represents does need to be made explicit to all those who may have a vested interest in the outcomes of the research.

From a pragmatic viewpoint it would seem that an important defining difference between these two philosophies is the way in which each paradigm treats its data. Whereas the qualitative researcher, using the naturalistic paradigm, begins with defining very general concepts, which as the research progresses, change their definition. The quantitative researcher using a positivist approach seeks to isolate and define variables which may be linked together to frame hypotheses often before the data are collected, and which are then tested on the data. These variables are central to the analysis and could be considered to be viewed through a ‘narrow lens’. Such a positivist view of the world sees science as the way to get to the ‘truth’ in such a way that we become able to both understand nature and predict and control it. The world is seen as deterministic, controlled by laws of cause and effect. These Laws are discernable if the correct method is applied, a method which requires a ‘top down’ approach utilising deductive reasoning to postulate specific theories that can then be tested through experimentation. Positivism requires a belief in empiricism, and empiricism espouses that authentic knowledge is knowledge that is based on actual ‘sense’ experience. It is dissociated from the personality of the researcher and holds that the key to gaining knowledge is observation and subsequent accurate measurement (Depoy 1994, Clarke 1998).
By contrast the qualitative researcher could be considered to view the world through a ‘wide lens’, searching for patterns of inter-relationships between previously unspecified sets of data or concepts. In this more fluid, reactive approach the resultant observed variables constitute the product or outcome of the search. With naturalistic designs the researcher themselves is the instrument of data collection. Indeed it is this ability of the researcher to be both reactive and flexible which gives the advantage of seeking out and exploring issues related to self that may otherwise be missed. Issues which may have influence on outcome that a purely positivist approach could not identify. By seeking out new relationships and concepts into a subject’s world the researcher is expected to be at the same time both flexible and reflexive and yet still be observant of these values and their own position within their study (McCracken 1988). Taking this approach to research reminds me of a quote by Atticus in ‘To Kill a Mocking Bird’ (Harper Lee 1960),

‘You never really understand a person until you consider things from his point of view…..until you climb into his skin and walk around in it’

This suggests a level of understanding which is both deep and insightful. If I am able to stand in my patients shoes and perceive things with their senses and experiences then a true understanding of why they are in my clinic, what they expect, and what are the factors which influence outcome may well be uncovered. If I look back through my research diary I see that this approach was both exciting and disturbing. Yes it suggested the ability to explore issues that I had not previously taken into account but only by considering an approach which was both new and uncertain.
This uncertainty was compounded further by the seemingly opposing ideas of some writers. For example this particular view was questioned by Gadamer (1990) who argued that if one does indeed ‘climb into his skin and walk around in it’ there exists a risk of withdrawing self from the phenomena under investigation. I had thought that idea of withdrawing self in an attempt to make ones research as value free as possible was something to be strived for in the quest for objectivity, a belief which probably reflects my own underlying philosophical bias. However, Gadamer (1990) thought that withdrawing of self from the phenomena being studied risked the loss of one’s own pre-understanding and prejudices. The idea of a relationship between researcher and researched is based on these pre-understandings where a central element is the researchers own exploration of self as well as that of the subject and forms the key factor in research using a Hermeneutic approach to understanding (Lamnek 1995). The researcher’s pre-understandings effect the way in which they understand and react with the subject who in turn will effect and change the researcher’s pre-understanding. Both researcher and researched develop in a mutually interactive fashion. Although this is more likely to be of relevance in research involving a repeated interview design where relationship and interaction have more time to develop I feel that even within one interview the interactions which take place cannot fail to direct and influence both participants as the process proceeds. Both the subject and the researcher will have certain preconceived ideas in regard of each other the minute that they see each other, ideas that are the result of all their past experiences and interactions. This interaction forms the basis of a process known as the Hermeneutic circle (Gadamer 1990). The data gathered through a process of interview will change and develop over time requiring a return to the
interview at a later date. With respect to my study the need for a longitudinal design with pre and post assessment measurements being taken would make the multiple interview process required to develop meaning, difficult in the available time frame. Additionally I do not think that this would be necessary in a study which is essentially looking for correlations between variables, would the factors involved change over time? Indeed would there be a risk of the subject failing to remember important issues as time progressed? It may well be that this in depth exploration would be useful to focus in on specific aspects of interest that are uncovered during the course of this study and could form the basis of future work.

In contrast to this very naturalistic approach and taking a more positivist stance the adoption of a more quantitative approach to my research could have been taken, one which used pre-determined and already finely tuned tools with accepted degrees of validity and reliability. This had certain appeal and would provide the numerical data with which I feel more comfortable. However, in isolation this approach would allow for less manoeuvrability, imaginative input and reflexivity and therefore risk producing data which is superficial in nature.

At this point I wonder whether my own positivist bias is not the result of my education from the earliest primary school days through to my post-graduate studies, which if I reflect on has clearly had this same empirical bias. Interestingly I have never really considered this bias in my education before, although it is a bias that should not perhaps be too surprising. Certainly the positivist approach to research methodological design has
been the predominant philosophical framework that has formed the ‘modern science’
approach to investigation. The origins of this approach can be traced back to the latter
part of the 17th century in the transition from oral to written communication and from
rhetoric to documentation as well as in the search for universal principles that would
apply in all locales and times (Toulmin 1990). Also referred to as logical positivism the
positivist approach employs a reductionist view of the person in its quest for mechanistic
rules which are culturally independent (Clarke 1998). This reductionist view sees entities
of one kind as reducible to another such as ‘societies to numbers’ or ‘mental events to
chemical events’ and even that ‘social processes are reducible to relationship between the
actions of individuals’ and ‘biological organisms are reducible to physical systems’
(Bullock 1992). The emphasis here is clearly on objective record and underlying laws to
support causal relationships, objective reality is characterized by stable, predictable, and
commensurable phenomena. The criticism of this positivist view must be that its
reductionism and universalism fails to appreciate the extent to which the so called social
factors it purports to uncover do not truly exist in the ‘real world’ but were themselves
the product of socially and historically mediated human consciousness. This classical
empiricism has to a large extent been rejected by many because of this very criticism that
the objective cannot be disconnected from the subjective viewer. The idea being that
scientific theories are in themselves abstract in nature and can only be tested indirectly by
reference to their implications; in other words the true content of our theories cannot be
verified by the classical scientific approach but only falsified.

This is not a problem to the naturalistic approach which emphasizes a more subjective
reality, characterised by complexity and an apparently infinite variation with
incommensurability. General rules evolve or develop from individual cases or observation of phenomena each unique in its own nature. One must therefore seek to uncover the truth based on the perceptions of others. Laws of cause and effect operate, but always within a unique set of circumstances determined by multiple factors (DePoy 1994).

At this point notes in my research journal suggested a degree of confusion. Where did this leave me? I felt that I clearly had a positivist leaning but increasingly did not feel that adopting an overly reductionist stance would be the most appropriate or fruitful approach to take if I wished to use my research to delve into an area not previously explored in depth. Was it possible to be a positivist with a naturalistic leaning? Or as my reading and indeed as most of my lectures had suggested did I need to clearly state my position as being in one camp or the other and subsequently stay with this viewpoint.

Certainly at a basic level these two world views, positivist and naturalistic would appear to be quite distinct however I believe that in reality these two views are just that they are ‘views’. If two people were to read a book or look at a work of art we might expect to get two different views on what had been read or observed. As these are views we cannot dismiss one purely because we do not agree with it. Rather if it represents a truthful perception of what an individual has observed at a particular point in time then we should value it as an insight not only in to that individual but also into ourselves as fellow human beings. Therefore at best I would see a qualitative or a quantitative approach in their purist sense representing either end of a continuum with a range of less purist and perhaps more practical approaches in between.
In relation to this continuum it is important to identify what my own ontological beliefs are. I believe that within a given framework and at a given point in time there are some absolute truths, and I certainly hold a position on the continuum which is relatively positivist. However, it must be recognised that in the Health Sciences when dealing with people, who are all fundamentally equal we are also dealing with subjects who are also fundamentally unique and therefore all have slightly different realities in terms of perceptions. This is particularly true with specific therapeutic interventions. This is important and central to my research study, namely is it possible in some way to predict outcomes resulting from a therapeutic intervention?

At this point I decided that taking a pragmatic view would seem the best approach to adopt for my study. That is identify my own position and make this clear but concentrate on the approach which would best answer the research question and make an attempt not to allow my own views to become too influential or overbearing. It is perhaps worth considering that when viewed from certain perspectives quantitative and qualitative research share similar values of science. Both traditions emphasize truth, consistency, applicability, and neutrality while taking different procedural approaches to ensure the quality of their processes, a view espoused by Lincoln (1985). Essentially I wanted to avoid being dogmatic in my approach and select the right tool for the job based on the job itself and not based solely on specifically held beliefs.

This pragmatic approach seemed to be reflected in the development of post positivism which distinct from positivism recognises that a single truth is not apprehensible, that
there is no absolute source of knowledge, and that findings cannot be proven to be true (Gortner 1999). In this sense the researcher is not seeking to confirm the hypothesis but to reject the null hypothesis within a specified probability, there exists recognition in post positivism that objectivity cannot be fully attained because reality is viewed by a subjective receiver, it is always someone’s reality even though I may be continually tempted to project my own prejudices and world view onto this reality. Post positivism sees human knowledge as not being based on unchallengeable, rock solid foundations, rather this knowledge is conjectural. By examining my own subjective involvement in the objective world, I may begin to accept people’s own subjective reality and in so doing may draw closer toward understanding some common, shared experiences. However, as outlined by Racher (2002) these experiences should never be interpreted as reality for all people at all times.

At first consideration post positivism would seem to imply a slight revision or adjustment to the stance taken by the positivist, but in essence it is a far more radical departure from this world view. The post positivist takes the view of the critical realist believing that there is a reality which exists as independent of self which can indeed be studied. However, unlike the positivist the post positivist critical realist also recognises that all observation is essentially fallible.

Post positivism assumes the constructivist view that we all create the world in which we live, based on our own perceptions of this world. These perceptions are taken to be fallible and unique in nature and so the notion that any individual is able to see the world
perfectly must be rejected as false. There exists a criticism of our ability to know reality with any degree of certainty and a belief that knowledge is constructed by the individual and not discovered from the world. There is therefore no single valid methodology.

Taking the view that any measurement is essentially fallible the post positivist recognises the importance of multiple measures and observations. As each is subject to error, but different error, this use of triangulation aims to produce a more ‘whole’ true picture of the event and represents an approach that I thought important to include in this study’s methodology.

The critical realist approach of post positivism seems to resonate with my own pragmatic view. To search for objectivity within phenomena while at the same time accepting objectivity only through an individual’s subjective reality has a strong appeal. Post positivism seems to attempt to explain, predict, and look for cause and effect relationships whilst taking on a realist perspective which does not seek to ignore the possibility of multiple realities.

From a practical point of view the post positivist critical realist approach would seem appropriate to my study. The use of a quantitative approach to examine outcomes pre and post intervention would provide me with objective data of degree of change in condition. This objective data searching for links between specific measurable factors such as anxiety, radiological evidence of osteoarthritis and outcome following intervention provides clear, objective and empirical, cause and effect like data. This promises to explain, and in today’s accountable NHS may help to justify the continued use of the
intervention. However, it fails to interpret and in isolation it remains data which is superficial in nature.

To provide a more complete picture, and indeed to take a more challenging approach, would be to include a qualitative element allowing a fuller understanding through a deeper exploration of subject’s perceptions. This does however necessitate a ‘wider’ thinking and basing methodological decisions less on my own views and taking into account the study itself and what its aims are. This pragmatic approach focused on the research question rather than on my own ontological and epistemological position promises to produce richer, more comprehensive data than if either a positivist or naturalistic paradigm is used in a purist design (Greene 1997). However, to obtain this more complete data set would necessitate the inclusion of an element of interpretation of the results of the intervention.

This degree of interpretation could possibly be gained through the use of a phenomenological approach. That is an exploration of the experience of the subject based on the subject’s own perceptions. In adopting this approach it should be feasible to gain as true an insight into the phenomena under investigation as possible. In the case of this study this means insight into the factors which influence outcome following injection.

As health research is plainly concerned with human beings we need to be mindful of the human state which can be characterised by the ability to reason and then act on the basis of free will. The degree of free will may of course vary, however the subject always
retains the freedom of how to respond to a particular situation. This uniqueness and the way in which it applies to each and every experience with which we interrelate in essence defines our being (Benedict 2007).

This distinctive ability to reason, unique to the individual is characterized by the individual’s capacity for abstraction and imagery, language and thought, sensation and emotion. The degree of individual uniqueness creates for each human being their own ‘lived reality’ and impacts on any research undertaken. Lived reality serves as a focus of inquiry with subjective and objective realities merging in an alliance between that reality and our knowledge of it. These realities and the everyday perceived world underlie the scientific explanation and for any research study concerned with the human experience a means of describing that experience is going to be of paramount importance.

Conscious experiences have features unique to the individual that experiences them as they live through them. These features have both phenomenological and ontological aspects for each experience they are part of what it is for the experience to be experienced (phenomenological) and part of what it is for the experience to be (ontological). This emphasis on the first-person, the experiential aspect of the phenomena, offers an approach that has the potential to provide richer, more in depth data on the phenomena of interest. This data which is person and experience centred is not constrained by the need to be overly reductionist as would be the case in a purely positivist approach (Smith 2007, Beyea 1997).
It should be noted that the term ‘approach’ is used here rather than method as despite researchers often describing the intention to ‘do phenomenological research’ the term is not truly a method, rather it may be considered to form one of the basic fields in the discipline of philosophy which have traditionally included at least four core fields, ontology, epistemology, ethics, and logic. However, phenomenology, the study of our experience and how we experience may be added to this (Stanford Encyclopedia of Philosophy 2003).

Each domain of study including that of phenomenology in these five fields is clearly different. This concept of an approach rather than a method is important, as the method used becomes less important and must sub serve the approach which precedes it. This approach is consistent with the post positivist, critical realist paradigm.

The term phenomenology itself has at least three meanings in the history of philosophy, firstly in the writings of Hegel (1770-1831), another in the writings of Husserl (1859-1938), and a third deriving from the work of Husserl in the writing of his former research assistant Heidegger (1889-1976).

For Hegel phenomenology was a philosophical approach concerned with an exploration of what presents itself to us in our conscious experience. It was a means to grasp the very essence that is behind the phenomena. This has been called ‘dialectical phenomenology’. (http://en.wikipedia.org/wiki/Phenomenology (2009)). Considered the founder of contemporary phenomenology Husserl viewed phenomenology as ‘the reflective study of
the essence of consciousness as experienced from the first person point of view’ and was concerned with the belief that prior to meaning and interpretation there is perception (Smith 2007).

This perception forms the core experience of the event the very ‘essence’ of the experience which is quickly lost as the experience is soon seen through the individuals own perspective, a perspective that is based on the individuals own world view. Husserl believed that it was the capture of this initial essence that was essential in understanding the experience and that much more could be known and asserted about the world if this could be uncovered. Husserl theorised that this was possible through a process of ‘transcendental phenomenology’. This process aimed to describe the experience not to interpret or explain it. At this level this requires the researcher to ‘bracket’ out their own personal experiences as they are considered essentially eidetic in nature that is remembered and interpreted. The researcher through transcendental phenomenology should strive to ‘transcend’ the distortions that come from one’s own culture and experiential history as well as those that come from the societal pressures of the day (Smith 2007).

According to Heidegger (1994) this approach by Husserl is burdened with aspects of the natural sciences, specifically the concept of certainty and absolute clarity. Heidegger believed that existence knows itself only in relation with others and other subjects and as such no experience is like any other with every perceived experience being unique. Heidegger opposed Husserl’s view of being able to transcend ones world view to seek the
essence of the experience. For Heidegger it was not possible to put aside the self that we inevitably bring with us, subjectivity is inevitable and should just be accepted. In this way research becomes a partnership between the researcher and the researched.

This acceptance of subjectivity as described by Heidegger allows for a more interactive exploration of the phenomena in my study and supports the belief that any experience is unique to the environment in which it takes place as well as being confined temporally. Additionally it should also be borne in mind that any experience will be anchored in the notion of the limits of methods to share and communicate that experience (Darroch 1982).

From this perspective the first step would be to identify the phenomena of investigation. In the case of this study this would be pain and perceived function and the factors that influence the changes in these two constructs following a therapeutic intervention.

Working within a phenomenological approach and seeking the perspective of the individual a method is then required which fulfils this need. This method needs to enable me to focus on describing subject’s lived experiences as they interact within their own context. Data may then be collected through observation, interviews or videotaping. Focal meanings or themes are identified by describing, analyzing, and validating subject’s words. This enables collection of rich, in-depth, and detailed descriptions of the subject’s lived experiences and the meaning of these experiences to the subject (Beyea 1997).
In regard to this study this would represent the experience of both the therapeutic intervention and also the condition for which the subject had presented to clinic. It is part of what it is for the experience to be experienced with the emphasis on the subject themselves. If I were to solely rely on the use of questionnaires which are quite clearly closed in nature I think that this element of reductionism would limit the ability of the subject to fully communicate their experience. To this end I decided to include the use of more open interviews in an attempt to gain an idea of the subject’s experiences as perceived by the subject.

I hope that through the use of a phenomenological approach to my study I will be able to gain a degree of interpretation that goes beyond numerical correlation. Such an approach can be used to explore more deeply into the phenomena and attempt to gain insight into subjects at a more individual level although the development of broader themes may also be possible.

Certainly the use of a mixed methodological approach is in keeping with the post positivist stance which holds that a triangulation approach to data collection helps to avoid the inherent fallibility of any one method or observation. This approach has been termed the ‘third methodological movement’ (Tashakkori 2003) as it does not represent a ‘new’ paradigm but a fusion of the theoretical and methodological approaches from both positivist and naturalistic paradigms. This mixing of methods represents a real challenge as the researcher who may be familiar and comfortable with one particular paradigm be it either a positivist or naturalistic must reach out across their ‘comfort zone’ and think outside their ontological perspectives. Having identified my own bias as being at its root
predominantly positivist in nature my challenge is to explore and incorporate the
qualitative approach into my research in an attempt to gain more in depth and valuable
data to best describe the phenomena in which I am interested, namely what factors
influence outcome post therapeutic injection. In addition I need to ensure that the use of a
mixed methods approach does not result in my bias emphasising the positivist aspect of
the study including the naturalistic aspect of the data in a merely tokenistic fashion. There
needs to be a genuine fusion of both the positivist and the naturalistic in such a way that
both approaches complement each other and produce the most complete data possible.

2.2 Reflections

Whilst considering both my own ontological position and pragmatically the requirements
of the research question I must also keep in mind the impact that I may have within the
environment in which I work. If I accept that every individual operates from within their
own unique ‘world view’ or paradigm then as a researcher I am no exception to this. I
need to consider from where my interest for initiating this investigation is derived. What
are my driving forces? What are my own personal experiences? As the idea for this
research question is rooted in my own personal values and beliefs then in some way they
will inform the ethical and moral responses to problems and issues that I will face
throughout the research journey. As outlined by Van Manen (1999) the challenge for me
as a researcher is to recognise this inherent position and subsequently through a process
of reflection overcome my own subjectivity, preferences and expectations to allow as
truthful an understanding as possible of the phenomena to emerge.
This degree of subjective involvement is not surprising as although traditionally all researchers try and remain unbiased we all carry with us values which have a position and a political viewpoint that cannot allow us to remain totally ‘value free’ (Clough and Nutbrown 2006). In regard to this I can take some comfort in the post positivist position which is accepting of the fact that we all have this personal world view, that we all carry our own ‘baggage’ which influences our perceptions and responses to experience. The post positivist need not see this as being particularly problematic and the belief of the relativist in the incommensurability of these different perceptions is rejected. Indeed the post positivist believes that we can all hope to understand, at least in part, our different experiences and come to a common understanding.

This said the researcher’s own personal stance in regard to their ontological and epistemological beliefs still needs to be considered carefully if not it may be these beliefs rather than an objective and critical approach to the research question take centre stage and govern the approach which is chosen. As mentioned I feel that the more pragmatic approach to my research would be to examine the question itself and then to use the most appropriate paradigm and methodological approach to provide the most complete, rich, and thorough data. In many ways the taught element of the professional doctorate has given me the opportunity to thoroughly explore the various different methodological approaches that could be used and to then make a more informed choice as to the most suitable ‘tool’ for the job. The importance of selecting the most appropriate tool was expressed by Inui (1996).
‘In science almost nothing is as unintelligent as always applying one method to every kind of problem and question’.

In addition a degree of honesty is called for in regard to making my own position within the research setting absolutely clear to the reader. The problem as I see it is that a potential issue exists in the fact that I am both lead clinician and manager of the department in which I work and carried out my research. This could clearly represent a conflict of interest with regard to researcher bias and the relationship that I have with both my staff and study subjects.

This is difficult as the reason for starting the professional doctorate was to gain the training and direction necessary to carry out a study within my own practice. It is unlikely that the disturbance outlined in the previous section could be addressed by conducting a study in someone else’s practice. I think this degree of researcher involvement may be in part addressed if a degree of honesty and transparency is adopted which allows for my own world view to be made explicit in such a way as to accept that a certain bias is inevitable. Such a stance sits comfortably with the post positivist critical realist position. Indeed to assume anything less would I think be dishonest and may make the reader suspicious of any outcome or conclusions that I may draw. Assuming then that it is not possible to eliminate all bias I should strive to minimize and make transparent to my audience any such issues within the study. One way around these issues is the objectivity of the scientific process itself. Such an approach involves using methodology in a systematic fashion to study particular phenomena of interest within the domain of interest of the researcher. The most important characteristic is that the research is carried out in a
systematic manner. The aim should be to minimize the contamination of results through my own bias by use of a sound and reproducible methodological design a process which needs to be reflected throughout the whole research journey.

In addition I need to be aware of my own theoretical perspectives and assumptions about my research topic and be able to reflect on these in an honest and open manner throughout the design of the study. The very term scientific research implies an exercise in objectivity from the inception of a research idea, through the design of the study, the methods used, collection of data and in the final analyses of the data. However although all researchers try and remain unbiased we all carry with us values, all have a position and a political viewpoint that cannot allow us to remain totally ‘value free’. All research and in particular research within social science is intrinsically value laden. These values are inherent in both natural and social science from the inception of the idea to its development as a viable project, to the choice of methods used, even to the decision as to which journal to publish in.

If as a researcher I am unable to divorce myself from the cultural, social, and political context of my work and my own intrinsic history does not allow for a truly unbiased and neutral position in relation to that work I need to do more than strive for a sound methodological design. To this end I feel that the best approach is to accept that I will bring my own values and beliefs to my research but to then try and be as reflexive as is possible. By reflexive I mean that I should use a process of self examination throughout the whole research journey. In a practical sense this means that I need to be continually
explaining and reassessing the thinking and action processes of my research so that others are able to agree or disagree with each analytic decision. They are then in a position to confirm, refute, or modify my own interpretations. In many ways I feel that this process of self reflection is something that has been facilitated throughout the doctorate programme both within tutorial sessions and through the action learning sets particularly in the earlier stages of the programme. The opportunity of being able to discuss issues with like minded colleagues in a neutral setting in a way which allowed me to ‘step outside’ of my normal work environment helped to gain a different perspective on the issues involved even if at times this may have not been too familiar or at times too comfortable.

Additionally if I am to be fully reflexive in my writing I feel that I also need to make my own expectations in regard to outcome clear to the reader. I need to consider that these expectations have always been there in the background of my thoughts from the earliest planning stages to the final analysis of my data, and just as we are shaped and influenced by significant people and events during our own development so my expectations of possible outcome will have in some way shaped this study. Do I hope for a particular result? Do I expect to find a particular correlation?

I would imagine I am similar to almost every other clinician in the world when I say that I hope my treatment helps. In the case of my study this hope would be that subjects do indeed benefit from the therapeutic injection administered. With regard to any specific correlation I think that this is a little more complex, which is why I initiated the study in
the first place. I suspect that as clinicians we place too much emphasis on the physiological aspects of a subject’s condition. These aspects are in many ways easier to measure in a clinical setting, for example degree of degenerative change as recorded on plain radiograph. I feel that it may be the non-physiological aspects such as anxiety and social functioning that in reality more likely to have stronger influence than is often considered, although the qualitative aspect of the study may identify other such issues. In this respect I am happy to admit that I make the assumption that those subjects who have poor social interactions, poor understanding of their condition and high levels of anxiety will be the ones who will least benefit from treatment. Why do I say this? Well from an experiential view patients who seem engaged and take an active part in their treatment, those that are interested and are aware of both their condition and the reason for their referral to clinic seem to do well. Conversely those that have little insight into their condition or indeed the reason why they were referred to clinic usually seem to demonstrate less engagement with the whole process, compliance seems low and overall outcomes are less positive. Of course this is based on my own view although evidence does exist clearly demonstrating outcome of intervention is often linked to psychosocial factors (Romano 1985, von Korff 1993). As my view it remains just that, a view. It is because this view cannot be substantiated that I started the professional doctorate and forms the very essence of why I wanted to initiate this study.

One other consideration that needs to be made in my quest for reflexivity is the investment that I have placed in this study in terms of the outcome. If I cannot demonstrate a positive effect of injection therapy is this potentially an indictment in
regard to my clinical ability? I do not think that this is the case I feel that as an experienced clinician of many years practice I am sufficiently confident to deal with any results that may be produced. I believe that I offer a good service to my patients and would like to make it clear to the reader that it is the aim of this study to attempt to refine the patient selection process that is seen as being just as important as the treatment outcome.

3 Justification of Methods and Aims

There now follows a description of a pilot study carried out in my clinic which investigated the use of injection therapy for the management of a variety of musculoskeletal conditions. This initial pilot project in part provided the motivation and direction for the initiation of my doctorate studies. Following this is a summary of the aims of this study before a subsequent description of the methods employed is considered.

3.1 Pilot Study

In the introduction I identified that there were no studies which examined the outcome of injection therapy in a Physiotherapy led clinic. In an attempt to address this and to support the extended role of AHP’s and their involvement in the substitution of traditional doctor led services and to reconcile concerns with regard to litigation, lack of confidence and fear of adverse reactions when using injection skills, factors which caused me some issue as well as having been identified within the wider profession (Milligan
2003, Ellis 2002), an initial pilot study was carried. This study was carried out in my clinic and aimed at evaluating injection therapy with in the physiotherapy department (Resteghini 2003). This prospective pilot study examined 69 patients referred to the physiotherapy clinic over a 6-month period. Patients were assessed for perceived pain levels and satisfaction at pre-injection and 1-month follow up.

Patients were either referred from their General Practitioner or from a Hospital Consultant and all patients deemed appropriate for injection during this period were asked to complete a questionnaire. In all 82 patients were injected, 3 patients declined to complete the questionnaire, 10 patients were not available for the 1-month follow up appointment and were therefore not included in the study.

Outcomes were assessed with a Visual Analogue Scale (VAS) (Huskisson 1983) and to gain more in depth information with regard to perceived levels of pain patients were also requested to complete the Short Form McGill Pain Questionnaire (SF-MPQ) (Melzack 1987) for pre-injection pain levels and pain levels at 1-month post injection. Patients were also asked to rate their overall level of satisfaction of the service on a simple Likert scale. Analysis of data was carried out using the SPSS software package. For the purposes of analysis all data was considered to be at ordinal level and a non-parametric statistical analysis was carried out using the Wilcoxon signed ranks test.

The Wilcoxon Signed Ranks Test demonstrated a significant improvement between the pre-injection and 1 week VAS (Z=-7.157, p=0.0005). The difference was also significant
between pre-injection and 1 month \((Z=-7.072, p=0.0005)\). There was no significant difference between VAS 1 week and 1 month post injection \((Z=-1.794, p=0.073)\) (Fig 8).

**Figure 8 Mean VAS scores pre-injection, 1-week post injection and 1-month post injection**

Statistical analysis between pre-injection and 1-month follow up with the SF-MPQ demonstrated a significant improvement between the two stages suggesting injection therapy is an effective therapeutic intervention for certain musculoskeletal pathologies \((Z=-7.170, p=0.0005)\) (Fig 9).

These results should however be considered in regard to lack of a control group and the possible confounding influence of the placebo effect particularly when the therapeutic intervention involved injection which has been shown to have a potentially greater impact on outcome in regard to subjective measures than other less invasive treatments (Zhang 2008). The issue of placebo in this study will be considered further in the discussion section.
The results also indicated a high overall satisfaction with such a service, 94% of patients being either quite or very satisfied with their treatment.

This pilot study was restricted in describing outcomes only and did not attempt to explain how these outcomes may have arisen. This was due to a lack of my own understanding of the research process and in particular the qualitative paradigm and its potential to explore in more detail phenomena of interest. This pilot study did however provide the motivation for this current study aimed at exploring the possible factors that may influence outcome following injection. In so doing it was hoped that some guidance could be produced which allowed for better selection of those patients who may benefit from therapeutic injection. The ability to predict outcome and target treatment has the potential to allow the development of more clinically and cost-effective treatment regimes, an important consideration in a modern, accountable NHS.

An added benefit of this pilot study was in its ability to assess the SF-MPQ with a view to using this tool in this current research study. In this regard the SF-MPQ demonstrated to
be a relatively simple tool in terms of ease of completion with few problems being reported. In a smaller prospective project carried out in my clinic the Arthritis Impact Measurement Scale 2-Short Form (AIMS2-SF) was also assessed with a view to including this as a tool in this current study. In order to review the ease of completion of the AIMS2-SF which had not been used in the original pilot a sample of 25 patients with diagnosis of osteoarthritis of the knee were asked to complete the questionnaire in clinic. 24 questionnaires were returned with few problems reported in regard to understanding and ability to complete (unpublished data). In addition to this the data gathered from the pilot study and in particular the SF-MPQ was used to help calculate the sample size required for this further study.

3.2 Study Aims

As previously indentified the aim of this study was to explore the factors that influence outcome following injection of either corticosteroid or hyaluronan in the management of osteoarthritis of the knee (Chapter I, section 6, page 20). As such this study needed to be conducted on two levels. Firstly an assessment of outcome was required and secondly an exploration of the factors that may have influenced these outcomes needed to be considered.

The Department of Health had identified a need for research to evaluate the role of extended practice within physiotherapy (Department of Health: Evaluating Models of Service Delivery 2006) and my own professional body had in its ‘Priorities for Physiotherapy Research in the UK’ (Chartered Society of Physiotherapy 2002) identified
as an area of concern physiotherapy management of osteoarthritis of peripheral joints. However, the use of corticosteroid and hyaluronan injection in the management of osteoarthritis of the knee had already significant support (Gossec 2006, Clinical Evidence Concise 2005). More recently although NICE had suggested that hyaluronan should not be prescribed on the NHS they had suggested that hyaluronan should still be considered on a private basis, this decision apparently based on cost rather than clinical effectiveness (NICE www.nice.org.uk/CG59 (2009)).

Given this available evidence there did not appear sufficient justification to employing a randomisation and control group in this study. Ethically withholding a treatment that was considered to be substantiated in the literature would be questionable. Indeed as this study could be considered to be exploring the factors which influence outcome as its primary concern randomisation and use of a control group did not seem necessary.

Therefore, this study was designed as a pre / post test design with the subject acting as their own control. Outcomes were assessed through the use of the Short Form McGill Pain Questionnaire (SF-MPQ) and the Arthritis Impact Measurement Scale 2-Short Form (AIMS2-SF). The hypothesis reflecting my own personal view as a clinician that injection has a positive influence on outcome such that pain is decreased and function increased.

However, unlike the pilot study previously described this study also used a correlational design to look for relationship between specific domains on the pre-injection SF-MPQ
and AIMS2-SF questionnaires, x-ray reported degeneration and the change in outcomes post injection. In addition subjects receiving injection of hyaluronan also took part in semi-structured interviews. These interviews were utilized to explore subject’s thoughts and perceptions in regard to their condition. Themes from these pre-injection interviews were used in further post-injection interviews when issues were explored in a more open manner.

The hypothesis was that high scores on the SF-MPQ and AIMS2-SF and particularly reported high levels of anxiety and social function (a subset of the AIMS2-SF) along with marked degenerative change pre-injection would result in poor outcomes post injection. Interview data was to be used to explore further themes in a more inductive fashion in an attempt to more fully understand emergent issues. Subjects receiving corticosteroid injection did not take part in any interviews due to clinic time constraints. In addition given the NICE published recommendations it was felt that the need for research to explore possible factors affecting injection of hyaluronan was of more importance as the ability to target treatment more effectively had the potential to address cost effectiveness issues which had been raised in these recommendations (NICE www.nice.org.uk/CG59 (2009)).

It should be stressed that no additional treatment or investigation was carried out on any subject beyond what was considered normal clinic practice other than the administration of the two questionnaires the SF-MPQ and AIMS2-SF, the semi-structured interviews and a longer term follow up appointment.
4 Evaluation of Outcome

4.1 Outcome Tools

Outcomes are 'the results of health care processes,’ they are the consequence of the interventions that patients undergo and represent the change they experience (Baumberg 1995). As such an outcome measure is an evaluation of this change, the difference from one point in time, usually before an intervention to another point in time usually following an intervention (Kendall 1997).

Identifying a post positivist ontology (Chapter II, section 2, page 74) data collection needed to reflect a constructivist view. This relativist stance assumed that any single measurement was essentially fallible and subject to error and therefore triangulation of data collection was utilised.

In practical terms this meant a mixed methods approach incorporating both quantitative and qualitative elements. The use of a quantitative approach included the use of questionnaires and radiological evidence of osteoarthritis to examine outcomes pre and post intervention providing objective and empirical data. To gain more depth and explore subjects own world views in greater detail semi-structured interviews were included.

This pragmatic approach focused on the research question rather than on my own ontological and epistemological position aimed to produce richer, more comprehensive
data than if either a positivist or naturalistic paradigm is used in a purist design (Greene 1997)

In terms of the quantitative data collection the decision concerning which indicator to use was dependent on a number of variables specific to the study itself. These variables included,

- Does the approach warrant a broad or disease/domain specific tool?
- What is the study population like, from where do they come?
- Will the tool be acceptable and appropriate?
- What levels of validity and reliability are considered to be acceptable?

This study focused on investigating subject’s perceived levels of pain, function and anxiety both pre and post injection. It was hoped that this would allow for the assessment of the therapeutic injection given but more importantly allow for that assessment of outcome to be examined for correlation with the reported levels of pain, function and anxiety pre-injection.

In choosing an appropriate indicator both the reliability and validity needed to be considered as it is these two measures by which an indicator can be gauged to be accurate. This in turn determines the extent to which the results can be confidently accepted. A measure should be reliable, valid, and responsive to the clinical change that occurs over time in an attempt to closely define and quantify subjective data in a robust
manner. Reliability representing how uniformly the test can be repeated when administered on more than one occasion or by more than one observer, validity the extent to which the measure measures what it intends to measure, is it asking the right questions? (Cole 1994). Finally, responsiveness is the ability of the measure to detect true change in patients' status over time (Binkley 1999). In addition to these three basic conditions an outcome measure should also be standardised, with explicit instructions for administration and scoring (McDowell 1996). Such instructions need to be convenient for use by clinicians and acceptable for the patient. Reliability and validity are measured in terms of achieved levels of coefficients of Cronbach’s alpha. Ware (1980) suggested that acceptable levels for both reliability and validity for Cronbach’s alpha range between 0.85 and 0.94, although 0.50 is often regarded by authors as representing an acceptable level for correlation coefficients.

The need for a reliable and valid but generic and patient centred indicator of health has led to the development of a number of different assessment indicators. In deciding which outcome measure should be used I wanted to chose a tool that had previously been demonstrated to have accepted degrees of reliability, validity and responsiveness as well as a tool that would be acceptable to my subject group. The measures used also needed to be pertinent to the questions being asked. In this study there were two distinct levels of question which were being explored, firstly, a measure of any perceived change between pre and post injection was required and secondly a measure that would explore the possible impact of pre-injection factors such as anxiety and social interaction on injection outcome was required.
Outcome measures may be broadly divided into either condition specific measures or more generic measures. It is generally assumed that the condition specific measures are more responsive to change whereas generic measures are better suited to assessing co-morbidities, a fact partly supported by the literature (Brazier 1999). As both responsiveness to treatment and exploration of other factors was required I decided to use two measures which included elements of both the condition specific and generic approaches. The aim was to address the needs of both aspects of my study and complement the qualitative interviews.

Measures examined as possible tools included the condition specific tools the Western Ontario and McMaster Universities osteoarthritis index (WOMAC), the Knee injury and Osteoarthritis Outcomes Score (KOOS), the Health Assessment Questionnaire (HAQ), and the Arthritis Impact Measurement Scale 2-Short Form (AIMS2-SF). In addition a number of generic measures were also examined, the Hospital Anxiety and Depression scale (HAD), the Short Form-36 (SF-36), the Euroqol instrument (EQ), and the Short Form McGill Pain Questionnaire (SF-MPQ).

In summary the WOMAC is a self-administered questionnaire of disease severity specifically for people with osteoarthritis of the hip or knee (Bellamy 1988). It produces an aggregate total score, and scores for three sub-scales: pain, stiffness, and physical functioning/disability. For every question people rate their pain, stiffness, or function as none (score 0), mild (1), moderate (2), severe (3), or extreme (4). The Knee injury and
Osteoarthritis Outcomes Score (KOOS) is a self administered questionnaire which consists of 5 subscales, pain, function in daily living, function in sport and recreation and knee related quality of life. The last week is taken into consideration when answering the questions and answer options are given in the form of 5 Likert boxes with each question having a score from 0 to 4. The KOOS can be used over short and long time intervals to assess changes from week to week induced by treatment. It has been used in patients from 14 to 78 years of age and takes about 10 minutes to complete (Roos 1998).

The HAQ contains 20 items covering 8 categories of disability such as grooming, eating, grip, and walking, which combine to give a single disability index which ranges from 0 to 3 (Kirwan 1986). The final condition specific measure considered was the AIMS2-SF developed by Guillemin (1997) and consisting of 26 items covering 5 different domains of health status, including physical function, degree of symptom, and affect, each item being scored on a 5-point Likert scale and being subject to a patients perception of the 4 weeks prior to assessment.

Generic measures considered included the HAD a patient completed mood scale rating 7 items related to feelings rather than symptom, specifically anxiety and depression, on a 5 point scale (0-4). The HAD has been demonstrated to be a valid measure of the severity of these disorders of mood and is therefore considered to be useful as a repeated measure to obtain information on progress of condition (Zigmond 1983). The SF-36 revised for use in a British population contains 36 items generating a profile of 8 dimension scores ranging from 0-100, where high scores indicate good health. Dimension scores include
physical function, pain, and mental health (Brazier 1992). The EQ is a short 2 page questionnaire of which the first page contains 5 items describing health status across 5 domains, mobility, self-care, usual activity, pain, and depression. The second page displays a visual analogue rating scale on which subjects mark an assessment of their overall health (Euroqol Group 1990). The third and final generic measure considered was the SF-MPQ developed from the longer McGill Pain Questionnaire. The SF-MPQ consists of 15 descriptors (11 sensory, and 4 affective) which are rated on an intensity scale as 0=none, 1=mild, 2=moderate, and 3=severe. The SF-MPQ also includes the PPI index of the standard MPQ and a visual analogue scale (VAS). The SF-MPQ takes up to 5 minutes to complete and is relatively easy to score which have made it one of the most commonly used measurement tools for pain in a variety of health care settings (Melzack, 1987).

Most experience with the HAQ seems to have been in the assessment of rheumatoid arthritis (Kirwan 1986). Brazier (1999) found that the WOMAC was more responsive than the HAQ in terms of physical functioning and together with the pain domain was more responsive than the equivalent dimensions of the SF-36. These results were supported by other studies comparing the WOMAC, HAQ, and SF-36 (Bombardier 1995, Hawker 1995). In regards to the EQ Brazier (1999) found it to be less responsive to change in rheumatology clinic group then many of the dimensions of the SF-36 and concluded that the EQ may be suitable for economic evaluations of surgical interventions but otherwise the SF-36 should be preferred. The KOOS although including the WOMAC and having construct validity comparable with the SF-36 (Ware 1992, 1993)
does include the subscale ‘Sport and Recreation Function’ which consists of questions aimed at a relatively high level of activity, such as squatting and jumping, it was unlikely that this level of activity would be appropriate to the subjects in my study.

The HAQ although covering a wide variety of functional categories does not include any assessment of the mental state of the subject, such as the degree of anxiety. In contrast the HAD although asking about a subject’s feelings does not include any assessment in terms of symptom. The SF-36 does include a domain category assessing physical function as well as assessing more generic categories however is not condition specific and therefore risks being less responsive in terms of sensitivity to change than an equivalent condition specific measure (Brazier 1999). The importance of a condition specific measure in terms of responsiveness to change was supported by Angst (2001) in a comparative study of the WOMAC and SF-36 in capturing improvement in subjects undergoing a rehabilitative intervention. Angst’s conclusion being that functional improvement could be better detected by the WOMAC than by the SF-36.

Considering the need in my study for measures that were capable of a high degree of responsiveness to change and at the same time be able to explore a variety of domains which were generic in nature and include an element of mental health, as these were all possible factors which may have influenced outcome, the decision was made to use the AIMS2-SF and the SF-MPQ. The AIMS2-SF enabled assessment of physical function as well as an exploration of mental health and social functioning and the SF-MPQ was considered to offer a high degree of responsiveness to change as well as being able to
assess mental health in regards to the affective nature of the subjects condition. The next section outlines these two measures in more detail and offers a review of their appropriateness in terms of reliability and validity.

4.2 Arthritis Impact Measurement Score 2-Short Form (AIMS2-SF)

The original Arthritis Impact Measurement Scale (AIMS) was extensively tested for both validity and reliability with coefficients of scalability and reliability in all nine domains exceeding 0.60 and 0.90 respectively (Meenan 1980). Test-retest correlation across the nine domains was 0.87 (Meenan 1980, 1982, Brown 1984). In 1992 Meenan and colleagues revised and expanded the original AIMS. The AIMS2 was shown to be reliable and relevant to clinical research and responsive to change in clinical trials (Liang 1985). In addition the AIMS2 is considered to be comprehensive and hold exceptional measurement properties. However, it is this high level precision and accuracy that requires an average 23 minutes to complete and therefore makes it difficult and time consuming to administer in a busy clinical setting. In an attempt to reduce the respondent time but maintain confidence, content validity and the psychometric properties of the AIMS2 a short-form AIMS2 (AIMS2-SF) was developed by Guillemin (1997) in a population of patients with rheumatoid arthritis.

The AIMS2-SF consists of 26 items covering 5 different domains of health status, each item being scored on a 5-point Likert scale and being subject to a patients perception of the 4 weeks prior to assessment. Domains cover physical function (mobility, walking, self-care etc), role function (employment, work), and social function (social activities), in
addition to degree of symptoms (pain), and affect (mood, self worth). Reading my research journal I see that I had originally thought of doing just this and including subjects with osteoarthritis of any joint that may be referred to clinic. After some further thoughts and discussions I decided that this was not achievable. The inclusion of any joint would have resulted in a poorly focused study as the majority of injections carried out for osteoarthritis are directed at the knee and including 1 or 2 other joints such as the thumb or hip would not be obviously useful. To include larger numbers of these joints would have required a much longer period of data collection, longer than would have been feasible within the structure of the doctorate, but would certainly be something to examine at a later date if appropriate funding could be secured. Ideally for a study population with a mixed diagnosis of osteoarthritis, that is osteoarthritis affecting different joints items on the AIMS2-SF assessing function also include assessment of the upper limb.

Guillemin and colleagues (1997) used a 2-step reduction process, initially using a Delphi technique which included input from both an expert clinical panel and a panel of patients. Secondly, a nominal group technique was used where members of both panels reached consensus on the final selection of items derived from item analysis. The procedure involved both groups selecting what they considered a minimal number of items from among the longer list of the AIMS2 which pertained to the concept being explored but which avoided measurement overlap and resulted in consensus on 26 items. This particular method was chosen as it preserves content validity and is closer to the methodology used initially to generate items when constructing a new questionnaire.
The inclusion of a panel of patients as well as expert clinicians to decide on item inclusion gives this indicator an added perspective which was expressed in the different numbers and types of items that were retained or rejected at the Delphi stage.

The conclusion of the authors was that the AIMS2-SF demonstrated similar psychometric properties as the AIMS2. Internal consistency was high in all domains with a Cronbach’s alpha of between 0.74 and 0.87 with the exception of the social interaction scale at 0.32. The internal consistency of a construct being a measure of homogeneity indicative of correlations between items in the scale, items within each scale domain, or between items and the total score. Cronbach’s alpha is based on the average correlation among the items and the number of items in the measure. A low coefficient (alpha<0.50) suggests that that particular item does not come from the same conceptual domain (Bowling 1997).

Convergent validity demonstrated similar correlation with AIMS2 and the reproducibility was also similar ranging from 0.76 for social interaction to 0.8 for the physical component as measured by a 10-day interval test-retest. The sensitivity to change over 3-months also proved similar to the longer form AIMS2. There are a number of potential limitations with this study, the first being that the patient panel was recruited from a self-help group and this may not be representative. Secondly, the use of expert clinicians who have knowledge of the disease process of rheumatoid arthritis may have resulted in their decisions being biased to the more severe cases with which they are familiar. In addition Guillemin’s (1997) study only validated the AIMS2-SF against patients with rheumatoid arthritis.
This limitation was addressed by Ren (1999) who used factor analysis to identify different domains of functional health to evaluate the AIMS2-SF for both reliability and validity in 147 patients in the USA with osteoarthritis. This study found that there was poor compliance in completion of the two work items (they were not answered) and based on factor analyses and unreliable psychometric tests excluded these from analysis. The reason for the lack of compliance with these two items may have been due to the age of the patient population studied which when considering osteoarthritis will always be representative of an older group. However, as employment has an important relationship with well being and may be a factor which influences outcome including these items was considered to be a useful addition when looking for correlations between outcomes and patient demographic variables.

In addition in the study by Guillemin (1997) the social function domain only demonstrated a Cronbach alpha of 0.32, which is well below the 0.70 for standard group comparison. Ren and colleagues (1999) found that by moving the item ‘enjoy the things you do’ from the social function to the affect domain that the alpha score increased to 0.67 (the affect alpha score remaining at 0.84). The AIMS2-SF used in this study reflects this finding and the item ‘enjoy the things you do’ is contained within the affect domain. All other domains demonstrated a high degree of reliability with an internal consistency as measured by Cronbach’s alpha of above 0.70.
In addition factor analysis suggested that the physical function domain of the original AIMS2 could be split into lower and upper body limitations as there was little overlap between these two split scales. If this was done internal consistency as measured with Cronbach’s alpha for these two scales gave scores of 0.82 and 0.86 respectively.

In this study the AIMS2-SF was used on a population of patients with a diagnosis of osteoarthritis of the knee and did not include pathology at other joints. Therefore following Ren’s study the physical function domain was split into upper and lower body scales to enable more meaningful analysis of data items specific to lower limb in regard to physical function. A copy of the AIMS2-SF as used in this study can be found in appendix 1.

After these modifications Ren (1999) demonstrated that in all 5 domains the AIMS2-SF had a high level of item discriminant validity. The item discriminant validity together with the convergent validity of an indicator can be considered as the two parts the construct validity of an indicator. In essence convergent-discriminant validity assesses the extent to which a new indicator is related to other measures of the same construct, in this case the correlation of the AIMS2 and the AIMS2-SF. The convergent validity requires that related variables demonstrate a degree of correlation; discriminant validity requires that they do not correlate with dissimilar variables. Ren’s study did however acknowledge that results were based on cross-sectional data and thorough examination of the AIMS2-SF as a longitudinal indicator of change was not fully addressed.
4.3 The Short Form McGill Pain Questionnaire (SF-MPQ)

Only the patient is able to really assess their own pain. Clinical assessment is only an attempt to put the patient’s report into medical terms. It always remains the patient’s report of his or her own symptoms, and so is open to subjective influences (Main 1995). Medical training tends to emphasis the diagnosis of the pathological cause of pain it pays little attention to the actual assessment of pain itself. Clinicians often rely on clinical impressions or observer judgement of pain, but these correlate poorly with the patient’s own report of pain. They are both unreliable and prone to observer bias (Fordyce 1995).

Most attempts at quantifying pain have been in the form of a patient centered scale or with a collection of descriptive words. The commonest is a form of scale which takes the form of a line exactly 100mm long. The patient is asked to place a mark on the scale that represents where they feel their pain is at present. The scale runs from no pain to severe pain. Examples of this are the Present Pain Intensity scale (PPI) (Melzack 1975) and the Visual Analogue Scale (VAS) (Huskisson 1983). These are relatively simple and quick for patients to complete and have the added advantage of being easy to score. The difficulty is how to interpret what the pain scale means. It is not an objective measure of pain and does not match any physiologic or pathologic change.

‘It is not an objective measure of pain and does not match any physiologic or pathologic change’, on reflection I re-read this sentence with interest as it clearly indicates a degree of positivist thought ‘we should be searching for an objective measure of pain’. I wrote this sentence fairly early in my doctorate journey and can now say with some confidence
this is not what I believe. Pain and its measurement must surely be a predominantly subjective phenomenon which is unique to the individual and linked to a particular experience at a particular point in time.

In addition these relatively simple scales provide no data on the quality of the pain or any depth to the patient’s perception of pain and its impact on their lives. However, such scales do provide data on the intensity of the pain and may be most useful for following individual patient’s progress over time, rather than comparing different patients a point of particular interest in a longitudinal pre and post study design such as this study. It is generally believed that most VAS work adequately for acute pain states (McQuay 1990).

The most frequently used and most tested measure used to provide more in depth assessment of pain is the McGill Pain Questionnaire (MPQ). The MPQ consists of lists of terms describing the quality and intensity of pain. Developed by Melzack and Torgerson (1971) it contains a total of 78 items which are grouped into 20 sub-classes of three to five descriptive words. The 20 sub-classes are grouped in four sections, sensory, affective, evaluative and miscellaneous. The disadvantage of this measure is that completion can take up to 15 minutes and for this reason a short version of the scale was developed, the Short Form McGill Pain Questionnaire (SF-MPQ) (Melzack, 1987). The SF-MPQ is both quicker to complete taking up to 5 minutes and easier to score. The SF-MPQ is one of the most commonly used measurement tools for pain in a variety of health care settings.
The main component of the SF-MPQ consists of 15 descriptors (11 sensory, and 4 affective) which are rated on an intensity scale as 0=none, 1=mild, 2=moderate, and 3=severe. The SF-MPQ also includes the PPI index of the standard MPQ and a visual analogue scale (VAS).

The SF-MPQ scores obtained from patients in post-surgical and obstetric wards as well as in outpatient physiotherapy and dental departments have been compared to the standard MPQ. The correlations were shown to be consistently high and significant. The SF-MPQ was also shown to be sufficiently sensitive to demonstrate differences between pre and post treatment due to treatment at statistical levels comparable to those obtained with the standard form (Melzack 1987). Reading (1983) stated that although the standard form had been shown to have good test-retest reliability the reliability of the shorter form has not been as well established. Grafton (2005) attempted to address this using an observational cohort study and serial observation of 57 patients with osteoarthritis. Utilising an interclass correlation coefficient an estimate of reliability was demonstrated of between 0.88 and 0.96.

Given the relatively short completion time of the SF-MPQ and its high correlation with the standard version MPQ in addition to its ability to demonstrate differences between pre and post treatment the SF-MPQ was chosen as an outcome measure for this study. This decision was further supported by the pilot study previously outlined where the SF-MPQ was used as the primary outcome measure and where it had demonstrated a high degree of acceptability with a similar subject population.
5 Method

There now follows an outline of the methods adopted in the implementation of this study including an outline of ethical and governance issues together with details of data collection and analysis.

Ethics approval was granted by the University of Brighton’s Faculty of Health Research Ethics Committee (FHREG). Following this approval Ethics was granted by the Local Research and Ethics Committee (LREC) (Camden and Islington Community Local Research Ethics Committee) with the Research and Development Committee at the Homerton University Hospital NHS Foundation Trust acting as sponsors (Appendix 3). Further ethical consideration is discussed in Chapter II, section 6, page 129.

5.1 Procedure

All General Practitioners (GP’s) within City and Hackney were sent a letter explaining the study in which their patient may be asked to participate (appendix 4). No correspondence was received from any GP stating that they did not wish their patients to be approached to take part in the study.
Normal clinic practice dictates that patients assessed in clinic who are deemed to have symptomatic osteoarthritis that may benefit from injection are referred to an injection clinic and given the opportunity of having an injection as part of their management.

For recruitment to this study any such patient was asked for their consent (appendices 5 & 6) and if given booked into an injection clinic as a study subject. Any patient declining to give their consent was also booked into an injection clinic but treated as normal clinic practice dictated taking no further part in the study.

Those patients giving their consent became study participants and at their initial appointment at the injection clinic were assessed using a standardised assessment form. This included an area of free text the patient was able to complete (appendix 7). In addition subjects were asked to complete the AIMS2-SF (appendix 1) and the SF-MPQ (appendix 2) questionnaires. X-rays of the joint involved were requested if this had not already been done by the referring doctor. X-rays were scored by an independent assessor for degree of degenerative change as described on the Kellgren-Lawrence Scale (1957) (appendix 8). The independent assessor was one of the reporting radiographers or radiologists at the Homerton University Hospital. This is in line with current practice and does not reflect an increase in the use of x-ray or radiology time for the purpose of the study.

In addition at pre-injection assessment subjects will took part in a short semi-structured interview in an attempt to gain some deeper insight into any emergent themes in regard to
their condition or treatment expectations. A copy of the interview schedule can be found in appendix 9.

After completion of the questionnaires participants would be offered an appropriate injection. This would be carried out as standard clinic practice. Participants were then reviewed at 1-month and 3-month post injection and the two questionnaires again completed. These two time points were chosen for a number of reasons, firstly the 1-month follow up allowed for assessment of outcome in the short term as well as serving as a check on any issues that the subject may have had, such as post injection flare up, this reflects current clinical practice. The second 3-month follow up allowed a longer term assessment of outcome it was considered that a longer term review would have resulted in a significant drop out rate.

Subjects were interviewed at the 3-month follow up with the benefit of data from the pre-injection interviews to explore emergent themes in more depth. The study design is summarised in figure.10.
**Figure 10 Diagramatic Representation of Study Design**

Referral from Primary or Secondary Care

Consent Gained

**Yes**

Booked into Injection clinic

**No**

Booked into Regular Clinic

Initial Assessment Pre-Outcome measures
AIMS2 SF
McGILL
X-Ray

Injection of Corticosteroid or Hyaluronan

1-Month Follow Up Post-Outcome measures
AIMS2 SF
McGILL

3-Month Follow Up Post-Outcome measures
AIMS2 SF
McGILL

Hyaluronan Group Pre-injection
Short Interview

Hyaluronan Group Post-injection
In depth Interview

Discharge or further treatment as appropriate
5.2 Injection Procedure

Injection was given either of corticosteroid or hyaluronan. The corticosteroid used was Triamcinolone Acetonide (Squibb) and the hyaluronan was Durolane (Q-Med AB).

Durolane is licensed for both the knee and hip and unlike many hyaluronans is given as a ‘one-off’ injection and not part of a series of injections. Triamcinolone Acetonide is prescribed under a patient group directive (PGD) which was written by the lead researcher (appendix 10). Durolane does not require a PGD as it is regarded a medical device and not a drug. The decision as to whether to inject corticosteroid or hyaluronan is a clinical one and based primarily on clinical assessment with support of radiographic evidence. The clinical algorithm outlining this process is outlined in fig 11.

Figure 11 Clinical decision algorithm
To achieve maximum potential therapeutic benefit both corticosteroids and hyaluronans need to be injected intra-articularly and not into the anterior fat pad or the synovial tissues. This is easier if effusion is present however effusion is not always present this particularly being the case when hyaluronan injections are being considered. Jackson (2002) examined accuracy of intra-articular knee injections using three commonly used approaches each of which was assessed for accuracy using fluoroscopic imaging. The approaches used were anteromedial, anterolateral and lateral mid patellar. In a series of 240 consecutive injections into joints without clinical knee effusion success rates were noted. An accuracy rate of 71% was noted when an anterolateral approach was used, 75% with an anteromedial approach, and 93% with a lateral mid patellar approach (fig 12).

**Figure 12 Diagram showing lateral midpatellar portal.**
F=Femur, T=Tibia, P=Patellar, FP=Fat pad

(Reproduced with permission: Jackson 2002)

Similar to Jackson (2002) it is considered normal practice in my clinic to use a medial mid patellar approach when injecting the knee joint. This approach is one advocated by the Society of Orthopaedic Medicine (Kesson and Atkins 2002). If the ability to aspirate
any effusion present is considered a positive guide to intra-articular needle placement the findings of my study demonstrate that all but 1 subject had fluid aspirated, and this may represent no available aspirate as opposed to inaccurate needle placement. If this is considered I would suggest that comparable accuracy with Jackson (2002) is achieved in my clinic.

Once the decision to inject had been made the procedure to inject follows the algorithm outlined in fig.13.

**Figure 13 Injection technique algorithm**

1. Assemble necessary equipment. Check name, strength, volume and expiry date of drugs with second staff member
2. Position patient and ensure adequate exposure of area to be injected
3. Wash Hands
4. Clean area for injection with a solution of 70% alcohol & 2% chlorohexadine
5. Withdraw appropriate amount of local anaesthetic and corticosteroid into a syringe
   - Or
   - Prepare preloaded hyaluronan syringe
6. Attach needle to empty syringe and enter joint from the medial patello-femoral joint. Aspirate any effusion present
7. Disconnect syringe with aspirate. Connect syringe with drug to inject. Inject drug
8. Remove needle and dispose of in sharps bin. Apply pressure to area. Apply plaster
9. Patient kept in clinic for 30 minutes post injection

Wash Hands
5.3 Subjects

Patients were recruited from those referred to the Locomotor Service based at City and Hackney Primary Care Teaching Trust and to the Homerton University Hospital NHS Trust. Patients were referred from either their General Practitioner or Hospital Consultant and appointments arranged either through the Clinical Assessment Service based in the Primary Care Trust or the Homerton Hospital Physiotherapy Department as is current practice.

The recruitment of patients took place using a convenience sampling process. That is patients were invited to take part in the study that from clinical assessment had a diagnosis of knee osteoarthritis and were deemed to be have the potential to benefit from injection therapy. All subjects booked into the study had previously been advised on strengthening exercises for the quadriceps muscles. Subjects were not included if undergoing other specific treatments at the time of the study (eg: acupuncture). Subjects were allowed to continue to take analgesia as they wished.

No age limits were placed however as the condition under investigation was osteoarthritis it was likely that the patient group would be made up of those from middle to late age. Patients under 18 years of age are not routinely injected in the department.

A patient whose first language was not English and who had difficulty with communication in English were offered a standard clinic appointment but not enrolled as study subjects. This decision was taken as I felt that neither the SFMPQ nor the AIMS2-
SF was validated in other languages. In addition I felt that the inclusion of interview data may have proved difficult even if adequate advocate support had been available.

None of the following were included in the study;

- Subjects who were healthy volunteers,
- Subjects who had a limited life expectancy due to a terminal illness,
- Subjects who were medical or nursing students,
- Subjects who were psychiatric patients and detained under the Mental Health Act,
- Mentally disabled patients unable to give informed consent,
- Subjects who were unconscious.

### 5.4 Sample Size

It would not have been ethical to include too many subjects in addition to being a waste of NHS resource. However, insufficient numbers would have lead to a study of insufficient statistical power. Therefore a sample size calculation was carried out using Minitab software. This was carried out with the support of a University of Brighton Statistician who was consulted on all aspects of the statistical analysis of the study.

In order to calculate a sample size it was necessary to establish what would be a clinically detectable change in outcome, one which may also be considered to be of clinical significance. Grafton (2005) examined the SF-MPQ for test-retest reliability and included calculation of the coefficient of repeatability (CoR) as a measure of the reliability of repeated measures. The CoR may be defined as the value below which the absolute
difference between test-retest scores may be expected to lie with 95% probability. It reflects the measurement error and represents the clinical minimum detectable change in the unit of measure being used. Grafton (2005) calculated a CoR for the sensory component of the SF-MPQ of 4.54. The sensory component of the SF-MPQ was a primary outcome measure used in this study and progresses from 0 to 33, 4.54 therefore represents a change of 14%. In support of this Todd (1996) determined the amount of change in pain severity, as measured by a visual analogue scale (0 to 100mm scale), that constitutes a minimum clinically significant difference as 13mm (13%).

The pilot study had demonstrated a standard deviation in pre-injection SF-MPQ scores of 4.6. Therefore to calculate sample size in this study a change of 14% in SF-MPQ sensory score which equates to an absolute change of 4.54 between pre and post injection and standard deviation of 4.6 was used.

Using a power of 0.95 and significance of 0.05 a sample size of 28 was calculated. Hansen (1990) conducted a meta-analysis of 86 longitudinal studies to establish normative attrition rates and demonstrated on average 78.3% of subjects were retained at 6 months. Given that this study had a final follow up at 3 months it was considered reasonable to assume a degree of attrition similar to or slightly less than 78.3%. Therefore the final recommended sample size was between 35 and 40 subjects.

5.5 Time Scale

Recruitment took place using a process of convenience sampling with subjects being recruited into the study over a period of 3-months. This resulted in a period of 6-month of
data collection as those participants recruited at the end of the 3-month period did not have a final review until 3-months subsequent to this initial pre-injection session.

5.6 Materials

The drugs used in the therapeutic management of osteoarthritis within clinic are the corticosteroid Triamcinolone Acetonide and Hyaluronan in the form of either Durolane or Ostenil. In addition the local anaesthetic Lignocaine at 0.5, 1.0, and 2.0% strengths was routinely used. This study utilized the corticosteroid Triamcinolone Acetonide (Squibb) and the Hyaluronan Durolane (Q-Med AB).

It should be noted that both the corticosteroid and local anaesthetic used in this study are licensed drugs and as such can be prescribed from a locally developed PGD (Appendix 10). However, the mixing of two licensed drugs, where one is not the vehicle for administration of the other, creates an unlicensed medicine. As the law stands AHPs may not mix two licensed drugs together. However, the clinics in which this takes place including those subjects involved in this study are attended by Medical Registrars as part of their ongoing training needs at the Homerton Hospital and therefore the use of the two licensed drugs could take place under medical supervision. In addition The Medicines Healthcare products Regulatory Agency (MHRA) have stated that ‘the MHRA would not consider taking enforcement action for breaches of medicines legislation by a practitioner engaging in the long standing accepted practice of prescribing and administering a mixture of licensed medication via a single injection’ (MHRA 2009).
5.7 Costing

Durolane (Q-Med AB) is a single 20mg/ml injection of non-animal stabilized hyaluronan. It is supplied in a 3ml pre-filled single use syringe. It is indicated for use with osteoarthritis of the knees and hips only. The advantage of Durolane is that it is a single use preparation this is particularly useful with injection under imaging and in reducing the chance of infection. Each injection costs £220. The cost of Triamcinolone (Squibb) is £1.70.

No extra cost was involved in the use of these drugs within this study to either the Homerton University Hospital or City and Hackney Primary Care Trust. All drugs are currently supplied by the Department of Pharmacy at the Homerton University Hospital and are funded by City and Hackney Primary Care Trust or Homerton University Hospital.

6 Ethics and Research Governance

6.1 Ethical Considerations

As this study was based in a busy and large hospital it was provided with a ready ‘supply’ of subjects although this did raise a number of issues with regard to my position as the primary researcher and as previously outlined requires a capacity to be reflexive throughout the study. In a practical sense this meant that I needed to be continually explaining and reassessing the thinking and action processes of my research.
As my study evolved into a post positivist design this would seem to dictate a deductive approach to sample selection. That is a clear definition of the study population can be given which describes the characteristics to be both included and excluded. From this total population a sample needed to be selected that was representative of the total. This process of sampling is important and needed to be truly representative otherwise the external validity of the study will be questionable.

A number of methods exist which fall under the broad headings of either probability or non-probability sampling. Probability sampling is useful when the parameters of a population are known and requires that every member of the population has the same chance of selection. Non-probability sampling may be used when the population parameters are not known and therefore the probability of selection is unknown. Although probability sampling is designed to reduce the sampling error and therefore increase the external validity this may not be necessary in my study design. Osteoarthritic knees are a common referral but those benefiting from injection are less readily available and given time constraints of the doctoral programme this form of sampling will increase the time required to meet the sample size. In addition I felt that inclusion of those that may not benefit from injection may be useful in regard to the interview data and identification of possible themes that could explain outcome.

Therefore I felt that although ethically unlikely to be an issue the use of a probability sampling frame may therefore prove impractical and unnecessary. The alternative was a non-probability method of which convenience sampling is one example. This form of
opportunistic sampling involved selection of subjects as they entered the study until the desired sample size was reached. Therefore in this study all subjects who fit the inclusion criteria and gave their consent were included. This sampling allowed the required number of subjects to be included in the study despite the clinics approximate ‘did not attend’ rate of 12% and the likelihood of questionnaires not being completed.

6.2 Data Protection Issues

All patient notes are routinely stored in the Physiotherapy Department while the patient is under the care of the department and for 2-years post discharge. Notes are subsequently stored off site at a secure facility agreed with the Homerton University NHS Trust for a further 5 years in agreement with current NHS guidelines. As the subjects in this study were treated as ‘normal’ patients within the department with the exception of additional questionnaires being administered to monitor pre-injection factors and outcomes the notes were stored in a similar fashion.

All questionnaire data was entered onto an excel data base immediately after each assessment. Therefore no paper record of the data contained in the questionnaire was kept. The excel data base was held on the Homerton University NHS Trust’s server as a password protected file along with current patient information. Subject names were not included on the data base. Interview data was transcribed as soon as possible post interview and kept independently of the patient’s notes but was not identifiable by patient name. No audio record of interview data was kept once transcription had taken place.
In the event of a subject having died of unrelated cause prior to follow up a system exists within the department with the current booking software which allows regular updates of such patients. This gives such patients an ‘RIP’ status and further letters asking the patient to attend follow up are not sent avoiding unnecessary stress to relatives.

6.3 Safety

6.3.1 Adverse Reactions

The overall incidence of side effects following local injection of corticosteroid is unknown. Sepsis has been reported but this seems rare with studies demonstrating an iatrogenic infection rate of 1 in 14,000-50,000 injections (Coombes 1996). Other reported side effects include local tissue atrophy and depigmentation, facial flushing, post injection flare and hypersensitivity reactions (Khan 2000). Tendon rupture with loading post injection has also been reported but this seems rare and may be associated with poor technique (Cottlieb 1980, Unverfrith 1973).

In regard to the use of hyaluronan injection few adverse reactions have been demonstrated other than an occasional local and transient flare up post injection. The overall incidence of this post injection flare has been reported as 2% to 3% per injection (Lussier 1996). A study by Adams reviewed 1,234 injections; only seven adverse reactions localized to the injected joint were noted. None were severe and all resolved within days (Adams 1993).
The only potentially serious adverse event to be noted is the possibility of a joint infection, which is rare and directly dependent upon the number of injections given. In theory this would be less likely to occur with higher molecular weight hyaluronan injection as this requires fewer injections. It is worth noting that in 8-years of regular use of injection therapy in my clinic at the Homerton University Hospital there have been no reported cases of infection or other adverse reactions other than occasional local transient flare up.

No infection has been related to contamination of any of the preparations of hyaluronan. Both high and low weight hyaluronan is very well tolerated in comparison to non steroidal anti-inflammatory drug therapy (Adams 2000). In the unlikely event of an anaphylactic reaction local protocols would have been adhered to and the subjects General Practitioner informed.

6.3.2 Patient / Drug Safety

All staff in clinic were aware of local guidelines relating to needle stick injury and in the unlikely event of such a needle stick injury having taken place Trust guidelines on sharps and splash incidents would have been followed.

All drugs involved in this study may be stored at room temperature, and are routinely kept in a locked storage facility, which is in turn secured to prevent possible removal.
7 Data Collection

7.1 Questionnaire Data

Pre-injection assessment and 1 and 3-month follow up assessment of outcome were measured using the Arthritis Impact Measurement Scale 2-Short Form (AIMS2-SF) Guillemin (1997) and the Short Form McGill Pain Questionnaire (SF-MPQ) (Melzack 1987). Both are described in detail in Chapter II, section 4.2 and 4.3, pages 110 and 115 respectively.

7.2 Radiographic Assessment

Part of the aim of this study was to investigate whether there is a correlation between the degree of degenerative change as seen on x-ray imaging and the perceived change in outcome following injection. It was therefore necessary to x-ray all patients prior to injection. This is in line with current clinic practice and does not reflect an increase in patient exposure to ionising radiation. For ease of statistical analysis a simple numerical scale was considered to be the most appropriate tool, one which already had a high degree of acceptability within the medical profession. To this end x-ray evaluation was based on the Kellgren-Lawrence Grading System (1957) (appendix. 8).

No additional cost was associated with radiographic evaluation of subjects in this study to either the Homerton University Hospital or City and Hackney Primary Care Trust. X-ray imaging is already routinely carried out in the department of radiology at the Homerton University Hospital and is funded by the City and Hackney Primary Care.
7.3 Interviews

In addition to assessing patients perceived level of pain and function using the AIMS2-SF and the SF-MPQ more inductive qualitative data was also collected through the use of semi-structured interviews. This aspect of data collection recognized the relativism of the unique experiences of each individual. As a research tool interview seeks to understand how the individual sees their world and how they create and share meaning about their lives (Rubin 1995). In this sense the interview can be seen to be a key research tool belonging to the philosophy that understanding is achieved by facilitating people to describe themselves and the perceived position in the world in their own terms.

Initial interview data was collected at the pre-injection assessment stage. Themes that emerged on reflection at this pre-injection interview were used as a guide to facilitate and direct more free flowing, less structured interviews at the 3 months follow up stage. It was hoped that these interviews would provide a basis from which a deeper understanding of the possible factors which influenced outcome may have emerged. Interviews were tape recorded for later analysis. A semi-structured style was adopted to allow subjects to freely respond to the questions posed.

The use of a free text area on the initial assessment form (appendix 7) allowed subjects the opportunity to write down their expectations prior to assessment. It was hoped that their responses could then be used as a basis for the interview. This ‘ice-breaker’ may have helped put subjects at ease and allow for meaningful and useful interview to develop.
As it was my aim to allow more ‘freedom of movement’ in the 3 month follow up interview rather than ask specific questions in a set order a number of possible questions were identified which included areas of interest identified from the pre-injection interviews. These questions were kept more as a check list to ensure that all necessary areas were covered although the subject was allowed to dictate the direction of flow.

Where responses were not forthcoming, non-directive, gentle probes were used to facilitate discussion. The aim of these was to motivate without bias and to enable the subject to clarify and expand on areas of dialogue that were pertinent to the research question. These probes included the following.

1. Repeating the question just as it is written.

2. An expectant pause, accompanied by a nod of the head.

3. A verbal ‘yes’ followed by an expectant pause.

4. A quizzical glance followed by an expectant pause.

5. Neutral comments such as ‘Why do you feel that way?’

A copy of the interview schedule can be found in Appendix 9.

In addition after each interview ‘field notes’ were completed in a research diary. Recording field notes requires more that capturing general impressions and an attempt was made to ensure they were an accurate description of observations made. As such notes were made of points of interest which included subject demeanour and degree of engagement with the interview process. These notes were subsequently used to add depth
to the interview analysis. The use of this additional data allowed a degree of triangulation which increased the credibility of the study.

Credibility had been something I had noted as an issue in my research journal in so much as I had concerns as to ‘how does one ensure validity in a study of naturalistic design?’ Credibility provides the validity in a qualitative research paradigm and attempts to ensure what is reported by the researcher is linked to the research question. At this point there was a further note in my journal which I had made in regard to field notes which is relevant to the mixed methods approach of this study. That is in isolation field notes remain inherently subjective as they rely heavily on researcher interpretation from the moment they come to mind, and although it may be possible to be accurate the risk of losing a sense of objectivity and recording ‘what you want to see’ remains a high risk strategy. However, as an adjunct to support findings I can see that their inclusion is extremely useful as it allows a greater degree of triangulation in the collection data.

8 Data Analysis

As outlined in Chapter II, section 3.2 page 100 this study was conducted on two levels which included both analysis of outcome and exploration of the factors that may have influenced this outcome. This involved three distinct analyses of the data collected two involving the quantitative elements from the initial assessment and questionnaires and the third involving data from the subject interviews. The statistical analysis was discussed with a statistician at the University of Brighton as being appropriate for the proposed
analysis. All the descriptive and inferential statistics were carried out using the statistical software package SPSS version 16.0.

8.1 **Analysis of outcome**

Distribution of the data was explored using the Shapiro-Wilks test to assess whether it was normally distributed or not. Where data were not normally distributed non-parametric tests were used.

Changes from pre-injection to 1 and 3 months post injection were initially explored using Friedman’s test for both SF-MPQ and AIMS2-SF measures. Subsequent analysis of individual time points was carried out using the Wilcoxon signed-ranks test.

The design was of a basic pre / post test experimental type. The subjects were the same pre and post test. The data was examined over 3 time periods each of which had 2 conditions as outlined below:

1. Pre-injection v. 1-month post-injection
2. Pre-injection v. 3-month post-injection
3. 1-month post-injection v. 3-month post-injection

Additionally subgroup analysis was performed for:

1. Pre-injection v. 3-month post injection with Hyaluronan only
2. Pre-injection v. 3-month post injection with Corticosteroid only
8.2 Correlation between pre-injection factors and outcome

The second statistical analysis was to examine whether or not any correlation existed between subject’s perceived anxiety and social function as measured by the AIMS2-SF, affective pain scores as measured by the SF-MPQ, duration of symptoms, x-ray grade, amount of aspirate, employment status and age at the pre-injection stage and that subject’s outcome at 3-months as measured by symptom and function domains on the AIMS2-SF and sensory pain on the SF-MPQ. Analysis of this data was again carried out using the Spearman rank order correlation coefficient test. A summary of the statistical analysis planned is outlined in figure 14.

Figure 14. Statistical Analysis Summary

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<th>Level 1: Analysis of Outcome</th>
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<td><strong>Statistical Test Used</strong></td>
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<td>Friedman Test &amp; Wilcoxon Test</td>
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<th>Level 2: Correlation of Pre-injection factors with Outcome</th>
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<td><strong>Statistical Test Used</strong></td>
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Thematic analysis of pre and post-injection interview data
8.3 Analysis of Interview Data

Analysis of interview data requires a degree of interpretation of the data. This interpretation has its roots firmly in the reader's own world view. It is necessary to use a methodological framework of analysis in order that the reader can follow the process and understand how the emergent themes were derived. Moreover, this then permits comparison to other studies (Attride-Stirling 2001). In an attempt to remain reflexive and provide clarity my own position was outlined in Chapter II, section 2 page 74. In addition it is my hope that this section and the subsequent section outlining the study findings are described in sufficient detail to allow the reader clarity in regard to both process used and findings reached. The aim is to demonstrate both transparency of process and of interpretation facilitating a clear audit trial.

A thematic analysis was chosen as the best approach to analyse interview data produced in this study as it is an approach that is not wedded to any pre-existing theoretical framework and can therefore be used within different frameworks and to do different things within each. Thematic analysis can be used within a realist method, reporting experiences, meanings and the reality of subjects, or it can be used in a constructionist method examining ways in which events, meanings and experiences are the effects of society itself (Braun and Clarke 2006).

Thematic analysis is a method used for identifying, analyzing and reporting patterns or themes within a data set. It involves searching across the data set to find repeated meanings and patterns through a ‘careful reading and re-reading of the data’. It is a form
of pattern recognition within data, where emerging themes become the categories for analysis (Rice and Ezzy 1999). The exact approach used being dependent upon the epistemological underpinnings to the study. Having identified my stance as post positivist and taking a realist approach thematic analysis can be used to theorize motivations, experience, and meaning as a unidirectional relationship may be assumed between meaning and experience and language, as language reflects and enables us to articulate this meaning and experience (Widdicombe and Wofitt 1995).

A theme was deemed a conceptualization that in some way captured something important in relation to the research question and represented some meaning within the data. Boyatzis (1998) defined a ‘good code’ as one which captured the qualitative richness of the phenomenon, a ‘pattern in the information that at minimum describes and organizes the possible observations and at maximum interprets aspects of the phenomenon’ (Boyatzis 1998, page 161). As this was qualitative analysis no hard and fast approach was used to answer the question of what proportion of the data set needed to display a particular identified concept as a theme and a degree of flexibility was maintained. The aim was to provide a rich thematic description of the entire data set so that a sense of the predominant and important themes could be identified by the reader. As identified themes would therefore need to reflect the entire data set some depth and complexity may have been lost but a rich overall description was maintained.

To achieve this richness of description themes within the data were identified in an inductive or ‘bottom up’ fashion with the themes being strongly linked to the data itself
An integral process was to allow the themes to emerge directly from the data. Such an inductive approach to analysis involves a coding of the data with no attempt to provide a ‘best fit’ either into an existing coding frame or to my own analytic preconceptions.

The process of identification and exploration of emergent themes and issues that subjects communicated during the course of the interviews was further supported with data from a research diary.

The method used was similar to Burnard’s method of analysis (Burnard 1991) which in turn was developed out of methods described in the grounded theory literature (Strauss 1986). The method assumes that semi-structured, open-ended interviews were conducted and that the data was recorded and subsequently transcribed in full. The step-by-step process of analysis used is outlined below and is included to demonstrate transparency of how the overarching themes were reached from the initial raw data. This clarity of process is essential if a trial of evidence is to be provided which demonstrates credibility and trustworthiness (Koch 1994).

The identification and interpretation of themes took place at a number of levels and was designed to be a dynamic rather than static process. Conceptual categories were identified based on specific phrases and words. Phrases and words which appeared to be of a similar shared domain were grouped together. As more data was reviewed and compared a process of moving and relocating data within the identified categories took place as
mutual relationships between them became more apparent and better understood. In addition to supplement and support the credibility of these themes a second reader was used to identify any further themes that may have been missed at both the initial emergent and subsequent reduced theme analysis.

As a clinician working in my area for some time I cannot ignore the fact that I would have some preconceptions with regard to subjects. The old saying ‘first impressions count’ is highly applicable here. It is difficult to divorce completely from inherent and deeply seated prejudices and I am aware of the danger of making initial assumptions regarding patients before an examination even begins. For this reason I was happy to ‘go with’ the subject during the interview and allow exploration of areas of interest as they emerged, no data analysis can ever take place in an epistemological vacuum.

A summary of this process can be seen in figure 15 overleaf.
Figure 15. Process used for analysis of interview data
The practicalities of this thematic analysis are outlined in the following steps. To maintain a degree of clarity of process each stage is authenticated with examples from an actual subject where appropriate (subject HA8).

1. **Free text on assessment form:** The use of a free text area on the initial assessment form allowed subjects to come to the initial pre-injection interview with any specific thoughts or issues that may have already been identified (appendix 7). This also served as an ‘ice-breaker’ to initiate dialogue.

<table>
<thead>
<tr>
<th>Table 1 Free text from initial assessment form (subject HA8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is your problem today? Can you tell me how it started and how it affects you?</td>
</tr>
<tr>
<td>Well the knee hurts...I can’t walk like I did and that’s a problem really...well I suppose it started about 1 year ago you know...no there was no injury I didn’t fall or anything...no it just came on really</td>
</tr>
<tr>
<td>2. What are your expectations of your appointment today? What do you expect to happen?</td>
</tr>
<tr>
<td>I hope it will help...the Dr said that if the tablets had stopped working then the next thing was here...I should come to the hospital and see someone...they mentioned injection and well I’m happy for that...for the injection if it will help</td>
</tr>
<tr>
<td>Subject HA8</td>
</tr>
</tbody>
</table>

2. **Pre-injection interview:** The structured pre-injection interview helped me to focus on issues in the subsequent more open post-injection interview. Additionally in recognizing the dynamic nature of this part of my study this stage allowed a degree of interpretation to take place. Issues identified by both myself and the subject could be re-visited during the post-injection interview. Data was transcribed immediately post interview.
Table 2 Extract from pre-injection interview (subject HA8)

<table>
<thead>
<tr>
<th>1. Do you think exercise will help with your arthritis?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well I used to do a lot walking the dog and even some swimming you know...but I had to stop a while ago because the pain had increased and it just felt too much. After doing it the walking or swim the knee felt very stiff for a day or more. I've tried some exercise since but it's really difficult.</td>
</tr>
<tr>
<td>Subject HA8</td>
</tr>
</tbody>
</table>

3. Re-reading of pre-injection script: Prior to the post-injection interview the pre-injection script was re-read to ensure that this initial data was 'fresh' as 3 months had passed since this was collected.

4. Post-injection interview: The post-injection interview began with a chance for the subjects to read their pre-injection script. This provided an opportunity to reflect on what was said and produced a shared verbal experience, one which was more likely to evolve as both subject and interviewer moved towards a better understanding of views and beliefs. Although the aim of this second interview was to be as 'free-flowing' as possible it proved useful to bring up issues identified from the first, pre-injection interview, and explore them in more detail, gaining greater insight into the issues previously articulated by the subject. For example, 'you said at our first interview that...now you have had the injection what are your thoughts regarding this issue?' It was hoped that this would produce more reflective data. Data was transcribed immediately post interview.
5. **Field notes made post-interview**: Field notes were made immediately following each interview. Notes were also made from the taped interviews as transcription took place. This additional information from the ‘live’ dialogue provided data regarding emotion, engagement with the process and fluency in an attempt to keep the data ‘fresh and rooted’ within the context in which it was given as this would be lost once transcription was complete.

**Table 3 Extract from post injection interview (subject HA8)**

<table>
<thead>
<tr>
<th>Well I have had exercise before when I went to the physiotherapist before I came to you I got given the exercise to do...I know they should help but the pain well it kind of stopped me from doing any...or I couldn’t do them very often...yes I know they should help that’s why I tried to do them I really did but when the knee was too painful it was very difficult to do that and...well to be honest that’s when I gave up a little.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I couldn’t be bothered too much...well the GP the Dr he gave me the brufen tablets to take and I took the other tablet...the paracetamol but that is all...no I haven’t had any other tablets or treatments...no no injection before this one I got here.</td>
</tr>
<tr>
<td><strong>Subject HA8</strong></td>
</tr>
</tbody>
</table>

**Table 4 Extract from field notes (subject HA8)**

<table>
<thead>
<tr>
<th>Clear and articulate appeared to demonstrate a sense of empowerment / confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear eye contact appeared happy to be interviewed / appeared relaxed and comfortable</td>
</tr>
<tr>
<td>Engaged during the interview required few prompts / active participant / there was a sense of joint working to a common goal</td>
</tr>
<tr>
<td>Appeared cheerful and happy throughout interview</td>
</tr>
<tr>
<td><strong>Subject HA8</strong></td>
</tr>
</tbody>
</table>
6. **Data from both interviews read and re-read:** Data from both the pre and post-injection interview was read and re-read. This process continued until content became totally familiar. I felt that this familiarity or saturation had been achieved when I was able to identify underlying common themes and recurrent issues and in a sense recognize individual subjects from their transcripts as if the subject was still engaging in an active dialogue. As reading continued phrases and words were highlighted and notes made in the margins of the transcripts.

7. **Notes and highlighting of interview scripts:** As the scripts were read and familiarity with the text was established notes were made in the margins and specific words or phrases considered to be of interest were highlighted.

   Table 5 Example of highlighted text and notes (subject HA8)

   | Well like I said I know it won’t go for ever if the joint is worn then that’s against me isn’t it I’m not going to get younger am I?...the pain won’t go completely...even if it did I expect the knee would still be worn away...you can’t turn back time if it’s worn it’s worn and that’s that...I think the important thing well that is to keep going...I don’t mean just the arthritis but well as you get older you can’t stop...if you do that’s it isn’t it...you would just fall apart |

   Subject HA8

   **Realistic – suggests degree of pragmatism**

   **Reasonable and rational**

8. **Emergent themes noted:** At this point phrases and words which were considered to have some common basis were grouped under a theme. Following this a second transcript was read and any phrases identified as being similar to those identified from the first transcript were noted under that theme. In addition any new phrase not identified in the first transcript was also noted. This process continued with each subsequent transcript until all had been read and phrases of
relevance noted for all transcripts. The number of themes at this stage was unlimited and included any theme identified no matter how frequently this may have been recorded.

Table 6 Identification of emergent themes by subject (subject HA8)

<table>
<thead>
<tr>
<th>Emergent Theme</th>
<th>HA8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that the injection will help</td>
<td>×</td>
</tr>
<tr>
<td>Positive information received</td>
<td></td>
</tr>
<tr>
<td>Realistic beliefs regarding injection</td>
<td>×</td>
</tr>
<tr>
<td>Little expectation of injection helping</td>
<td></td>
</tr>
<tr>
<td>Previous treatment did not help</td>
<td></td>
</tr>
<tr>
<td>Unrealistic beliefs regarding injection</td>
<td></td>
</tr>
<tr>
<td>Negative experiences</td>
<td></td>
</tr>
</tbody>
</table>

9. Second reader reviews emergent themes: Once this process had been completed a second reader was asked to read the transcripts and identify any further emergent themes that they thought had not been included in the initial reading. The second reader was a senior lecturer in Physiotherapy at the University of East London. The University of East London has close links with Homerton University Hospital both in geographical terms and in regard to joint working initiatives. The use of a second reader allowed a degree of ‘investigator’ triangulation which added to the completeness of data and further facilitated validation and trustworthiness increasing the credibility and subsequently the methodological rigor of the study. This ‘investigator’ triangulation resonates with Schutz’s postulate of adequacy which identified the need for consistency between the researcher’s constructs and of those found in everyday common sense experience (Schutz 1973).
Table 7 Additional theme identified by 2\textsuperscript{nd} reader

<table>
<thead>
<tr>
<th>Initial Theme</th>
<th>HA8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belief that the injection will help</td>
<td>×</td>
</tr>
<tr>
<td>Positive information received</td>
<td></td>
</tr>
<tr>
<td>Realistic beliefs regarding injection</td>
<td>×</td>
</tr>
<tr>
<td>Little expectation of injection helping</td>
<td></td>
</tr>
<tr>
<td>Previous treatment did not help</td>
<td></td>
</tr>
<tr>
<td>Unrealistic beliefs regarding injection</td>
<td></td>
</tr>
<tr>
<td>Negative experiences</td>
<td></td>
</tr>
<tr>
<td>extit{Expectation of problems due to age}</td>
<td>×</td>
</tr>
</tbody>
</table>

10. **Emergent themes reduced to key themes**: Once all the transcripts had been read and phrases and words considered of significance grouped under initial emergent themes these themes themselves were grouped together under reduced themes. These final reduced themes were identified as they comprised the majority of data items and were interpreted as describing the most significant elements of the data and those which could contribute towards possible influencing factors.

Table 8 Emergent themes linked to produce reduced theme

<table>
<thead>
<tr>
<th>Reduced Theme</th>
<th>Initial Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Expectation and Ownership</td>
<td>Belief that the injection will help</td>
</tr>
<tr>
<td></td>
<td>Positive information received</td>
</tr>
<tr>
<td></td>
<td>Realistic beliefs regarding injection</td>
</tr>
<tr>
<td></td>
<td>Little expectation of injection helping</td>
</tr>
<tr>
<td></td>
<td>Previous treatment did not help</td>
</tr>
<tr>
<td></td>
<td>Unrealistic beliefs regarding injection</td>
</tr>
<tr>
<td></td>
<td>Negative experiences</td>
</tr>
<tr>
<td></td>
<td>extit{Expectation of problems due to age}</td>
</tr>
</tbody>
</table>
11. Second reader reviews reduced themes: Agreement was again sort from the second reader in regard to the reduced themes produced.

12. Reduced themes linked to key phrases: The scripts were again re-read and key phrases previously highlighted were linked with the reduced themes to act as both supportive statements and evidence to allow the reader a greater depth and transparency. This process of ‘going back to the data’ was designed to increase interpretive rigor and demonstrate how interpretations of the data had been reached with subjects reflections conveyed in their own words strengthening the face validity and credibility of the study (Rice 1999).

Table 9 Reduced theme linked back to raw data

<table>
<thead>
<tr>
<th>Reduced Themes</th>
<th>Illustrative Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Expectation and Ownership</td>
<td>“I know the injection is not a permanent cure” (subject 8)</td>
</tr>
<tr>
<td></td>
<td>“I think people can just say what do you expect you wear down at your age....take it easy...well I don't want to take it easy do I” (subject 8)</td>
</tr>
<tr>
<td></td>
<td>“It started to take over a bit (the pain) I didn't like that....you feel kind of out of control....I feel like I am in a bit more control now it's not pushing me around” (subject 8)</td>
</tr>
</tbody>
</table>

9 Summary

In summary data was analyzed at a number of levels. This included outcome pre and post-injection using Friedman’s test which explored:

1. Pre-injection v. 1-month post-injection and v. 3-month post-injection

2. 1-month post-injection v. 3-month post-injection

Where differences were detected, the data was interrogated at each level of difference with the Wilcoxon signed rank test.
A subgroup analysis was also performed for:

1. Pre-injection v. 3-month post injection with hyaluronan
2. Pre-injection v. 3-month post injection with corticosteroid

In addition an exploration of possible correlation between factors was looked for between:

1. Pre-injection factors and outcome

To explore possible factors that may have influenced outcome analysis also included:

1. Thematic analysis of interview data and field notes

The collection of both empirical and qualitative data to measure outcomes post injection and subsequently explore possible influencing factors enabled a degree of triangulation in methods which would help decrease specific deficiencies form any one approach and facilitate completeness of data collection. Additionally the use of a second reader not only complemented this completeness but was also designed to increase the study’s rigor thorough a process of enhanced credibility.

This triangulated approach aligns itself well with the post positivist stance with which I had identified. Taking this stance and the constructivist view that we all create the world in which we live based on our own perceptions of this world. There exists a criticism of our ability to know reality with any degree of certainty and that perceptions are essentially fallible and unique in nature. Therefore, taking the view that any measurement
is essentially fallible the post positivist must recognise the importance of multiple
measures and observations and incorporate these into their methods.

The following section presents an overview of the demographics of the study subjects,
statistical analysis of data and a presentation of the subject’s views in terms of a thematic
analysis.
Chapter III Findings

1 Introduction

This section presents an overview of the study results beginning with a review of the demographics of the study subjects and followed by a statistical analysis of the data and a presentation of the subject’s views in terms of the thematic analysis. The findings of the study need to be considered in light of the study’s objectives. These original objectives were twofold, firstly to analyse the results of injection therapy on symptomatic osteoarthritis of the knee and secondly to investigate possible factors which influenced this outcome.

2 Subjects

In all 48 patients were deemed eligible for inclusion into the study. Of these 3 declined to give consent and were treated as normal clinic practice dictates, of the remaining 45 subjects 12 were deemed appropriate for corticosteroid injection of which 2 were lost to follow up. A further 33 were deemed appropriate for injection of hyaluronan of which 5 were lost to follow up and from the hyaluronan group 18 subjects completed the pre-injection interview and 16 the 3-month post-injection interview as 2 subjects were lost to follow up (figure 16).
Figure 16. Subject flow chart

Demographic data describing subjects is outlined in table 10.

**Table 10 Subjects characteristics and demographics**

<table>
<thead>
<tr>
<th></th>
<th>All Subjects (n=38)</th>
<th>Corticosteroid Subgroup (n=10)</th>
<th>Hyaluronan Subgroup (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD) age in years (min &amp; max)</strong></td>
<td>59.0 (11.7) (39-80)</td>
<td>72.0 (5.5) (64-80)</td>
<td>54.0 (8.0) (39-72)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>22 female 16 male</td>
<td>6 female 4 male</td>
<td>16 female 12 male</td>
</tr>
<tr>
<td><strong>Mean (SD) duration of symptoms in months (min to max)</strong></td>
<td>15.3 (15.6) (3-60)</td>
<td>20.5 (21.0) (3-60)</td>
<td>15.0 (16.0) (3-60)</td>
</tr>
</tbody>
</table>
3 Descriptive and Normality Statistical Analysis of Data

The data from the AIMS2-SF and SF-MPQ were tested for distribution using the Shapiro-Wilk test. The Shapiro-Wilk test is essentially a test for goodness of fit for normal data. The Shapiro-Wilk test was chosen as it is more reliable when the sample size is less than 50 as was the case in this study.

The Shapiro-Wilk tests the hypothesis that,

\( H_0 \) There is no difference between the distribution of the data set and a normal one.

\( H_a \) There is a difference between the distribution of the data set and a normal one.

Significance was set at \( p<0.05 \). If the significance was \( p<0.05 \) the null hypothesis (\( H_0 \)) was rejected. That is there is a significant difference between the data set under testing and a normally distributed one, the data is not normally distributed.

The analysis of the AIMS2-SF lower limb function, symptom, affect and social domains were tested for normal distribution and the values represented in table 11. The AIMS2-SF lower function domain was normally distributed (\( p=0.063 \)). All other domains were not normally distributed (\( p<0.05 \)).
Testing of the SF-MPQ sensory, affective, VAS and PPI domains suggested that all domains were not normally distributed (p<0.05). These values are represented in table 12.

Table 12 Pre-injection SF-MPQ Normality Tests

<table>
<thead>
<tr>
<th>Shapiwo-Wilk</th>
<th>Statistic</th>
<th>df</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>pre MPQ sensory</td>
<td>0.940</td>
<td>38</td>
<td>0.043</td>
</tr>
<tr>
<td>pre MPQ affective</td>
<td>0.852</td>
<td>38</td>
<td>0.005</td>
</tr>
<tr>
<td>pre MPQ VAS</td>
<td>0.922</td>
<td>38</td>
<td>0.012</td>
</tr>
<tr>
<td>pre MPQ PPI</td>
<td>0.801</td>
<td>38</td>
<td>0.005</td>
</tr>
</tbody>
</table>

In light of the data distribution, non-parametric tests were employed on the data.

Descriptive analysis in regards to the range, minimum, maximum, mean and interquartile range values for the demographic data including sex, age, duration of symptom, grade of x-ray degeneration and amount of aspirate obtained at injection and AIMS2-SF and SF-MPQ values for all domains at the pre-injection and 1 and 3 month follow up stages can be found in Appendix 11.
4 Inferential statistical analysis of data

4.1 Pre/post test analysis of outcomes

Pre and post test analysis was carried out on the key domains AIMS2-SF lower limb function and symptom, and SF-MPQ sensory, VAS and PPI scores.

Initial analysis was carried out using Friedman’s test to explore data sets with subsequent analysis being carried out using the Wilcoxon signed rank test to investigate specific time points in detail.

4.1.1 Pre-injection v. 1 and 3 month post-injection all Subjects

Initial statistical analysis using Friedman’s test is outlined in table 13.

Table 13 Friedman’s Test for key domains pre-injection 1 & 3 month post injection all subjects

<table>
<thead>
<tr>
<th>Domain</th>
<th>Mean Rank</th>
<th>X^2</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre, 1 &amp; 3 month AIMS lower limb function</td>
<td>2.76, 1.67, 1.57</td>
<td>35.761</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Pre, 1 &amp; 3 month AIMS symptom</td>
<td>2.70, 1.68, 1.62</td>
<td>30.623</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Pre, 1 &amp; 3 month MPQ sensory</td>
<td>2.88, 1.64, 1.47</td>
<td>48.014</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Pre, 1 &amp; 3 month MPQ VAS</td>
<td>2.84, 1.68, 1.47</td>
<td>47.515</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Pre, 1 &amp; 3 month MPQ PPI</td>
<td>2.45, 1.64, 1.91</td>
<td>17.115</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

N = 38 for all domains Df = 2 for each domain

The results of Friedman’s Test for the key domains were examined pre-injection, 1 and 3 month post injection for all subjects. The results indicated that there was a significant
change from pre-AIMS2-SF lower limb function and symptom, the pre- SF-MPQ sensory, VAS and PPI scores compared to these scores measured again at 1 and 3 month follow up.

Examining the mean ranks it can be seen that this difference appears to be between the pre-injection stage and the 1 and 3 month post injection stage. Mean rank values would suggest little change between the 1 and 3 month stage.

Subsequent analysis using the Wilcoxon signed rank test was carried out on all subjects at pre-injection, 1, and 3-month post-injection.

4.1.2 Pre-injection v. 1 month post-injection, pre-injection v. 3 month post injection and 1 v. 3 month post injection AIMS2-SF and SF-MPQ: All Subjects
The results for the analysis of the pre-injection and 1 and 3 month post injection scores for the key domains of AIMS2-SF lower limb function and symptom and the SF-MPQ sensory, PPI and VAS are demonstrated in figure 17.

These results indicate a significant improvement in reported lower limb function and symptom as measured by the AIMS2-SF following injection at the 1 month follow up stage (p<0.0001). There was also a similar significant reduction in subject reported pain levels as measured by the SF-MPQ following injection at the 1 month follow up stage (p<0.0001).
In addition the results indicated that the significant improvement in reported lower limb function and symptom as measured by the AIMS2-SF and the reported pain levels as measured by the SF-MPQ following injection at the 1 month follow up stage were maintained at the 3 month follow up stage for all domains (p<0.0001).

Further analysis of scores at 1 and 3 month post injection indicated no statistical difference (p>0.05) suggesting that although there is a significant improvement in all the domains measured by both the AIMS2-SF and the SF-MPQ following injection at the 1 month follow up stage and that this improvement is maintained at the 3 month follow up stage there was no further improvement or deterioration in reported domains between 1...
and 3 months. Additional subgroup analysis for Hyaluronan and Corticosteroid groups was also carried out but only at the pre-injection and 3-month post-injection stages as outlined below.

4.1.3 Pre & 3 month post injection AIMS2-SF and SF-MPQ: Hyaluronan and Corticosteroid Subgroups

Subgroup analysis indicated that subjects who received Hyaluronan injection reported a significant improvement in lower limb function and symptom as measured by the AIMS2-SF and reported pain levels as measured by the SF-MPQ sensory, PPI and VAS following injection at 3 month (p<0.05) as demonstrated in figure 18.

Figure 18. Graphical representation of the key domains for the AIMS2-SF lower limb function and symptom and the SF-MPQ sensory, PPI and VAS pre-injection and 3 month post injection: Hyaluronan Group

The means and interquartile ranges for each domain examined are outlined in appendix 12.
Subgroup analysis of subjects who received corticosteroid injection demonstrated a reported significant improvement in lower limb function and symptom as measured by the AIMS2-SF and reported pain levels as measured by the SF-MPQ sensory and VAS following injection at 3 month (p<0.05). The exception being the PPI domain on the SF-MPQ which indicated no improvement in reported pain following Corticosteroid injection at the 3 month follow up stage (p>0.05) as demonstrated in figure 19.

Figure 19. Graphical representation of the key domains for the AIMS2-SF lower limb function and symptom and the SF-MPQ sensory, PPI and VAS pre-injection and 3 month post injection: Corticosteroid Group

The means and interquartile ranges for each domain examined are outlined in appendix 12.
4.2 Correlation between pre-injection factors and outcome: All Subjects

Exploration for whether or not any correlation existed between subject’s pre-injection perceived anxiety and social function as measured by the AIMS2-SF, affective pain scores as measured by the SF-MPQ, duration of symptoms, x-ray grade, amount of aspirate, employment status and age with outcome at 3-months as measured by symptom and function domains on the AIMS2-SF and sensory pain on the SF-MPQ was carried out using the Spearman rank order correlation coefficient test.

4.2.1 Correlation between pre-injection duration of symptoms, x-ray grade, degree of aspirate, employment status and age with outcome at 3-month post injection

Positive correlation was demonstrated between grade of x-ray degenerative change and 3-months post-injection AIMS2-SF symptom score (p<0.05). Correlation was also noted between age and AIMS2-SF symptom score (p<0.05) and lower limb function score (p<0.05). Such that more significant degree of degenerative change or subjects who were of greater age correlated with poor outcome.

Neither the duration of symptoms, the degree of aspirate, nor employment status of subjects demonstrated any correlation with the outcome measures recorded.

Correlation coefficients and significance levels are outlined in table 19.
Table 14 Correlation between Pre-injection duration of symptoms, x-ray grade, aspirate, employment and age with outcome

<table>
<thead>
<tr>
<th>Spearman's rho</th>
<th>Duration of symptoms</th>
<th>Correlation Coefficient</th>
<th>3 month AIMS symptom</th>
<th>3 month AIMS lower limb function</th>
<th>3 month MPQ sensory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.634</td>
<td>0.326</td>
<td>0.515</td>
<td></td>
</tr>
<tr>
<td>Grade of X ray</td>
<td>Correlation Coefficient</td>
<td>0.386*</td>
<td>0.291</td>
<td>0.253</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.017</td>
<td>0.076</td>
<td>0.126</td>
<td></td>
</tr>
<tr>
<td>mls of aspirate</td>
<td>Correlation Coefficient</td>
<td>0.018</td>
<td>-0.010</td>
<td>-0.116</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.915</td>
<td>0.955</td>
<td>0.488</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td>Correlation Coefficient</td>
<td>0.242</td>
<td>0.206</td>
<td>0.250</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.144</td>
<td>0.215</td>
<td>0.129</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Correlation Coefficient</td>
<td>0.344*</td>
<td>0.347</td>
<td>0.226</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.034</td>
<td>0.033</td>
<td>0.173</td>
<td></td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed).

4.2.2 Correlation between pre-injection anxiety, social interaction and affective scores with outcome at 3-month post injection

Strong positive correlation was demonstrated between subject’s pre-injection AIMS2-SF anxiety and social score and SF-MPQ affective score with outcome as measured by the AIMS2-SF symptom and lower limb function score and the SF-MPQ sensory score (p<0.01).

These results suggested that subject’s pre-injection levels of perceived anxiety regarding their condition and level of reported social interaction with family, friends and colleagues impacted strongly on outcome, such that, high levels of reported anxiety and low levels of social interaction correlated strongly with poor outcome (p<0.01).
Correlation coefficients and significance levels are outlined in table 20.

**Table 15 Correlation between Pre-injection anxiety, social interaction and affective score with Outcome**

<table>
<thead>
<tr>
<th></th>
<th>3 month AIMS symptom</th>
<th>3 month AIMS lower limb function</th>
<th>3 month MPQ sensory</th>
</tr>
</thead>
<tbody>
<tr>
<td>pre AIMS anxiety</td>
<td>Correlation Coefficient</td>
<td>0.728**</td>
<td>0.839**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>pre AIMS social</td>
<td>Correlation Coefficient</td>
<td>0.726**</td>
<td>0.792**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
<tr>
<td>pre MPQ affective</td>
<td>Correlation Coefficient</td>
<td>0.748**</td>
<td>0.718**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>0.001</td>
<td>0.001</td>
</tr>
</tbody>
</table>

*Correlation is significant at the 0.01 level (2-tailed).

5 **Interpretation of Interview data**

This section represents the findings from the interviews conducted in this study. These findings are designed to expose the ideas, experiences and perceptions of those subjects who took part.

Data analysis required the identification of themes as outlined in Chapter II, section 8.3, page 139. From the initial emergent data subsequent reduced themes were produced. Both emergent and reduced themes are presented and illustrated with quotes from interview transcripts. These quotes were used to illustrate findings and to give subjects a voice. Quotations are shown in italic font so that these unabridged extracts from the data can clearly be distinguished from my own text and interpretations.
This section also includes abbreviated field notes recorded during and after each interview concerning issues that were not articulated during the course of the interview.

In total 18 interviews were conducted at the pre-injection assessment stage. At the 3 months follow up stage 16 interviews were conducted as 2 of the 5 subjects who dropped out of the study had been those interviewed initially and were therefore lost to this second in depth interview.

Data from the initial pre-injection interviews were grouped into 25 themes, 23 from the initial reading with a further 2 being added following the second readers comments. Emergent themes from pre-injection interviews were used to direct subsequent post-injection interviews at the 3-months follow up stage. At this second interview round a further 22 themes emerged, 18 from the first reading with a further 4 being added by the second reader.

In all examining the pre and post-injection interviews 47 themes emerged, 41 from the first reading with a further 6 being added by the second reader.

The initial emergent themes were subsequently reduced into 4 themes covering the following areas;

1. Expectation and Ownership,
2. Experience and Knowledge,
3. Exercise Beliefs,
4. Social Interaction,

An example of how emergent themes were distilled from the raw interview data is outlined in Fig 17.

Figure 20. Development of initial emergent and subsequent reduced themes from the raw interview data

<table>
<thead>
<tr>
<th>Raw Data</th>
<th>Initial Themes</th>
<th>Reduced Theme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Well like I said I know it won’t go for ever if the joint is worn then that’s against me isn’t it. I’m not going to get younger am I?...the pain won’t go completely...even if it did I expect the knee would still be worn away...you can’t turn back time if it’s worn it’s worn and that’s that...I think the important thing well that is to keep going...I don’t mean just the arthritis but well as you get older you can’t stop...if you do that’s it isn’t it...you would just fall apart.</td>
<td>Realistic – suggests degree of pragmatism</td>
<td></td>
</tr>
<tr>
<td>Well no one is going to help are they at the end of the day it’s you it’s your body...you know it’s my knee...not yours so it’s me that has to do something about it...I mean you’re the expert...the injection helps that’s great but you can’t keep doing that so people should help themselves a bit. (subject 8)</td>
<td>Reasonable and rational</td>
<td></td>
</tr>
<tr>
<td>Beliefs appear reasonable</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Realistic in regard to injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self reliance / independence / happy to take control</td>
<td>EXPECTATION</td>
<td></td>
</tr>
<tr>
<td>Self-determination a sense of autonomy</td>
<td>OWNERSHIP</td>
<td></td>
</tr>
</tbody>
</table>
This figure outlines an extract from a raw transcript (subject 8). The first column demonstrates how after reading and re-reading of the text key phrases or words were initially underlined in an attempt to reduce the amount of meaningful data. Subsequently text which was considered to be from a similar domain in terms of its meaning and implication was highlighted with the same colour. These highlighted phrases and words were then described in my own terms a process which is outlined in the middle column. These interpretations were then examined and reduced themes developed which were thought to cover all domains identified. Finally the raw data was again read to ensure that the reduced themes were representative.

The initial emergent and subsequent reduced themes as identified by subject are outlined in Appendix 13 and an example of a pre and post-injection interview script can be found in Appendix 14.

Table 21 summarises all the reduced and initial emergent themes and also includes some illustrative quotes in support of each area.
### Table 16 Reduced and Initial Themes with Illustrative Quotes

<table>
<thead>
<tr>
<th>Reduced Themes</th>
<th>Initial Emergent Themes</th>
<th>Illustrative Quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1 Expectation and Ownership</strong></td>
<td>Belief that the injection will help / Positive information received / Realistic beliefs regarding injection / Previous treatment did not help / Unrealistic beliefs regarding injection / Negative experiences / Expectation of problems due to age / Little expectation of injection helping</td>
<td>&quot;Well if the injection is able to calm things down and I can get running again&quot; (subject 17) &quot;I suppose I thought it would work I mean I always like to have a positive attitude&quot; (subject 18) &quot;I know the injection is not a permanent cure&quot; (subject 8) &quot;To get better 5 out of 3...I always live in hope...yes to get better at least to be able to to exercise again&quot; (subject 21) &quot;I was told the injection should help&quot; (subject 2) &quot;I think people can just say what do you expect you wear down at your age....take it easy...well I don't want to take it easy do I&quot; (subject 8) &quot;I want the injection to help and take the pain away&quot; (subject 3) &quot;He sent me to you for this injection so here I am&quot; (subject 10) &quot;I suppose as I get older the pain will get worse...I'm 62 so getting on really&quot; (subject 6) &quot;The pain has been there so long now....well an injection you know it probably wouldn't work&quot; (subject 6)</td>
</tr>
<tr>
<td></td>
<td>Self reliance &amp; ownership of problem / Initiated referral / A desire to do more / Demonstrates wish not to take too many tablets / Does not use regular analgesia or NSAIDs / Describes the importance of being in control / Dependent upon others / Reliant on others to initiate referral or treatment / Belief no one has helped / Demonstrates ulterior motive / Uses regular analgesia or NSAIDs / Sense of needing to blame others</td>
<td></td>
</tr>
<tr>
<td><strong>2 Experience and Knowledge</strong></td>
<td>Describes no post injection flare / Describes a positive outcome in terms of pain / Describes a positive outcome in terms of function / Less analgesia or NSAIDs / Describes the importance of a break from the pain / Describes some post injection flare / Describes no positive outcome / Describes being depressed due to pain / Describes slowing down with age / Describes other significant musculoskeletal pains</td>
<td>&quot;Well I was happy with the injection....I didn’t really notice any side effects&quot; (subject 9) &quot;Well no I had no probles it felt a little well sort of bruised but no not really...no real problems&quot; (subject 4) &quot;You know I would say it is better than I expected really&quot; (subject 20) &quot;It feels looser...less pain and I think I can do more...well it feels quite good&quot; (subject 5) &quot;Tablets ...well that is why I didn't like to take too many I mean they don't really help do they...I don't want to become reliant on them&quot; (subject 1) &quot;It started to take over a bit (the pain) I didn't like that...you feel kind of out of control...I feel like I am in a bit more control now it's not pushing me around&quot; (subject 8) &quot;I'm stuck with it I mean I won't be able to do very much will I....they don't think that people like me may need more help&quot; (subject 2) &quot;Help with the shopping would be good yes that would be good that and a bus pass&quot; (subject 10) &quot;I've had this problem for too long and no one has done anything...they need to do something about it&quot; (subject 2)</td>
</tr>
<tr>
<td></td>
<td>Demonstrates appropriate knowledge of condition / Clear appropriate goal for treatment / Demonstrates inappropriate knowledge of condition / No clear goal for treatment / Describes being worried about condition / Describes the need for further investigations</td>
<td></td>
</tr>
<tr>
<td>Reduced Themes</td>
<td>Initial Emergent Themes</td>
<td>Illustrative Quotes</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------------------</td>
<td>---------------------</td>
</tr>
</tbody>
</table>
| **3 Exercise Beliefs** | Positive belief regards exercise / Keeping active is seen as important / Sensible and considered return to activity post injection / Too painful for exercise / Negative belief regards exercise and non-compliance / Belief that they are too old to exercise / No evidence of return to activity levels | "I read that exercise is good for a joint if it has arthritis in it....you need to keep the muscles strong to help the joint" (subject 17)  
"I think exercise is important but if it hurts the knee I can't do the exercise....and then I will get weaker" (subject 5)  
"I've tried some exercise but it's really difficult....I was worried I might make it worse....if the injection helps I would be able to do more exercise and may be get back to swimming" (subject 8)  
"I don't want exercise....I don't need more exercise....I need some treatment" (subject 2)  
"I was told to do exercise well I can't....exercise you need to have good joints may be younger....not me with these knees" (subject 6) |
| **4 Social Interaction** | Active in regard to work and or family commitments / Clear social commitments / Unable to do the things they used to do / Little evidence of work, family or social commitments | "I'm always busy....you know I still work and then the family and the dog...I wouldn't like to work full time....too busy" (subject 8)  
"I am a very busy person....I work and go to the gym....I garden....tennis I try and play twice per week" (subject 18)  
"I used to go out but don't....not now no....I stay in mostly.....well the television mostly I watch that yes mornings and in the afternoon and at night" (subject 7)  
"The rest of the time well I watch television....well I suppose everyone watches the television most nights" (subject 2)  
"I watch television mostly well I can't do more because of the knee....and all the other things that are wrong with me" (subject 10) |
Additional field notes taken at the time of interview and recorded in a research journal were read and re-read noting which comments appeared either positive or negative in terms of observations made. These observations are outlined in table 22 and were used as additional data in support of the interview transcripts.

Table 17 Field notes related to subject

<table>
<thead>
<tr>
<th>Positive Observation</th>
<th>Negative Observation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear and articulate appeared to demonstrate a sense of empowerment / confident</td>
<td>Appeared to be &quot;angry&quot; unwilling to except responsibility / it was someone else’s problem / the NHS was to blame</td>
</tr>
<tr>
<td>Positive outlook / upbeat / willing to try and engage / compliant (subject 1, 5, 17, 21).</td>
<td>Demonstrated little responsibility for own health / happy to hand over control / disempowerment (subject 2, 6, 19).</td>
</tr>
<tr>
<td>Clear eye contact appeared happy to be interviewed / appeared relaxed and comfortable (subject 1, 5, 8, 21).</td>
<td>Poor eye contact / not engaged (subject 2, 3, 6).</td>
</tr>
<tr>
<td>Engaged during the interview required few prompts / active participant / there was a sense of joint working to a common goal (subject 1, 5, 8, 17).</td>
<td>There appeared to be a need to blame others (subject 2).</td>
</tr>
<tr>
<td>Interested and keen to find out more / questioning appropriately (subject 1, 5, 17).</td>
<td>Appeared unkempt, little care demonstrated with personal hygiene (subject 6, 10).</td>
</tr>
<tr>
<td>Appeared cheerful and happy throughout interview (subject 1, 5, 8, 17).</td>
<td>Appeared anxious, uncomfortable and unwilling to be interviewed (subject 3).</td>
</tr>
<tr>
<td>Appeared educated and informed / was aware of relevant issues concerning condition (subject 1, 5).</td>
<td>Required much prompting (subject 3, 6).</td>
</tr>
<tr>
<td>Confident (subject 8, 17).</td>
<td></td>
</tr>
</tbody>
</table>

5.1 Expectations and Ownership

I felt that the two themes encompassing expectation and ownership were intimately linked in terms of sharing a common basis of meaning and therefore linked these two descriptive terms into one reduced theme.

Expectations may be viewed as general outcome or recovery expectancies as well as expectations about the helpfulness of specific treatments and expectations about the
process involved, for example the risks, and potential side effects. From the analysis of the interview data there seemed that the belief that the injection would help and the importance of this belief being realistic seemed to be of particular importance in those subjects who had good outcome.

"I suppose I thought it would work I mean I always like to have a positive attitude" (subject 18) and "I know the injection is not a permanent cure" (subject 8).

I note in my field notes an indication that two subjects (1, 5) appeared to be well educated in terms of their ability to articulate their problem and informed with regard to what might be expected of the health service in terms of treatment. They appeared empowered in regard to their condition and were happy to articulate what they wanted and expected in terms of intervention. Conversely those subjects who had poor outcomes seemed to relate to negative experiences, unrealistic beliefs, and poor expectation of a successful outcome. There was a sense of disempowerment with loss of control over their health.

"The pain has been there so long now, well an injection you know it probably wouldn’t work" (subject 6) and "I suppose as I get older the pain will get worse...I'm 62 so getting on really" (subject 6).

In particular beliefs that previous treatment had been of no help seemed to dominate most subjects who reported poor outcomes.

“The GP gave me the tablets but they didn’t help…they were a waste weren’t they…they didn’t touch the pain really” (subject 10).
Only one other subject described the expectation that their problems were due to their age.

“I’m not going to get younger am I?...the pain won’t go completely...even if it did a
expect the knee would still be worn away...you can’t turn back time if it’s worn it’s worn
and that’s that” (subject 8).

However, this subject still had good outcome and maintained a positive outlook.

“I think the important thing well that is to keep going...I don’t mean just the arthritis but
well as you get older you can’t stop...if you do that’s it isn’t it...you would just fall
apart” (subject 8).

In addition subjects who seemed engaged with their treatment appeared to do well. The
idea of ownership of ‘their knee’ seemed to be of particular relevance, an idea which
seemed to resonate with the sense empowerment.

"It's my problem the knee I mean...well...it's not yours...you need to do it yourself"
(subject 5) and "I'm not the kind of person to sit around and do nothing...so yes I will get
going if I can” (subject 21).

A sense of being in control was seen as important.

"It started to take over a bit (the pain) I didn't like that....you feel kind of out of control...I
feel like I am in a bit more control now it's not pushing me around” (subject 8).
In addition a demonstration of an unwillingness to take many tablets also seemed to resonate with good outcome.

“Well I never really took any tablets...I mean they never really helped" (subject 5) and "Tablets...well that is why I didn’t like to take too many I mean they don’t really help do they...I don’t want to become reliant on them" (subject 1).

This sense of ownership seemed to correlate with observations made in my field notes. Subjects who engaged well required few prompts (subjects 1, 5, 8, 17), seemed happy to be interviewed and were clear and articulate (subjects 1, 5, 8, 17, 21).

Poor outcome seemed linked to a lack of self reliance and dependence on others. "I’m stuck with it I mean I won’t be able to do very much will I...they don’t think that people like me may need more help" (subject 2) and "Help with the shopping would be good yes that would be good that and a bus pass" (subject 10).

Additionally the belief no one has helped seemed to resonate with some subjects. "I’ve had this problem for too long and no one has done anything...they need to do something about it" (subject 2).

This last observation was supported by the entry in my field notes that subject 2 appeared ‘angry’ and unwilling to accept responsibility, giving little eye contact during the interview and seeming to be focused on blaming others for their problems.
6.2 Experience and Knowledge

The description of a temporary post-injection flare up seemed to be a problem in a few subjects both in those who did well in regards to outcome (subjects 20 and 21).

“after the injection...well it did ache for 3 days or so...I took some paracetamol...ice as well...a frozen pack of peas...as you said” (subject 20)

And in those that did not (subjects 2, 3 and 10).

“I wouldn’t really want another one I know that (injection) I mean I know you said it might hurt but well it felt bad...how long may be a few hours” (subject 2).

Subjects describing no flare up were predominantly those that had good outcome with the exception of subjects 19 and 22 who had a poor outcome.

“Very little (flare up) none really...no just like that first day you know like a bit uncomfortable but I rested it for a little while well certainly no real pain” (subject 22).

In regard to positive outcome there seemed to be a high correlation between interview data and subject’s perceived outcome as reported on the AIMS2-SF and SF-MPQ. Subjects considered to have good outcome all reported positively in regard to decrease in pain and increase in function.

"You know I would say it is better than I expected really” (subject 20) and "It feels looser...less pain and I think I can do more...well it feels quite good" (subject 21).
Conversely those that were considered to have poor outcome all described such thoughts during interview.

"The pain is still there in the morning...I mean I'm still in pain" (subject 2)" and “I don’t think the injection helped really...I can’t really work...no I don’t think I should go not when the knees are so bad” (subject 10).

A feeling of slowing down with age was reported in subjects with good outcome.

“It’s part of growing old...but well I suppose it’s the idea of getting old...well I suppose you think that you will live forever...you don’t think of yourself as well as old...I think I’ve slowed down I bit and well I fell my age” (subject 4).

This was also noted in subjects with poor outcome.

“No not good I don’t see any help for it I suppose as I get older the pain will get worse and worse and that’s it” (subject 6).

Subject 8 who had had a good outcome described the importance of having a break from the pain.

“I think that is important even if the pain only goes for a while it helps and that break well it really can make a difference...kind of like a holiday” (subject 8).

In those subjects with poor outcome there was some description of other joint problems.

“The knee isn’t the only problem I have pains in the back...and this arm and leg...it’s been there for years and hasn’t been sorted out” (subject 10).
Only three subjects described a sense of being depressed due to the pain (subjects 1, 3, and 7). Of these two had poor outcome (subjects 3 and 7) with field notes indicating subject 3 giving little eye contact, requiring significant prompting and giving a sense of being uncomfortable or unwilling to engage in the interview process.

Subjects who demonstrated a clear and appropriate understanding of their condition seemed also to have more clarity in terms of what they hoped to achieve by having the injection. There appeared evidence of a goal planning to their thought process. These subjects were generally the ones who had good outcome, for example.

"That the joint wears away and the cartilage is thinner...the oil in the joint...this oil in the joint it helps keep things moving but with arthritis it sort of dry up" (subject 18)

And,

"Well I know it isn't a cure...it won't be like the knee when I was younger" (subject 21).

In addition field notes suggest that those subjects who had good outcome demonstrated an interest in ‘finding out more’ there was an engagement a sense of joint working between clinician and subject (subjects 1, 5, 17).

A lack of appropriate knowledge seemed linked to unrealistic goals and poor outcome.
"My mother she ended up in a wheelchair and died...I don't think I will die but it feels like
I might be like that sometimes...it's when the bones crumble away...they crumble to
nothing and then you can't move or walk” (subject 10)."

Poor outcome and inappropriate knowledge of condition also appeared to be associated
with request for further investigation by three subjects (subjects 2, 3, and 7) all of whom
had poor outcome. For example
"May be I need a scan...what about that MRI that’s for the knees...my dad yes I remember
he was bad with it (osteoarthritis) really bad and had to give up work” (subject 2).

Two subjects described a sense of being worried about their condition (subjects 3 and 8).
“I suppose I was worried it had started to take over a bit...I didn’t like that (subject 8).

However, this did not seem to be linked to outcome or knowledge of condition as subject
3 had a poor outcome and demonstrated a lack of understanding of their condition.
“I do know of someone...well they are in a chair you know a wheelchair I don’t want
that” (subject 3).

While subject 8 had a good outcome and a sound knowledge.
“I think it’s where the bones the bones and joints wear they are worn down and jelly in
the knee dries out so that the bones well the bones they rub together they rub on each
other and that causes the pain” (subject 8)
6.3 Exercise Beliefs

Subjects who had a good outcome almost uniformly expressed positivity in regard to exercise and the idea of staying active as being an important part of their lives in general and their condition in particular.

"I read that exercise is good for a joint if it has arthritis in it...you need to keep the muscles strong to help the joint" (subject 17).

There also seemed to be an understanding that the pain needed to be controlled to enable exercise to take place and this subsequently lead to an appropriate return to post-injection activity.

"I think exercise is important but if it hurts the knee I can't do the exercise...and then I will get weaker" (subject 5).

And,

"I've tried some exercise but it's really difficult...I was worried I might make it worse...if the injection helps I would be able to do more exercise and may be get back to swimming" (subject 8).

Field notes suggested that those subjects who had good outcome also had a generally positive outlook, a sense of engagement and willingness to participate in their own healthcare (subjects 1, 5, 17, 21).
Poor outcome seemed associated with negative exercise beliefs, a focus on the knee being too painful to do anything and lack of compliance. There also appeared the perception that exercise was not really a ‘treatment’ and that one could be too old to exercise.

"I don't want exercise...I don't need more exercise...I need some treatment” (subject 2). And,

"I was told to do exercise well I can't...exercise you need to have good joints may be younger...not me with these knees” (subject 6).

“Exercise no...I can’t do that...that kind of thing is alright for people who are younger but not me too old to be doing jumping around and all that. No I need help or something I don’t need more exercise I need something else something more than just that” (subject 10).

6.4 Social Interaction

There appeared a clear divide between subjects in regard to this theme and outcome. Those subjects who had good outcome clearly described being active with either family, work or other social commitments such as the church. There appeared a strong desire to remain active and an expectation that the injection would help them do this. In a sense there was a clear goal in regard to treatment outcome. The injection would control the pain but this was a ‘means to an end’ in that they would then be able to be more active.

"I'm always busy...you know I still work and then the family and the dog...I wouldn't like to work full time...too busy” (subject 8).
And,

"I am a very busy person...I work and go to the gym...I garden...tennis I try and play twice per week" (subject 18)

“Very active...I go to the gym that was 3 times a week...I had been going only 1 or 2 times when the knee was bad but I can go 3 again now and I push things more than before (subject 20).

This degree of social engagement was supported by field notes in that these subjects demonstrated a positive outlook (subjects 1, 5, 17, 21), they appeared ‘cheerful’ (subjects 1, 5, 8, 17, 21) and in the case of two subjects’ confident (subjects 8, 17).

In those subjects who had poor outcome there appeared to be a general malaise, with little social engagement. This was particular evident in subjects 6 and 10 who appeared to be ‘unkempt’ with little evidence being demonstrated of regard to personal hygiene. This seemed to be different to not being able to do things solely because of knee pain as many of the subjects who had good outcome reported this. Those subjects with poor outcome seemed to describe more of a deep seated lack of interaction.

"I used to go out but don't...not now no...I stay in mostly...well the television mostly I watch that yes mornings and in the afternoon and at night" (subject 7) and "The rest of the time well I watch television...well I suppose everyone watches the television most nights" (subject 2).
6 Summary

Initial data analysis pre and post intervention was carried out using Friedman’s test on the key domains AIMS2-SF lower limb function and symptom, and SF-MPQ sensory, VAS and PPI scores. For each domain a significant difference was demonstrated which suggested an improvement in reported measures (p<0.05).

Subsequent analysis using the Wilcoxon signed rank test demonstrated significant improvement in subject reported lower limb function and symptom as measured by the AIMS2-SF following injection and the in subject reported pain levels as measured by the SF-MPQ following injection at the 1 month follow up stage (p<0.05). This reported improvement was maintained at the 3 month follow up stage for all recorded domains (p<0.05).

Additional subgroup analysis for Hyaluronan and Corticosteroid groups at pre and 3-month post-injection stages indicated a significant reported improvement in all domains other than the PPI domain on the SF-MPQ which indicated no improvement in reported pain following Corticosteroid injection at the 3 month follow up stage.

Correlation between pre-injection factors and reported outcomes was examined using a Spearman rank order correlation coefficient test. Results suggested that pre-injection levels of perceived anxiety and levels of reported social interaction correlated strongly with poor outcome such that high levels of reported anxiety and low levels of social
interaction correlated with poor outcome (p<0.01). In addition more significant x-ray reported degenerative change also correlated with poor outcome but only as measured on the AIMS2-SF symptom domain (p<0.05) and age correlated with the AIMS2-SF symptom score and lower limb function scores (p<0.05) such that older age was linked with poorer outcome.

Analysing themes generated from the interview data exposed a number of issues that potentially impact on outcome following injection for osteoarthritis of the knee. In all 47 themes emerged from the pre and post-injection interviews, 41 from the first reading with a further 6 being added by the second reader. These initial emergent themes were subsequently reduced into 4 themes covering the following areas;

1. Expectation and Ownership,
2. Experience and Knowledge,
3. Exercise Beliefs,
4. Social Interaction,

Although the absolute significance of each theme cannot be measured and indeed may be assumed to be different for each subject given their own unique set of experiences and perceptions a conceptual framework was constructed from the thematic analysis. The individual elements of the framework were compared to the recorded comments from each transcript for each subject in an attempt to ground the framework in the data. This conceptual framework is outlined in figure 18 and has at its centre the themes of experience and knowledge which seemed at the heart of many subjects dialogue. Past
experiences seemed to inform a subject’s expectation of treatment while knowledge of condition appeared to influence the degree of demonstrated ownership and the beliefs that were held in regard to exercise and its place in the overall management of their condition.

In the way that experience and knowledge seemed to be a strong and deep seated internal influence on outcome social interaction appeared to be more of an external influence. However, it may also be fair to assume that the degree to which subjects interacted with their family, friends and colleagues was also dependent upon their ability to deal with their condition and in that way becomes influenced by the subjects experience and knowledge. The implications of this conceptual framework are considered in the final section of the discussion.

**Figure 21 Conceptual framework of the relationship between themes**

![Diagram showing the relationship between themes]

- **Expectation and Ownership**
  - Taking control of condition
  - Positive and realistic beliefs

- **Experience and Knowledge**
  - Appropriate knowledge
  - Previous treatment

- **Exercise Beliefs**
  - Advice and knowledge
  - Experience
  - Beliefs regarding osteoarthritis

- **Social Interaction**
  - Interactions with family, friends and colleagues
  - Self worth
The inclusion of interview data and development of key themes enabled subjects to have a voice and articulate issues of importance to them. This communication between provider and service user has the potential to target treatment more effectively and explain outcomes in greater depth than reliance on physical measures alone.

I had identified my own personal history as stemming from a more positivist ideology, my intention during this study was to try and incorporate a qualitative and reflexive approach to my research in an attempt to enhance the depth of understanding of subject’s views and experiences. This mixed methodological approach, the ‘third methodological movement’ as described by Tashakkori and Teddlie (2003) required a fusion of the theoretical and methodological approaches from both positivist and naturalistic paradigms which ran throughout the study and which were centred at its very heart. The following section aims to continue this duality of purpose and discuss these findings in light of current literature.
Chapter IV Discussion

1 Introduction

The aim of this study was multi-factorial, endeavouring to assess the outcome of intra-articular corticosteroid or hyaluronan injection in the management of osteoarthritis of the knee and also to utilise a correlational design to explore any relationship between pre-injection factors and outcome. Subjects receiving injection of hyaluronan also took part in semi-structured interviews, these interviews were employed to explore subject’s thoughts and perceptions in regard to their condition. Interview data obtained was used to explore further emergent themes in an inductive fashion in an attempt to more fully understand the factors which may influence outcome post injection.

The findings of this study need to be considered in light of the geographical and sociological setting in which the study took place as these elements have the potential to influence outcome and effect pre-treatment perceptions and expectations and thus impact on the study’s findings in terms of their generalisability (outlined in Chapter I, section 3 page 9). In addition my own position as researcher needs to be taken into account while the findings are discussed.

In summary the findings of this study demonstrated that in a prospective population based cohort of subjects with symptomatic osteoarthritis of the knee injection with intra-articular corticosteroid or hyaluronan was effective in the short to medium term in alleviation of reported symptoms. Moreover a number of factors were identified which seemed to affect subject’s outcome. The factors which correlated significantly with
outcome were related to subject’s reported levels of anxiety and social interaction such that high levels of reported anxiety and low levels of social interaction correlated with poor outcome. In addition x-ray reported degree of degenerative change correlated with outcome but only on one construct the AIMS2-SF symptom domain. The greater degree of degeneration correlated with poorer outcome. Similarly age was also correlated with outcome in relation to the AIMS2-SF symptom and lower limb function score in that younger subjects had a better outcome. Other factors such as duration of symptom, and effusion were not identified as affecting outcome. This is important as it is those dimensions related to the physical aspects of osteoarthritis that are frequently used to determine treatment options.

Further analysis of themes generated from the interview data exposed a number of additional issues that potentially impacted to a much greater level on outcome. In all 47 such themes emerged from the pre and post-injection interviews. These initial emergent themes were subsequently reduced into 4 themes as previously identified (Chapter III, section 5, page 165).

Appreciation of these factors and their importance in determining and shaping outcome is perhaps an area that has to date been overlooked with the traditional model of health assessment focusing more on a patient’s reported symptoms and physical measures such as x-ray findings.

There now follows a detailed review of the study’s findings within the context of current research and theories of health and well being with the emphasis on what this study adds
to our current knowledge. The subsequent section aims to draw these findings together and outline possible implications for future practice. Following this is a discussion outlining the limitations of the study gained with the benefit of hindsight, with the final section being a reflective analysis in regard to the methodological choices made in the formation of this study.

2 Findings

Initial consideration of the study’s findings will be in regard to the pre and post injection outcome, followed by results from the correlation of pre-injection factors and outcome including the interview data.

Preliminary data analysis carried out on the key domains AIMS2-SF lower limb function and symptom, and SF-MPQ sensory, VAS and PPI scores for all subjects revealed a significant reduction in reported symptoms between the pre-injection and 1 month follow up for each domain. This reported improvement in symptoms was maintained at the 3 month follow up stage for each domain.

Subgroup analysis of the hyaluronan and corticosteroid groups at pre-injection and 3 month follow up revealed a similar significant difference in regard to the p values demonstrated for all domains other than the PPI domain in the corticosteroid group which demonstrated no significant difference.

These results are in concordance with evidence described by Gossec & Dougados (2006) and as outlined in Clinical Evidence Concise (2005). These two reviews analyzed data
concerning the short and long term efficacy and potential side effects of both corticosteroid and hyaluronan injections. In regard to the injection of corticosteroids the conclusion was that they seemed to be effective for reducing short term pain with a benefit lasting for up to 4-weeks. The injection of hyaluronan was considered to have a modest but long lived symptomatic effect on pain and function with effect occurring by 1 to 2-months, but with efficacy extending from between 4-months to 1-year.

The importance of this study’s findings are in the demonstration of a similar positive outcome at 3 month follow up regardless of whether the injection was corticosteroid or hyaluronan. This is in disagreement with the findings of Gossec & Dougados (2006) and Clinical Evidence Concise (2005) in that they suggested that corticosteroid has only a short term benefit. Additionally issue is raised in relation to recently published National Institute for Clinical Evidence (NICE) guidelines for the management of osteoarthritis. NICE guidelines concluded that the use of intra-articular hyaluronan did not have sufficient evidence to support its use in the NHS based on cost effectiveness considerations. (NICE www.nice.org.uk/CG59 (2009)).

This issue of cost is of some importance in regard to injection of either corticosteroid or hyaluronan as the former costs £1.70 (Triamcinolone 40mg. Squibb) whereas the latter costs £220 (Durolane 60mg. Q-Med AB). The evidence produced in this study would suggest that the use of corticosteroid injection is capable of a much longer term benefit than the 4 weeks previously indicated (Gossec & Dougados 2006, Clinical Evidence Concise 2005). Certainly if corticosteroid injection is able to produce a similar longer
term benefit to hyaluronan then based on cost they should be considered as a first line treatment modality in keeping with NICE guidance.

This study did not allow for follow up beyond the 3 month period and therefore further comparison between both drugs is not possible and it may be that as previous evidence suggests the benefit of hyaluronan does extend significantly beyond that of corticosteroid in the longer term. This 3 month follow was chosen as the final review due to the perceived difficulty in retaining subjects beyond this time period particularly given the transitory nature of Hackney’s population.

A possible explanation for the differences noted in this study compared to the available literature may rest with the commonly held idea that all osteoarthritis is essentially ‘the same’ and therefore should be treated in a similar fashion, it may be that injection is not routinely used in a selective manner in many clinics and that subsequent results are therefore mixed. Although only anecdotal my own experience suggests that intra-articular injections of hyaluronan are often given with little thought to the level of degeneration present or functional ability of the patient. This lack of selection is also apparent in research with little clear delineation being made between degrees of osteoarthritis or a reflection of the activity of that osteoarthritis in terms of the degree of synovitis present. Certainly future research should aim to clarify exactly what stage of osteoarthritis is being addressed.

This study based the use of either corticosteroid or hyaluronan injection on the presence or absence of an effusion. Clinically this makes sense as a joint effusion suggests a
component of active synovitis which may more readily respond to the anti-inflammatory action of the corticosteroid, a view supported by Gossec & Dougados (2006). However, this makes direct comparison difficult as injection is then carried out for essentially different presentations of osteoarthritis. It is therefore beyond the remit of this study to say which approach is the most efficacious. Indeed this would be potentially unhelpful as it may result in one approach being recommended over the other based on cost alone, an approach which may have been responsible for the recently published NICE guidance (NICE www.nice.org.uk/CG59 (2009)). However, based on the evidence produced from this study it would seem that both injection of corticosteroid and hyaluronan demonstrate a similar positive outcome maintained up to 3 months post treatment. Additionally it would seem that the presence of an effusion is important in determining which therapy is the most appropriate to utilize, a factor which makes patient selection easier to determine.

In summary it would seem that this study’s findings suggest that hyaluronan injection is effective in the management of osteoarthritis of the knee and that it need not be as costly a therapy as described by NICE if a selective approach based on the presence of an effusion is adopted (NICE www.nice.org.uk/CG59 (2009)). The selective approach recommended would be the one advocated in this study and outlined in Figure 19.

**Figure 22 Injection of Corticosteroid or Hyaluronan based on presence of effusion**

(From Figure 11; page 122)
In addition findings also suggest that there is a perceived benefit in those subjects receiving injection of corticosteroid that appears to be maintained for longer than previously outlined in the literature. It is therefore suggested that the use of these drugs has the potential to provide an extended time frame to facilitate a program of exercise which may have otherwise been restricted due to pain.

The ability to predict outcome with greater clarity in those who may benefit from injection therapy was the primary aim of this study. As suggested it would seem that the presence of an effusion may be significant in determining which injection should be given at a particular point in time for best outcome. The findings from the correlation and thematic analysis will now be discussed in regard to the possibility of being able to further predict outcome.

Statistical correlation between pre-injection anxiety and social function as measured by the AIMS2-SF, affective pain scores as measured by the SF-MPQ, duration of symptoms, x-ray grade, amount of aspirate, employment status, and age with outcome measured at 3-months by symptom and function domains on the AIMS2-SF and sensory pain on the SF-MPQ was carried out for all subjects.

Analysis demonstrated positive correlations between subject’s pre-injection AIMS2-SF anxiety and social score with scores at 3-months post-injection for AIMS2-SF symptom score, lower limb function score, and SF-MPQ sensory score. In addition pre-injection SF-MPQ affective score demonstrated a similar positive correlation with scores at 3-
months post-injection for the AIMS2-SF symptom score, lower limb function score, and the SF-MPQ sensory score.

Weaker positive correlation was demonstrated between grade of x-ray degenerative change and 3-months post-injection AIMS2-SF symptom score such that more a significant degree of degenerative change correlated with poor outcome. However, this correlation only applied to the AIMS2-SF symptom domain. Additionally correlation was identified between age and outcome as measured on both the AIMS2-SF symptom and lower limb score such that younger subjects appeared to have a better outcome.

Considering Rosemann’s (2006) findings that medical assessment often focuses on physical measures such as radiographic assessment and range of movement then these findings are important as they force us to raise the question as to whether appropriate questions are being asked at initial consultation. The findings of this study suggest that levels of perceived anxiety and levels of reported social interaction with family, friends and colleagues have a high degree of impact on perceived outcome, such that, high levels of reported anxiety and low levels of social interaction result in poorer outcome. However, these issues seem not be taken into consideration or given the weighting that they deserve at initial or subsequent assessment.

In terms of the physical factors examined the degree of degenerative change as measured by x-ray did demonstrate correlation with outcome with a greater change correlating with poorer outcome. These findings are in keeping with some of the evidence discussed in the introduction, in particular the findings of Vad (2003) and Toh (2002) (Chapter I, page
However, not all the evidence supports this with Lohmander (1996) demonstrating the opposite effect, such that a greater degree of osteoarthritic change corresponded to a better outcome. Certainly it would seem fair to assume that subjects with less advanced osteoarthritis might be expected to do better following injection as demonstrated in this study but the lack of clarity in the available evidence suggests that there is more than a simple ‘cause and effect’ model at work. An idea supported by Birrel (2005) who concluded that although mild to moderate radiographic change was frequently noted in the hip it did not relate to pain.

In terms of other physical factors measured this study demonstrated correlation between outcome and age but no such correlation between employment status, duration of symptoms, or effusion. Hill (2004) found that among the occupational, physical activity, and lifestyle factors, “not working” was significantly linked to persistent neck pain, although this may represent a “healthy worker” bias, as individuals with persistent pain are more likely to stop working a factor that could equally apply to knee pain. In this study Hill (2004) found none of the specific occupational factors and physical demands such as standing, sitting, digging, driving, and lifting were considered predictive of persistent neck pain. Previous studies assessing the impact of physical activity on the development of osteoarthritis of the knee have demonstrated a positive correlation with excessive joint loading increasing the risk of the development of osteoarthritis (Schouten 2002, Maetzel 1997, Cooper 1994, Anderson 1998). However, these studies tended to relate to what may be considered very high physical demands related to heavy work. It may be that as the population in this study was generally more sedentary in nature and did not describe particular ‘high-load’ occupations that no correlation was identified, a
finding supported by Coggon (1998). In other studies such physical factors have been shown to be prognostic for chronicity among occupational cohort studies (Ariens 2001, Ariens 2000, Palmer 2001, Viikari-Juntura 2001).

The findings of this study would suggest support for the view that there is no link between the degree of osteoarthritis present in a knee and participation in a ‘moderate’ degree of physical activity as measured by employment. This is significant as previous studies have demonstrated the erroneous beliefs that osteoarthritis is caused by physical activity (Turner 2005) resulting in a decrease in participation in exercise and physical functioning. As physiotherapists we generally advise our patients who complain of osteoarthritis to exercise, a view which is currently high on the NHS and government agenda. If patients believe activity to have a negative impact on their pain this suggests the need for re-education. This important concept will be discussed further when considering the interview data which further supported this belief.

The finding in this study that greater age correlated with poorer outcome is also identified by a number of other studies as being a factor that predisposes individuals to persistent symptoms. In a general population with neck pain Hill (2004) found that age was the strongest predictor for persistence. Comparable results were also found with mechanical back pain presenting to general practice (Office of National Statistics 1991) and also with low back pain prevalence data (Papageorgiou 1995). Croft (2001) identified that while gender predicted neck pain onset it was age which predicted persistence and Hoving (2001) identified age (>40 years) in the primary care setting as being a strong predictor of poor prognosis. However, these findings need to be considered carefully as it could be
assumed that the higher prevalence of structural change associated with more advanced osteoarthritis is more likely to be found in an older age group. It may therefore be that the link between age and outcome reflects the degree of osteoarthritic change present rather than age being the primary issue. Again this is important as if not considered carefully it may reinforce the belief that older people can expect more pain due to osteoarthritis when it is the osteoarthritis which causes the pain not the age of the person per se.

In terms of impact on injection contradictory evidence to this study is provided by Lohmander (1996) who described injection of hyaluronan as being more efficacious in patients over 60 years of age who demonstrated the most severe osteoarthritis. Similarly Creamer (1999) found a non-significant trend which suggested that older and more educated subjects experienced a better response when treated with acupuncture for osteoarthritis of the knee although no indication for this trend is suggested. The average age in Creamer’s study was 65 years comparable with this study which had an average age of 59 years.

In terms of age there may also exist an element of self selection with patients seeking treatment based not on their actual symptoms as such but on their expectations of what they should be experiencing. This will be examined when considering the thematic analysis of the interview data but is a view supported by Ross (2001) who demonstrated that age can affect expectation in regards to older patients being more stoical and accepting of their pain. Consequently the older patient is less likely to seek treatment for pain than when they were younger as they expected to be experiencing pain at their age.
There may also be a link between age and the increased risk for persistent pain, such that older patients tend to have more co-morbidity. The link between chronicity and co-morbid musculoskeletal pain is supported by previous research (Croft 2001) and distinguishing between individuals who suffer isolated pain and those who have concurrent chronic co-morbid pain syndromes may be clinically important particularly in research aimed at assessing outcome. The link between co-morbidity and pain persistence may be explained by an underlying predisposition to regional musculoskeletal pains (Ariens 2001, Linaker 1999, Linton 2000). This may in part explain why a positive correlation was demonstrated in this study between poor outcome and pre-injection factors such as perceived anxiety and affect if we assume these factors may in part suggest other medical problems.

In terms of the relevance of whether an effusion was present or absent this study demonstrated no identifiable correlation between outcome and effusion a view supported by the literature Friedman (1980). Indeed as previously discussed if any conclusion may be drawn from this study in regard to effusion it is that effusion may guide which injection is most appropriate but that the presence of effusion itself cannot predict outcome as such.

The lack of clear correlation between outcome and ‘physical’ factors in this study suggests that outcome may at least be related to multiple issues and that subject’s individual beliefs and attitudes have an important role to play. This belief is supported by the strong positive correlation between subject’s pre-injection AIMS2-SF anxiety and
social score and SF-MPQ affect score with outcome at 3 months indentified in this study. A finding further supported by the data produced from the subject interviews.

Previously few studies have been carried out to investigate the possible influence of other factors on outcome following injection and those which have been carried out have demonstrated no identifiable predictors of response. In addition these studies have generally being considered to be of poor methodological quality (Jones 1996, Creamer 1999). The findings of this study in demonstrating a positive correlation between outcome and pre-injection levels of anxiety, social function and affect are therefore significant and would strongly suggest that clinical assessment should include a component of these issues at initial consultation if we are to accurately evaluate and implement successful treatment packages.

The lack of research in this area may be due to the fact that traditional medical assessment has tended to focus on physical measures such as radiographic assessment and range of movement to diagnose, plan and implement treatment regimes for most musculoskeletal conditions. In so doing it has tended to underestimate the significance of socioeconomic and psychological aspects of patients’ problems with such non-specific treatment effects being recognized but grouped together under the umbrella term of ‘placebo’ (Rosemann 2006). Such effects as patients’ beliefs, attitudes, treatment preferences, expectations, nature and setting of the intervention, as well as characteristics of the clinician such as their therapeutic style, status as a professional, the words they use and their confidence with their approach and treatment choices are often considered by
the healthcare provider as secondary to the primary proposed treatment effect (Crow 1999).

There are many reasons to consider beliefs, preferences and expectations and how these might influence the outcome following a therapeutic intervention. Certainly any intervention should be assessed in relation to both safety and effectiveness but additionally this assessment should include reference to individual patient preferences and values incorporating these factors into the decision making process (Mead 2000). Recent NHS healthcare policies have called for the inclusion of more patient choice not only about what treatment is provided but also about when and where patients receive treatment (Department of Health 2003). In addition there has been increased attention paid to understanding how preferences and expectations can be incorporated into the clinical decision making processes (Thomson 2001). The importance of this patient centred approach to healthcare with emphasis on an understanding and subsequent addressing of patients’ beliefs and expectations is underlined by the high reported rates of non-adherence to treatment plans (Meichenbaum 1987). It seems likely that strong pre-treatment factors will be highly influential on compliance with treatment and subsequent outcome and the need to identify such factors was the main catalyst to this study.

The findings of this study in regard to the significant role played by the pre-injection factors of anxiety, social function and affect as measured by the questionnaire data were further developed and deepened with the inclusion of the thematic analysis of the interview data. In regard to this data the themes produced helped in understanding the
issues that surrounded successful outcome following intervention. These 4 reduced themes covered the following areas;

1. Expectation and Ownership,
2. Experience and Knowledge,
3. Exercise Beliefs,
4. Social Interaction,

Although no direct ‘cause and effect’ relationship can be established analysis of interview data suggested that certain attitudes and beliefs seemed to be associated with better outcome. Those subjects who demonstrated realistic expectations linked with a sound knowledge of their condition generally appeared empowered in their decision making. Support for this finding may be gained from the systematic review by Mondloch (2001) who examined the evidence for a relationship between patient’s recovery expectations and health outcome. A wide range of health problems were explored and the conclusion was that positive expectations were associated with better outcome.

In addition and of importance to any clinician prescribing an exercise program was this study’s demonstration that subjects with positive expectations and appropriate knowledge of their condition appeared to hold positive beliefs in relation to exercise and activity. Subjects who did less well generally seemed to hold the belief that their pain meant that they should avoid activity and subsequently had poor compliance with exercise. This has important implications for as previously indicated and suggested by this study there is little evidence to suggest that a moderate degree of physical activity increases either the
risk of the development of osteoarthritis or exacerbates an existing condition. However, certain subjects appeared to use their pain as a justification for the abandonment of their normal active roles. Certainly patients with such fear avoidance beliefs have been shown to be more likely to develop chronic disability and forsake their normal levels of function (Vlaeyen 2000). Subjects’ beliefs regarding their pain and likely outcome seemed to be grounded in their own subjective experiences established by comparing themselves to others and to their own previous health state. Those subjects demonstrating greater understanding and knowledge seemed able to take a more objective, rationale view based on this knowledge and better aligned with current medical thinking. This would suggest that despite the efforts of government and the NHS in the promotion of healthy living and the importance of the role of exercise to date certain groups of society may be either missing this message or through the entrenched views held in relation to activity and joint pain are not willing to adopt this way of thinking. This implication is that there is a need for a fundamental evaluation of our approach to these patients. There may be little point in prescribing life style changes if the rationale for these adjustments is not fully understood or welcomed.

Additionally the danger exists that clinicians unintentionally perpetuate this situation in certain groups of patients they see in the clinical setting. Skelton (1998) recognized this and demonstrated that General Practitioners seemed to use their perception of a patients’ social standing to inform their approach to treatment. Therefore working class patients were provided with a less detailed explanation of their problem compared to those patients from middle class backgrounds. Certainly this study would concur with the
stance that sound understanding of osteoarthritis has the potential to result in better outcome whereas erroneous beliefs are associated with poorer outcome.

Thematic analysis also identified expectation as being a significant influence on outcome and therefore this also needs to be taken into account in relation to patient preference for a particular given intervention. Preference being an expression of a value held over alternative options based on an informed consideration of the possible risks and benefits known to that subject at that time (Bowling 2001). The example of erroneous beliefs and exercise demonstrates how closely knowledge and preference are linked (Turner 2005). Of course a particular preference may be based on insufficient or erroneous information and it is interesting that those subjects who appeared to do well generally had a good knowledge of their condition and what they might be able to expect from treatment. In addition it would seem realistic to assume that preferences and indeed expectations would change over time as a result to exposure to interventions and influences. Certainly in this study a number of subjects who had previously experienced unsuccessful interventions appeared less hopeful of an injection being likely to help and expressed more negative attitudes and beliefs. It would seem reasonable to assume that if a patient receives the treatment they prefer and for which they hold a higher expectation of benefit then better outcome may follow (Van der Windt 2000).

This view would seem to be supported by the few subjects who requested further investigation in the form of MRI scan. Such a procedure is not justified for osteoarthritis of the knee but in those subjects requesting MRI poor outcome seems to have followed and may have been the result of these subjects feeling that they were not treated
appropriately. They did not receive their treatment of choice and therefore their expectations were not met. It has previously been noted that patients referred to other practitioners by their GP or for further investigations seemed to consider this an indication that their problem was being taken seriously and that all possible treatment options were being explored to help them obtain suitable resolution (Lambert 2000, Espeland 2001). Although MRI is not appropriate all subjects in this study did receive x-ray confirmation of their diagnosis and this could in itself have affected outcome such that subjects felt they were being ‘taken seriously’.

The basis of these patient held views seems grounded in the fact that when patients present in clinic they want to be believed and not seen as malingers. Gaining an objective diagnosis has been demonstrated as a key issue by patients as a means to having their symptoms legitimised (Beaton 2001). In this way investigations such as x-ray may be considered to be a form of therapeutic intervention becoming an effective tool in successful outcome if patient’s overall satisfaction with treatment is considered.

The importance of subject preference may also be linked to the ability of a subject to articulate that preference. For example, Thomas (2004) examined corticosteroid injection versus physiotherapy for shoulder pain, a good functional outcome was achieved in a higher percentage of subjects who had been given their pre-treatment preference of therapy compared to those who had not. This finding supports the belief that it is the ability to articulate treatment preferences which is important. This corresponds with the findings in this study in that those subjects who were noted as being clear, articulate and engaged during the interview process and who appeared educated and informed with
regard to relevant issues concerning their condition seemed to do better. This demonstration of appropriate knowledge allowed these subjects to make informed choices and express clear preferences.

Knowledge of condition was identified in my journal in which I noted an apparent link between an educated and informed outlook and demonstration of empowered decision making processes. This factor was identified by Creamer (1999) who correlated better education with better physical function, less pain and what was termed as ‘learned helplessness’. The term ‘learned helplessness’ was defined as a state whereby the subject, as a result of past experiences holds beliefs that any current efforts directed at their problem will be ineffective. A point which corresponds with the finding in this study that those subjects whose previous experiences of treatment had on the whole been negative subsequently seemed to have little belief in future treatments being successful.

As previously indicated the importance of an appropriate awareness and knowledge of condition seems closely linked to attitudes in regard exercise and activity. Subjects who demonstrated poor outcome generally seemed to take the view that exercise was either not useful or not possible due to pain. These subjects appeared more fixated on their pain and the lack of ability to function because of it. Other studies suggest that an excessively negative orientation toward pain and fear of movement are an important factor in the aetiology of chronic low back pain and its associated disability (Fritz 2001, Vlaeyen 2000). These findings are consistent with a cognitive-behavioural perspective that underscores a maladaptive interpretation of body sensation. Subjects, who catastrophically misunderstand innocuous bodily sensations, including joint pain, are
more likely to become fearful of pain. The result of which may be reflected in two processes, firstly pain related fear may be associated with avoidance behaviours and in particular this applies to avoidance of movement. In practical terms subjects avoid exercise. Secondly, avoidance may also mean a withdrawal from rewarding activities such as work, leisure, and family commitments (Vlaeyen 1995). This point has resonance with my study’s identified theme ‘social interaction’, as subjects with poor outcome generally described as sense of exclusion from society in that they had few social interactions with family or friends.

Exploring an individual’s belief in regard to exercise identified issues that influenced a subject’s compliance. Exercise behaviour seemed dependent upon the individual capacity to exercise, motivational factors, exercise beliefs in regard to condition and social interaction and perceived support. The importance of exercise belief as a determinant of exercise behaviour has been previously found in a survey of outpatients with arthritis, where perceived benefits of exercise were seen to be a significant predictor of exercise participation (Neuberger 1994). This would suggest the need to address those exercise beliefs in patients who are identified as being unlikely to be compliant with an exercise program rather than assuming that all will be compliant. Such an approach is likely to result in poor outcome and subsequent frustration for both patient and practitioner.

The importance of social interaction as a determinant of outcome seems to transcend the other themes in that those subjects demonstrating little interaction with family or friends and who seemed to have less self worth had little expectation of treatment outcome, a poor knowledge of condition and little interest in exercise. This detachment was
described by Orem (1991) in terms of ‘self-care’ and was seen as a learned ‘human regulatory function’ that is a function based on individuals’ capabilities to perform self-care functions on their own. According to Orem (1991) self-care behaviour differs from person to person because of differences in individual knowledge, motivation, technique, life experience and available resources. Yang (2001) demonstrated that knowledge of condition correlated positively with self-care behaviour with the inference that it may be a significant self-care predictor. The results from this study would appear to be in agreement with this finding in that knowledge of condition appeared to be associated with greater social interaction and better subsequent outcome.

Orem (1991) postulated that a functioning social support system operates as an environmental resource which facilitates self-care by meeting social interaction needs and by enhancing a patient’s motivation to subsequently engage in self-care behaviour. Such social support may be seen to consist of inter-relationships between family, friends, and colleagues and reflects the recipient’s subjective perceptions regarding those upon whom they rely when in need of help (Sarafino 1994, Yang 2001). Social support may then be seen as a measure of perceived satisfaction in an individual being helped by another given individual. Social support is thus a multidimensional construct, encompassing emotional support (concern, trust and love), appraisal support (affirmation of self-worth), informational support (advice and information), and instrumental support (tangible and objective goods) (Sarafino 1994). Social support may also help a patient to adjust and come to terms with a life-long condition and if provided in an effective manner may also provide a context for learning coping strategies and feedback to correct inappropriate actions and behaviours (Gonzalez 1990). This importance of appropriate feedback in
terms of information given regards pain, exercise, condition and activity promises the chance to correct inappropriate beliefs.

In summary the findings of this study suggest both intra-articular corticosteroid and hyaluronan have a place in the management of osteoarthritis of the knee and that their selective use may be facilitated by the identification of a joint effusion. Importantly this study also identified that physical factors should not be relied upon alone to predict outcome of treatment and that other factors such as anxiety, social interaction, expectation and knowledge of condition all have significant impact on patient’s perceptions and subsequent engagement in the treatment process. From a practical view it would seem that the inclusion of such factors at initial assessment may help identify those patients who are less likely to benefit from treatment unless certain fundamentally held views are identified. In particular the findings suggest that an appropriate knowledge of condition may significantly help to re-educate patients and subsequently gain enhanced compliance with exercise regimes. In addition better knowledge of condition may empower patients and so facilitate more informed choices which in turn will allow patients a feeling of active involvement in their treatment. The next section will draw together these findings to discuss the value of this study’s conclusions in terms of possible future implications to practice and other research ideas generated.

3 Implications of the Study

From a risk/benefit perspective the use of injection therapy has certain advantages as although non-steroidal anti-inflammatory drugs (NSAIDs) have a proven therapeutic efficacy and are one of the most commonly used pharmacotherapy’s in the management
of osteoarthritis their long term use, particularly in those considered at high risk such as the elderly, is not without the potential for serious gastrointestinal side effects. Given the nature of osteoarthritis it is often those patients who would be considered as belonging to this high risk group that complain of symptomatic osteoarthritis and who require treatment. Potential side effects include gastric upset which not infrequently can result in peptic perforation and subsequent haemorrhage (Bell 2001). Indeed, as many as 20-30% of all hospital admissions and deaths due to peptic ulcer disease in the elderly have been reported to be related to the use of NSAID’s and many more patients may suffer from gastric upset (Griffin 1998). Cyclooxygenase-2 (Cox-2) inhibitors appear to cause fewer gastrointestinal side effects then do NSAID’s, however, recent data suggested that these drugs can also be associated with other potential side effects (Ray 2002).

In regard to the factors that may influence outcome following injection my own professional experience would suggest that the findings of Rosemann’s (2006) study are correct and that the medical assessment of osteoarthritis of the knee focuses principally on physical measures such as radiographic investigation and range of movement. However, from the quantitative data produced in this study it is clear that correlation with outcome is significantly linked to non-physical domains such as perceived anxiety and levels of reported social interaction with family, friends and colleagues. In addition qualitative thematic analysis of the interview data suggested that subject’s expectations, knowledge, and beliefs were also of importance to outcome.

These findings are important as an understanding of the ‘non-physical’ factors which may influence outcome has the potential to inform strategies which could increase patients’
and practitioners’ satisfaction with the care they receive and give. It may be reasonable to assume that such strategies would subsequently improve clinical outcome and may do so with little additional financial investment. This point has particular significance in the context of the current financial climate and the fiscal ‘belt-tightening’ which seems likely over the next few years.

This study’s findings suggest that patients may be more accurately targeted and supports the view that provision of patients with an appropriate level of information regarding their condition and possible treatment options is important if we are to secure the best possible outcome. Information of this kind could be provided in a group setting prior to any formal intervention such as injection providing patients with suitable facts on which they could make more informed choices. It seems likely that the addition of such group work would offer a relatively low cost adjunct to the overall treatment package offered.

This provision of appropriate patient information in the form of education is endorsed in the conceptual framework developed towards the end of the findings section. Here it can be seen that knowledge and experience appeared central in terms of influence on outcome. Appropriate knowledge of condition has the capacity to correct erroneous beliefs and inform choice in terms of treatment. Additionally in subjects with more chronic symptoms knowledge may allow for correction of misunderstanding in relation to innocuous bodily sensations being perceived as painful. If such misinterpretation is left unchecked it can feed into maladaptive and chronic pain states, reinforcing inappropriate exercise beliefs and reducing ownership. Further chronic pain may lead to fear avoidance behaviours with a steady withdrawal from activity and social commitment (Vlaeyen
Given the likely future demands on the NHS from a growing and ageing population the empowerment of patients to take a greater control of their own health, avoiding inappropriate beliefs, should be considered of paramount importance a fact recognised and supported by the findings of this study.

Knowledge of a condition encourages empowerment with subsequent autonomy and certainly the medical profession has seen a gradual shift in recent years from a traditional and paternalistic approach to patients and their treatment to an approach with emphasis on this increased autonomy. This greater degree of patient autonomy can be seen in the ‘patient centred’ approach to health care delivery (Emanuel 1992). Although the traditional and paternalistic approach was not without some advantages, patients and relatives were spared the difficulty of making decisions in regard to treatment regimes, not having to weigh up all possible benefit and risk issues and to a degree not to have to worry about cost implications. The disadvantages were manifestly obvious in the ability of the clinician to freely determine what themselves was in the patient’s best interests without any recourse to the patient. This approach does not encourage ownership or empowerment of a problem. Additionally, biases based on the inherent prejudices and influenced by sex, race and socioeconomic status could all be allowed to overly influence the decision making process. Deprived of patient involvement there exists little opportunity to make decisions that reflect the reality of the patient’s condition.

Reasons for greater patient autonomy would seem multi-factorial and reflect the greater changes within society as a whole. The consumer movement has certainly encouraged patients to be more assertive and to question decisions and recommendations that are
made. Many patients may feel empowered to demand treatments that might otherwise be withheld. This empowerment has been particularly influenced by the explosion in the information, and in many cases misinformation, available in the popular press and on the internet which all too often depicts the possibility of grand successes and an over simplification of problems through what would seem safe, obvious and appropriate interventions. In addition to this the increased risk and perceived risk of medical litigation has left a feeling among many clinicians that making available the full range of choices while withholding their own personal recommendations based on experience is perhaps the safest approach to take in their practice (Green 1988).

It may be therefore that this apparent autonomy may not truly represent a real increase in empowerment at all. It may well be that we have moved from a paternalistic model of health care delivery to an approach which devolves all responsibility from clinician to patient. However, in reality the patient may feel more secure and empowered if the experience of the clinician was included in the dialogue that takes place during consultations,

‘well I don’t know what to do...you’re the doctor you tell me...that’s why I came to you isn’t it!’ (Subject 2. Interview data).

According to the independent choice model of health care the clinician’s primary role in the process of medical decision making is to inform the patient about their options and to provide a percentage figure of the likely success of any particular option. This information must be given in a completely unencumbered and unbiased fashion free from any contaminating influence born from personal clinical experience. This sounds very
similar to the idea of a ‘value free’ study which forms the goal standard for the quantitative researcher working very much in the positivist paradigm. However, is this ever tenable? I think not, a fact that is recognized in post positivism which accepts that objectivity cannot be fully attained because reality is viewed by a subjective receiver; it is always someone’s reality even though I may be continually tempted to project my own prejudices and world view on others. Van Manen (1999) saw the challenge in terms of research and outlined the need for the researcher to recognise their own inherent position and subsequently through a process of reflection overcome their subjectivity, preferences and expectations to allow as truthful an understanding as possible of the phenomena to emerge. However, this need for reflexivity is just as real in my clinical setting as it is in my research as for the clinician to be completely value free and abstract out all subjectivity from the clinician/patient dialogue is unrealistic.

The independent patient choice model can be seen as the basis of the NHS system ‘choose and book’ where the clinician is expected to empower patient choice through the giving of information on a multitude of different factors but to try and avoid overly influencing this choice through personal experience and recommendation. The duty of the clinician is to answer questions in an objective manner avoiding opinions as much as possible even if these are asked for by the patient. Following the patient making their decision the clinician’s duty then becomes one of implementation of the medical aspects of that decision.

Taking this model to its natural conclusion it would make sense to remove the clinician altogether as they seem to become an impediment to rather than a resource for the
decision making process due to their inherent experiences and values. More objective
treatment algorithms could be presented to the patient in the form of a computer software
program, the clinician only being involved in the subsequent implementation phase. The
patient may be left to negotiate the complex process of clinical decision making free from
any appropriate medical guidance. Clinicians themselves working within this model may
come to a position where they no longer value their own recommendations. The
intellectual dialogue that represents the multidisciplinary meeting and combined clinic
are replaced with a process based on the odds of a treatment being successful or failing.
We arrive at a point where we may have moved so far from the old paternalistic model to
be considered at the other end of a continuum of clinician-patient empowerment, a
position that is removed from the old model but just as problematic.

The problem seems to be that the independent patient choice model assumes that the
patient is best served by making their own decisions in a manner which abstracts them
from the medical profession even though most patients would admit limited knowledge
and understanding of their condition. Additionally and of importance the findings of this
study would support the view that this limited knowledge of condition if left unchecked is
likely to result in poor outcome with both subsequent health and financial implications.

Is there room for a middle ground, a third way combing the best of the old and new
models? The Pew Health Professions Commission (Pew-Fetzer 1994) used the term
‘relationship centred care’ as opposed to ‘patient centred care’ and this would seem to
take a sensible middle ground. This enhanced autonomy requires that the clinician
engages the patient in an open and frank dialogue, informs the patient about their options
and the different therapeutic possibilities that are available to them. It becomes incumbent on the clinician to consider the patient’s values and be honest regarding their own. Only then may they offer recommendations that are rooted firmly in both sets of values. This approach is certainly supported by this study’s findings in regard to the importance of knowledge, expectation and belief.

In a similar manner to the need for the researcher to be reflexive the clinician who openly exposes their own biases and is explicit concerning their own values is less likely to coerce or inappropriately manipulate the patient in their decision making. Any attempt to ignore these inherent beliefs is likely to result in a subtle infiltration of the clinician - patient dialogue even though an outward attempt at neutrality is made. Indeed empirical studies have demonstrated that enhanced support of patient autonomy and decision making is associated with better outcomes in substance abuse treatment, weight reduction, and adherence to treatment regimes (Ryan 1995, Williams 1996, Kaplan 1996).

This enhanced autonomy model must be centred round an interactive dialogue between the clinician and the patient. This dialogue should include active listening, an honest sharing of perspectives and a suspension of personal subjective judgment (Senge 1990). The objective of such interactive dialogue is to achieve as full as possible an understanding of the meaning of the issues at hand. This can only occur if the clinician is free to include their own beliefs, personal experiences and ultimately recommendations within the discussions that take place. In so doing the patient is guided in their decision making without being coerced into something they do not truly want. At the same time
the clinician retains ‘power’ in regard to making recommendations to the patient while the patient is able to make an informed choice and therefore also retains a high degree of control.

If we assume that the core element of patient autonomy is respect for the patient as a person then just as coercion is not acceptable, the practice of withholding information in the form of recommendations based on personal experience is not an acceptable practice either. Respecting the patient as a person means taking time to listen and then making an attempt to integrate treatment with the patient’s own personal biography (Cassell 1982).

Identification of the need to deliver appropriate information to patients to allow an increased knowledge of condition with subsequent empowerment also needs to be considered in terms of delivery. It would seem that such provision of appropriate knowledge needs to involve all clinicians responsible for patient care, although interestingly GP’s feel that education of patients in regard to their condition is important they described not having sufficient time within a normal consultation to deliver this (Skelton 1998). Additionally patients report that they do not listen to advice given to them because it is often vague, unclear, and impractical for everyday life and what they require is more practical advice on how to apply it (Skelton 1995).

Information which is of practical value and has functional meaning to a patient would seem to fall well within the remit of the physiotherapy consultation. It may be that the most useful conclusion which can be drawn from this study is the need to ensure that our patients are well informed and have appropriate knowledge to encourage autonomy and
subsequent compliance with treatment. It may be that as a profession we need to ensure that education of condition is given primacy over the traditional therapeutic interventional model. This approach may also be extended to our professional training programmes both at the under and post graduate level ensuring physiotherapists are able to and willing to deliver appropriate education.

Practical application in regard to this approach may also include ensuring an efficient prevention programme revolving around prioritising patients and targeting effective strategies such as health education and exercise programmes. Additionally there may be a role for occupational health strategies that encourage individuals to remain at work while pursuing pain management approaches that address issues of education and knowledge rather than physiologically perceived symptoms.

Finally this study would also suggest a number of further lines of exploration which could be undertaken. Given the relatively short follow up period an additional review may be useful with particular interest being focused on whether the reported benefit following injection is maintained. Recognising the transient population of Hackney any attempt to include significant numbers may be of issue. However, it may be possible to conduct further in depth interviews or specific focus groups relying on smaller sample size but exploring issues in greater depth. Additionally this study limited itself to include only those subjects that were able to use English effectively. Acknowledging the diverse population of Hackney specific ethnic groups could be targeted to investigate issues pertinent to these groups. Certainly exploration of the specific factors identified in this study may be of interest and in particular the issues regarding subject’s level of
knowledge and experience concerning their condition may help inform specific and effective education programs.

The next section will explore some of the limitations identified during and after completion of this study in terms of the methodology and methods.

4 Limitations in Methodology and Methods

Given the existing evidence supporting the use of corticosteroid and hyaluronan injection in the management of osteoarthritis of the knee (Gossec 2006, Clinical Evidence Concise 2005) there did not appear sufficient justification or need to employ a randomisation and control group within this study (Chapter II, section 3.2, page 100). However, given my previously identified positivist leanings this lack of a control group resulting in a direct ‘cause and effect’ explanation not being possible still held some concern.

Consideration of the phasic nature of osteoarthritis would indicate that this lack of control may be of particular relevance. However, in terms of assessment of outcome this would have been ethically questionable as the use of injection therapy and in particular the use of corticosteroid has been demonstrated to have a significant impact on symptoms. Therefore denying one group of subjects’ injection would seem to raise particular issues. Clinically it is well known that the pain associated with osteoarthritis fluctuates and by nature patients normally seek medical assistance when the pain is at its worst. Therefore, any positive results observed in a cohort study may well be due to a spontaneous recovery and regression towards the mean in terms of perceived symptoms. In regard to the findings in my study not being attributed only to a natural reduction in symptoms some
support may be gained from examining the mean duration of symptoms. In this study the mean duration of reported symptoms was 15.3 months, with a minimum duration of 3 months and a maximum duration of 60 months. This relatively long length of reported symptoms by the subjects at inclusion into the study would tend to reduce the likelihood of spontaneous recovery although certainly this cannot be said with certainty.

In addition to the possibility of spontaneous recovery the potential for a placebo effect should also be considered and in the absence of a control group cannot be dismissed. Although the term “placebo effect” is often associated with negative connotations in health care its possible impact on a patient’s symptoms and on the observed outcome in any research study should not be underestimated. Placebo effect was defined by Shapiro (1961) as:

‘Any therapeutic procedure (or that component of any therapeutic procedure) which is given deliberately to have an effect, or unknowingly has an effect on a patient, symptom, syndrome, or disease, but is objectively without specific activity for the condition being treated.’ (In Noon (1999) p. 133).

Recruiting the positive benefits of the placebo effect has been used in medicine throughout the centuries (Straus 1996). Research by Schwartz (1989) revealed that among 110 physicians studied 24% intentionally prescribed drugs for their placebo effect. Although these positive benefits may be extremely desirable in a clinical context when considered in the research setting the impact of placebo may serve to confound findings. This should particularly be considered when the research study is concerned with the assessment of a therapeutic intervention as studies examining placebo have demonstrated
that it may be clinically beneficial in 60-90% of diseases (Benson 1996) with up to 30-40% of pain patients demonstrating a positive response of up to 30%. This seems to be particularly noticeable with subjective measures such as perceived levels of pain (Noon 1999, Ross 1981, Zhang 2008).

Ross (1981) described placebo as having 4 characteristics that may mimic active therapeutic intervention. The first being a direct effect mimicking active treatment by increasing or decreasing the effect of that active treatment, secondly a placebo may demonstrate an equivalence of strength to that of the active treatment, thirdly placebo has been found to mimic the side effects of active treatment, and fourthly placebo has been demonstrated to mimic the length of time of an active treatment with Boissel (1986) reporting duration of effect of 6 months for patients with angina pectoris.

With particular regard to osteoarthritis Zhang (2008) examined 198 studies which included 1167 subjects to assess the impact of placebo in the treatment of osteoarthritis. This meta-analysis yielded 3 key findings: placebo is effective in the management of osteoarthritis; the effect is superior to non-treatment and appears to be most effective for those outcomes measured subjectively; and the main determinants of the placebo effect in osteoarthritis are the effect size of the active treatment, the baseline symptom severity, the route of delivery and the sample size. In regard to my study the relevance of placebo should therefore be considered with respect to its ability to directly mimic the effects of a therapeutic intervention and/or augment this effect, particularly given that placebo has been demonstrated to have greater effect with injection than if treatment was prescribed orally Zhang (2008). Additionally, the ability of placebo to mimic treatment effect in the
longer term should be borne in mind when considering the study findings especially in the absence of a control group.

Additionally there appears to be some evidence to suggest that anxiety and depression may be inversely related to the degree of response to placebo (Creamer 1999). In his study Creamer demonstrated that the anxious or depressed subject showed less response to placebo during an intervention than those subjects who were less anxious or depressed at the time of treatment (Creamer 1999). It would follow that those subjects who respond to treatment are less likely to have their outcome unduly biased by a placebo effect and more likely to have the treatment itself to thank for a positive outcome.

Ultimately the best possible resolution to these issues would have been to use a randomized study including a control group. However, given that this would have been ethically difficult to justify another possibility, one which would at first seem to be ethically sound, would have been to increase the longitudinal nature of the study. In this way it would have been possible to track the reported changes in subjects’ pain and function scores for some time prior to the therapeutic intervention rather than only assessing immediately to that intervention. If this was carried out at monthly intervals it would have been possible to identify whether subjects were improving, worsening or in an unchanging state prior to injection. This would have allowed an increased confidence in the injection itself being the source of reported positive outcome rather than a spontaneous improvement in symptoms. This was a method I had thought of engaging but on careful consideration realized that this approach also had possible implications. Firstly it could be argued that it would have been unethical to withhold treatment for 2 to
3 months in order to gather baseline data on subjects’ reported symptoms. Secondly the repeated use of the questionnaires over this pre-injection period may have increased the influence of a learning effect in each subject as they repeatedly completed the questionnaires. In addition there would have been the risk of an increased drop-out rate due to what the subjects perceived as an imposition on their time for no interventional reward.

A further concern that was identified in my research journal and which probably also stemmed from my positivist leaning and lack of prior experience in regard to the qualitative paradigmatic approach to research, was the analysis and collection of the interview data. In this regard my primary concern was the act of analyzing the data which the interviews produced as this was undoubtedly going to be influenced and informed by my own theoretical assumptions and perspectives. In the case of this study these assumptions included that a poor compliance with prescribed treatment regimes, in the form of exercise previously given, would possibly result in poorer outcome. Similarly, a lack of perceived ownership and a decreased sense of empowerment in regard to the subjects reported symptoms would also be potential barriers to recovery. In this sense I certainly did not come to my initial research question with a completely open mind and in truth do not believe that this would have been possible or desirable. After working in the NHS for 20 years I could hardly be value free. Indeed to do so removes the ‘experience’ from the clinical interaction, such experience is invaluable within this interaction and one that the patient should expect when they seek advice and help for their condition.
However, the need to reduce this degree of interviewer bias was important. As an interviewer I attempted to do this by being as non-judgemental as possible, practically this involved trying not to appear to be surprised or disapproving of a particular response. As interviewer an element of polite interest is necessary to engage the subject but this should not appear to be too intense. Any prompts which were made were done in such a way as to avoid leading the subject in a particular direction. Of course bias cannot be completely eliminated and consideration of the interviewer’s unconscious use of leading questions and prompts, and social desirability bias must be taken into consideration.

In an attempt to avoid bringing an excessive degree of my own assumptions and biases to the interviews I used the pre-injection interview to ‘gauge the mood’ and utilize themes that the subjects themselves identified as being of relevance to direct the second and more in depth post injection interview. Therefore the aim of the pre-injection interview was not so much to initiate an in depth exploration of the issues but to provide an overview of these issues and to raise any others which may not have been considered at a later date. This overview provided a journey planner, a route map to the later in depth, less structured format of the post injection interviews. At this time issues raised and articulated pre-injection were returned to and an attempt to explore them in more detail made.

In addition I wanted to ensure that my approach to interview was as ‘trustworthy’ as possible. Recognising that interviewing a subject is inherently a unique interaction specific to the time of that interview and including many variables affecting the subject’s responses in a way that may not all come into play again this presented a challenge. I felt
that there was a need to standardise procedure as far as was possible but this would not have been appropriate or true to the naturalistic aspect of my mixed methodology. Although this may have been something that was not possible to standardise I felt that it was still important to structure the interview in such a way as to minimise any bias that I or the environment may have had on the subject. In this way my behaviour as an interviewer was essential for both the reliability and validity of the whole research process, and in terms of the naturalistic paradigm the ‘trustworthiness’ of the study.

This was a concern due to the lack of expertise that I had had in the interview process related to research. It was therefore, my aim that the approach I took as interviewer endeavoured to establish a good rapport with a variety of different subjects, it needed to be friendly but professional. Moreover, it required that the subjects were listened to allowing them to express their thoughts while at the same time I was able to prompt and probe to gain depth.

I also needed to consider that subjects may respond differently to the perceived characteristics of different interviewers. For example Yang (2008) reported that interviewees with little education reacted to more highly educated interviewers by giving more substantive answers to questions posed. These findings are consistent with concepts in social psychology in that interviewees are able to deduce from the interviewer’s appearance and behaviour whether the interviewer seems to be more knowledgeable than them. Subsequent interaction results in the less well educated interviewee trying to conform to perceived expectations (Yang 2008).
Additionally the sex and age of the interviewer in relation to that of the subject is known to have an effect on response. Matching interviewer to subject is rarely going to be either possible or practical and in itself has issues in regard to consistency. I felt that in my study the best approach was to attempt to be as consistent as possible with minor alterations in style dependent upon the subject being interviewed. In effect an approach which should be familiar to any good clinician, although the clinical interview and subjective examination should be considered different to the interview which takes place as part of a research study. On reflection I feel that prior to undertaking any future qualitative research involving in depth interviews it would be beneficial to video record an initial sample and have this examined by an experienced researcher in this field to gain feedback on method and technique.

A further consideration in regard to the qualitative aspect of the study was that although the use of the semi-structured interviews post injection promised to provide detail not normally available in clinic and as such gave an insight into patients own beliefs and perceptions there were possible weakness to this method. Silverman (1998) asserted that one major weakness of the interview method is that data is collected in a retrospective manner. It is the subject’s description of their experience of an event that happened in the past and therefore cannot be a completely accurate account of that experience. In conducting my interviews at 3 months post injection part of the account obtained pertains to the experience of the injection itself and of the experience of attending the hospital for that injection. Certain thoughts may have changed or been forgotten in the intervening time period. However, the moment we experience anything in our lives it becomes part of our past. Thus making sense of our lives and experiences always occurs retrospectively.
There is also the issue of being able to articulate our experiences which needs to be considered. The average reading age for English speaking residents of Hackney and therefore subjects within this study is considered to be 11 years old. I need to consider this in any assumptions that might be made regarding data collected. I would certainly not deny that an experience for someone who has a less advantageous education is less real than someone fortunate enough to attend a University but is their ability to articulate this experience different? This capacity of subjects to comprehend all aspects of the study may have also impacted on their ability to be able to understand the questionnaires in a meaningful way, a way which truly reflects their perceptions and thoughts in regard to their condition. Some support in this regard may be gained from the pilot study carried out which demonstrated that both questionnaires utilised seemed to have a high degree of acceptability. Although this is of course no guarantee of their legitimacy.

In addition if my socioeconomic background is significantly different to that of my subjects will we truly be able to communicate in such as way as to fully be able to articulate to one another what it is we want to say. The inclusion of ‘raw data’ in the form of quotes from the interviews is aimed at the reader such that my interpretations are transparent and therefore subject to consideration.

The tools that the study utilises as well as the manner in which the data is collected by them may also have influenced a change independent of the effect of participating in the study (Depoy 1994). This recognition of possible ‘instrument reactivity’ is an inherent issue with any tool and acknowledges that any instrument has the potential to react with
that it seeks to measure. Within the context of this study the instrument is the questionnaire. It is hoped that any reactivity is small relative to the variable being investigated and can therefore be considered inconsequential but this might not be the case and without a control group is difficult to know. Instrument reactivity may affect a subjects’ attitude to completing a questionnaire and it may change behaviours when a subject knows they are being observed. This adverse interaction may occur in two ways. Firstly, an instrument may directly affect subjects so that true measurements are distorted. This would seem less likely within the context of this study and as long as any distortion was constant comparisons could still be made between variables. The second issue is the interaction that may occur between the subjects’ treatment and the instrument such that the responses to treatments are changed this has the potential to confound the study.

One solution would be to test for instrument reactivity within the design of the study itself. It would be possible that a number of subjects would not receive the pre-injection questionnaires. Outcomes could then be compared between the groups that did or did not fill in the questionnaires at the pre-injection stage. The problem with this pseudo-control would have been it would have significantly reduced the numbers of subjects that could have be used to examine whether there were differences between the pre and post injection phases of the study.

The Hawthorne effect (Roethlisberger 1939) may also have introduced an element of distortion and refers to the phenomena that can occur when subjects know they are taking part in a study. In essence this is similar to instrument reactivity but does not have to involve the instrument itself. The mere knowledge that the subject has awareness of being
in a study may affect behaviour even if no observations are being made. This is difficult to control and is dependent upon the subjects own world view, perceptions, and expectations. The solution would to have been as unobtrusive as possible but this has its limitations. In an attempt to reduce this effect all subjects were equally well informed prior to the study in regard to why and what was going to happen thus holding knowledge of the study constant.

Two final factors to consider are differential subject loss and preferential recruitment. In this study as in any other that have a longitudinal design subjects may be lost due to refusal to continue or to events that preclude continuation. It is worth remembering that the normal ‘did not attend’ rate at the clinic where this study took place is approximately 12%. This is comparable with other clinics and departments in the hospital. The problem is that this attrition rate may not be random and those who complete the study may be very different from those who do not. This has the potential of reducing the study’s generalisability. Shorter follow up may help but this again raises the question of benefit over the longer term. In this study of the 48 subjects identified as being eligible for inclusion 3 declined to take part and a further 7 were lost to follow up. Little can be ascribed to these subjects but further follow up perhaps by telephone interview may have been useful here. In terms of preferential recruitment a recent systematic review of the effects of patients’ preferences across a wide spectrum of health conditions, found some support for the idea that patients’ preferences might affect recruitment to clinical trials although the evidence suggested that external validity was not critically compromised (King 2005).
5 Reflections

I have outlined and discussed my research findings, I now plan to use this final section to reflect on the overall research process that I undertook. I found this process was facilitated by re-reading notes made in my research journal. This comparative analysis between my thoughts at completion of my research study and the thoughts and ideas that I had during the course of my research I found to be both useful and instructive in terms of a learning experience. In particular the benefit of hindsight proved to be enlightening and made me question the journey I had taken in terms of its overall value, the methodological choices adopted and the practical implications of my findings.

I found a useful starting point to this reflective process was to examine my thought processes from the time of starting the doctorate program. Consequently the first question that I was forced to ask myself and one that brought my research journey ‘full circle’ was,

“What was wrong with my practice that I needed to do research into it?”

There had been an issue, something which had made me feel ill at ease and something that was less than tangible and which therefore could not be defined or clarified such that it could be subject to rigorous methodological enquiry. Examining my research journal I see that I had many thoughts as to what might be interesting avenues of enquiry to explore but had never really probed any in detail. Additionally I feel that I was firmly entrenched in a positivist world of as I saw it ‘science’ and would, I believe have been limited in any methodological choices that I may have made.
In retrospect the ability to spend time away from work with a multidisciplinary group all of whom had an issue to be explored proved constructive. This and the subsequent discussions which took place during action learning sets and with tutors enabled me to explore and perhaps widen my views in regard to my own practice, my views as to what science is and what was required to answer my question. This ability to pose the correct question must be the first consideration of anyone starting out on a journey of enquiry. The danger for me would have been a head long rush into what I perceived to be the issue, very much a ‘knee jerk’ response. This clearly ran the risk of producing an answer which would neither be the one I had expected or one that I may have found to be useful as the question posed was likely not to be the one that was needed. I am reminded of The Hitch Hikers Guide to the Galaxy (Adams 1995) in which a super computer is built to answer the ultimate question. After many centuries of computation the answer produced was 42. Unsurprisingly this is met without much enthusiasm but did not reflect an incorrect conclusion. Rather the problem lay with the initial question posed, as the saying goes ‘rubbish in, rubbish out’.

Therefore the first thing I asked was if the practice in which I worked was as it was and had been this way for sometime did anything need to be changed? Had anyone else noted that anything was wrong, if not why not? Had it already been investigated and had conclusions led to the practice being this particular way for a good reason? It should be borne in mind that the NHS has seen many changes to practice not all of which have resulted in the most agreeable of outcomes. Indeed within my own practice I have increasingly felt that much of the rapid change that has occurred has been brought about through a combination of political posturing and financial saving. It is then at some latter
point in time that any true attempt at service re-evaluation takes place, if it takes place at all.

I feel that these questions concerning the necessity to do research must not only be asked at the start of the research journey but continually revisited throughout the course of that journey in an attempt to remain focused. The desire to ask questions was effectively expressed by Brookes (1976) who described ones work as a flow of actions. Ordinarily this flow of action would be smooth and undisturbed. However, at other times the flow would be disturbed, the action would not produce the results that were expected.

In response to this disturbance it would be tempting to come up with a clearly defined problem as quickly as possible to explain its existence. The knee jerk response previously mentioned and a personal trait with which I feel I have affinity. In so doing there would always exist the possibility of coming up with an erroneous theory, one that missed the mark but had still resulted in significant investment in both time and effort being utilised in an unfruitful search for the truth. This reflects the hazard of producing the ‘so what piece of research’, one produced purely for the sake of completing a prescribed course. I feel that this indicates the importance of how the research problem is framed and that this should be considered paramount as it is this framing of the question which will influence and shape the future development of each theoretical and practical step of the entire research journey.

In an attempt to avoid this error I initially tried to adopt a position that would enable me to be research minded. The aim was to allow my work place disturbance to lead me and
hopefully guide me to the heart of the problem. This problem would then become a question that could be examined through rigorous application of a sound methodological approach.

In addition the reflective process also made me realize the need for this research question to be precise in nature and clearly defined for purpose. The use of the ‘Russian Doll’ principle and the ‘Goldilocks’ test developed by Clough and Nutbrown (2006) and previously outlined (Chapter I, section 5, page 16) enabled me to construct what I hope was a focused research question. However, as data was collected it still proved tempting to stray from the original planned method. Similarly with the data set complete and analysis underway the temptation to go on a ‘fishing trip’ was difficult to avoid. A significant amount of data was produced and a number of comparative analyses examining different domains and factors would have been possible. In order to prevent this and stay focused I needed to continually remind myself of the original objectives of the study.

This frequent and recurrent return to my original research objectives had the consequence of making me reconsider the methodological choices which underpinned the study to provide justification of the particular and pragmatic approach that I had adopted in attempting a fusion of paradigms. This reflection caused me to speculate as to whether I had chosen the correct approach or whether a different approach would have better suited my objectives. In addition if this approach was the most appropriate to take was it successfully achieved in terms of the fusion of methods which were adopted. This is perhaps as important as the findings of the study itself for as a relatively inexperienced
researcher the very act of carrying out this study in an appropriate manner would indicate a successful apprenticeship.

Therefore was the approach adopted appropriate and was it accomplished in a successful manner? It would seem that many clinicians have been traditionally concerned with quantitative indicators of health pertaining to the effectiveness of their interventions, indicators which are rarely patient focused (Rosemann 2006). However, it is increasingly recognised that key outcome measures for any health-care intervention is change in health-related quality of life. As a condition that cannot be cured osteoarthritis is no exception and instead of cure the aim is often to provide symptomatic relief and to facilitate rehabilitation in order to optimise function and consequent well-being. This focus on management rather than cure requires that any indicator of change be patient centred and include elements of the patients perceptions of their health and health status. This seemed a key point to me and was an underpinning principle to the development of my research methodology in particular to the methods of data collection.

In evaluating whether the approach I adopted answered this point I found it useful to consider my choices in terms of the classification of methodological design described by Adams (1991). In this classification Adams places methodological design onto one of three levels, exploratory, descriptive, or explanatory. In the exploratory model are studies conducted in the natural setting with the purpose of discovery, whether of phenomena, variables or theory. Although variable with regard to their methodology exploratory studies can be characterized by the fact that there is no active manipulation or alteration of the context in which the research is set by the researcher. Exploratory studies may
include both inductive designs that are capable of discovery and theory generation and
deductive designs that examine the characteristics of specified variables. The purpose of
the research study is to reveal theory not necessarily to test and support existing theories.
In regard to my study this would seem an appropriate level of enquiry in regard to the
exploration of possible influencing factors related to outcome following injection given
that there was a lack of available research in this area.

Adams’ (1991) next level of design is the descriptive research study. The purpose of this
study is to yield knowledge regarding specific population parameters and relationships
among these parameters. Such studies are usually based on priori theory and have
preconceptualized areas of interest to which the study is limited. They tend to rely on
measurement and quantitative methods. In examining relationships or correlations the
researcher investigates the way in which different factors relate to each other but is
unlikely to be able to demonstrate causality. This level of study seemed to fit my question
regarding the ability to predict outcomes based on the correlations between these
outcomes and factors measured pre-intervention. However, a descriptive level of
questioning would only work if there was a priori theory which could be ‘tested’, and as
my literature review demonstrated little knowledge seemed to exist in regard to these
influencing factors and what they might be.

To look for a cause and effect and follow my positivist leanings would have required
taking Adams (1991) next level of design the explanatory research model. This form of
methodology is what is commonly termed the experimental design and sets out to reveal
causal relationships. In a positivist mind this represents the most desirable and powerful
form of research available. The essential characteristic of this type of design is that
research is founded on an accepted theoretical frame of reference and seeks to support
theory through a process of hypotheses testing and prediction. The positivist would view
the ‘true experiment’ as the ultimate standard by which the truth can be obtained
however, to be able to be counted as a ‘true experiment’ a number of criteria need to be
meet. These are random assignment, control, and manipulation. The aim is control over
the influences of the basic threats to internal validity and unwanted or extraneous
phenomena that could confound and invalidate any causal claims. If there were sufficient
time to justify an examination of causality with regard to the factors such as anxiety,
function, and pain on the outcome following injection the ability to use controls and
randomization in an area of an already recognised treatment technique would be
questionable from an ethical point of view and one that I would feel uncomfortable with
when having to justify. I addition given the lack of knowledge concerning possible
influencing factors the use of an explanatory model would also have limited the extent of
exploration possible given the degree of control required for this research model.

On reflection the exploratory design at its most naturalistic level would not alone focus
sufficiently on the specific area that I wanted to investigate. Additionally relinquishing
control of my study to the subjects in a purely naturalistic design may have uncovered
unknown avenues of interest but may have made the necessity of assessment of outcome
difficult within the context of my doctorate. Given the available literature it would seem
that there was enough evidence to start with a hypothesis based on existing theory with
regard to the assessment of outcome and therefore the need for exploration only through
qualitative study was not appropriate. At the other end of the spectrum the ‘true-
experiment’ of an explanatory research methodology although very focused required parameters such as randomisation and control that would prove difficult from an ethical viewpoint and therefore made this an unlikely approach to assess outcome. It would seem that my research study fell most comfortably into the methodological design of a descriptive research study in regard to outcome but exploratory in terms of the factors that affected this outcome.

The study design therefore needed to involve a degree of verification of existing theory which was best answered by a more positivist approach but also required an element of generation of new theory best answered with a more naturalistic approach. This duality of design necessitated the use of both elements from the naturalistic paradigm which focused on question refinement as it emerged from the action of conducting the research itself as well as elements from the positivist paradigm whose question was structured in such a way as to be definitive having been derived deductively before the research began.

With this in mind it would seem that the use of a pragmatic approach in designing my research and the incorporation of elements from both the quantitative and qualitative paradigms in a fusion of methodologies and methods was the most appropriate to enable the most comprehensive and inclusive description of the phenomena possible within the context of what was measurable.

Having at an early stage identified my background as being relatively positivist in nature this ‘mixing’ of approaches represented a real challenge as it required that I reached across my ‘comfort zone’ and thought outside my ontological and epistemological
perspective. The identification of my bias towards the positivist paradigm meant that my challenge was to fully explore and incorporate the qualitative approach and not include it in a tokenistic fashion only.

Notes in my research journal outline my aim to design a study which fused appropriate elements of both paradigms at it’s very core and did not result in what appeared to be two separate studies. Reflection on the ability of my study to appropriately incorporate these two paradigms may have been questioned by Morgan who described a strategy dependent upon the researcher asking themselves two questions (Morgan 1998). Firstly, what is the primary research method and what is the secondary method? Secondly, what method will come first and which second. The answer to these two questions then directs the researcher into one of four possible designs. This ordering of designs would have had its limitations with regard to time scales and in particular in my study the need for a longitudinal data set within the time parameters of a doctorate meant that this approach was unlikely to be ‘do-able’. In addition this approach would not have resulted in a true fusion of methodologies, a point that I had noted as being a concern. A more realistic approach and one that supported the one I took was offered by Creswell who suggested that a mixed methodology could run concurrently, making no distinction between primary or secondary method (Creswell 2004). This approach offered by Creswell seemed to be more appropriate to my study aims and allowed for a better fusion of approaches.

This pragmatic approach was also supported by Burgess who used the term ‘multiple research strategies’ to describe the use of diverse methods in tackling a research problem
Burgess’s argument centred round the ability of the researcher to be flexible in the selection of a range of methods appropriate to the research problem. I believe that the approach of the Professional Doctorate in terms of providing more general research training encouraged a wider world view and facilitated subsequent thinking outside my comfort zone. It facilitated a broader apprenticeship.

Was this mixed methodologies and methods approach, this ‘third way’ as described by Tashakkori (2003) the correct approach to choose for my study and if it were with hindsight did I achieve a true fusion of approaches? Although a fusion of methodologies and methods is supported by a number of authors (Tashakkori 2003, Greene 1997) it is not without its sceptics. The degree of flexibility required needs to be considered carefully and was a concern described by Baker (1992) who viewed such a level of flexibility as leading to inconsistency and lack of coherence. He termed the result ‘method slurring’ and raised the point that inter-changeability of method can dilute the value of consistently pursuing the integrity of a single approach from beginning to end, from its founding philosophical underpinnings to the specificity of the methods it adopts.

Reflecting on lectures and discussions within action learning sets during the course of my studies I had the impression that purity of methodology was often considered of first importance with pragmatism coming second to the need for purity. Within the context of the doctorate course this bias seemed to be towards a purity of qualitative methodology.

Of course purity of methodological approach need not be a problem but does become so when the methodology and its associated methods are privileged over all other
considerations through an overly ardent adherence to a perceived need for purity. This approach to research has been termed ‘methodolatry’ a term Janesick (1994) defined as,

‘.....a combination of method and idolatry, to describe a preoccupation with selecting and defending methods to the exclusion of the actual substance of the story being told. Methodolatry is the slavish attachment and devotion to method that so often overtakes the discourse in the education and human services fields.’

Methodolatry then assumes there is a ‘right way’ that must be adhered to if one is to conduct a meaningful research project. Any deviation or compromise of these methodological canons will lead to a lack of clarity, authenticity, and run the risk of an overly critical review and rejection from one’s peers. I think that this reliance on methodological approach risks diminished originality of thought, verging on a fundamentalism so often evidenced in our history when the dogmatic approach ascends to take primacy to the exclusion of all else.

I felt that this dogmatic approach needed to be avoided as at the heart of my study was a need to try and ‘get inside’ what was going on when subjects received an injection and how this impacted on outcome. However, it was still necessary to be mindful of the need to examine outcome itself and this was perhaps best done with a more quantitative approach. It was this need to address the two aspects of my research question that I felt required the use an integrated design. The quantitative element offered an examination of outcome while the use of semi-structured interviews allowed for the chance to move to a level of real interpretation. Potentially a much more useful and insightful outcome being
the result with the chance to connect themes and categories and account for interrelationships to provide interpretation of what was happening.

Was my study able to successfully fuse these elements to enhance knowledge as was the aim? From a practical view point the implementation of an effective integration occurred at two levels. The first was the quantitative assessment of outcome and remained within one methodological strategy rather than crossing boundaries. This level of investigation was carried out in such a way as to provide a multiple perspective of the phenomena in that it related to the use of more than one questionnaire exploring subject’s perceptions on various constructs as well as the use of x-ray evidence of degree of degenerative change. Indeed each questionnaire itself contained different domains which each sought to explore perception of the constructs under investigation. An example of this can be seen in the McGill Pain Questionnaire which uses a variety of written descriptors with which a subject is able to use to describe their pain as well as a scale to indicate their present pain level and a further visual analogue scale with which they can indicate their perceived pain level. The use of these different scaling tools to describe the same phenomena helped to provide confirmation of the authenticity of the information derived. This ‘triangulation’ within questionnaires, between questionnaires and with x-ray evidence helped to confirm the data collected and add the convergent validity of the study. That is each scale and each domain within a particular scale provided confirmation of the reliability of the information that was obtained (Depoy 1984).

At a second level, one which required the use of an integrated approach, my study design needed to stretch across methodological strategies, as I recognised that quantitative data in itself would not necessarily provide insight as to the various processes that underlie the
empirical data produced from the questionnaires and interpretation required a greater qualitative input.

To use a qualitative strategy in the form of the semi-structured interviews then became more than a mere triangulation and hopefully represented the true mixing of strategies or the ‘multimethod’ as Brewer (1989) described. I make no claims as to the value of either sets of data or assumptions regarding a linear relationship between the two but hope to perceive both as equal and complimentary in nature, a fact that is hopefully reflected in my findings.

The approach I adopted may be best described by Depoy and Gitlin (1984) who used the term ‘nested’ strategy. That is the researcher develops a research inquiry based on their own paradigmatic framework and then borrows specific methodological techniques from another paradigm in an effort to strengthen the study. In my study the semi-structured interviews became ‘nested’ within the quantitative aspect of the study and provided additional data of a more qualitative nature helping to explain, elaborate, and interpret. Providing the researcher remains reflexive and open with regard their own methodological stance and rigorous in their pursuit of a clear appropriate approach to their question then this integrated approach would seem to be an acceptable stance to take and as the ‘third methodological approach’ was an appropriate method to use for this study.

Could any alternative approaches have been taken when designing this study? In considering this question I found it a useful reflection to take into account the level of theory which already existed in regard to the subject under investigation. If this level of
prior knowledge is made an important consideration then the identification of a lack of theory becomes sufficient to justify a ‘theory generating’ approach while a sufficient level of existing knowledge requires a ‘theory verification’ approach.

Considering theory as a set of related ideas that have the potential to explain or predict human experience in a logical fashion. Then in the experimental design an existing theory becomes essential to begin with as this approach uses a deductive process that seeks to simplify and reduce the theory, operationalising constructs such that they become observable and measurable. A hypothesis is then presented in an attempt to articulate the expected relationship between the variables under investigation. This hypothesis may be non-directional or directional dependent upon the strength of the data that generated the initial theory. With regard to this study lack of previous evidence concerning the ability to predict outcome following injection for osteoarthritis of the knee did not allow for verification of existing theory but suggested that a ‘theory generating’ approach would be most appropriate.

Theory generating demands a more naturalistic design in so much as the researcher is concerned with the development and generation of theory using an inductive approach rather than primarily being concerned with testing. Themes, patterns and constructs emerge from the observation of phenomena in a natural setting. Based on these emergent patterns within observed phenomena and the relationships that they share the researcher is able to develop a theory to explain and understand through an inductive process of reasoning. In this way as opposed to the experimental approach theory does not direct data collection, rather the data itself suggests which theory may be most appropriate and
relevant to the phenomena under investigation. The naturalistic approach offers the researcher a number of practical research methodologies by which they are able to achieve their goal however they all share the common underlying principle that phenomena are embedded within their own unique context, their ‘natural setting’.

The most non-structured methodology that I could have used would have been an endogenous design. The most unique feature of this type of design is that it would have required me to hand over control of the research plan to those who were the subjects in my study. Knowledge would have been seen as emerging from individuals who know the best way of obtaining that information. The research is essentially conducted by insiders and there are no external principles to guide the selection of thought and action processes within the study itself. The degree to which I would have needed to relinquish control of the study would only have worked with difficulty within the context of a study administering a therapeutic intervention, although would certainly have had the potential for a richness of data if only a few subjects were included. However, it is unlikely that a small number of subjects would have been sufficient to have allowed for a true assessment of outcome. The assessment of outcome was an important facet of the study both in terms of my own needs and in terms of the service for which I worked and was of particular importance given the recently published NICE guidelines on the use of hyaluronan (NICE www.nice.org.uk/CG59 (2009)).

Other naturalistic designs include Heuristic research which would require the complete emersion of self into the phenomena of interest and subsequent self reflection of the experiences resulting from that emersion. Here there is a subtle shift from endogenous
and phenomenological design in that not only are the experiences of the subject population important but there is also concern in the experiences of self.

A further approach which seeks to integrate quantitative and qualitative thinking and action processes is grounded theory. Developed by Glaser and Strauss (1967) it attempts to locate or ‘ground’ theory into the context in which the phenomenon that is being investigated occurs. A more structured gathering of data takes place and a process that is termed ‘constant comparative method’ used to enable each data item to be compared with others to look for similarities. In this way theory is still generated but can also be verified using an inductive process. This comparative method would enable a thorough exploration of subject’s experiences and could be used to look for links among these experiences with regard to pain and function. However, this approach may not have focused in with enough direction and allow correlation to be sort between outcomes and potential underlying factors such as anxiety that would affect that outcome. Additionally given the financial pressures in the NHS I felt that a pragmatic approach which included ‘numbers’ and an element of quantitative statistical analysis was required if any future recommendations with regard to outcome could be made.

Additional methodological approaches such as life history and ethnography were considered, however these approaches focus very much on the individual in their own social setting. With life history relying on the subject not only producing data but also providing analysis of the meaning of that data and ethnography imposing more researcher control with regard to the way in which data is collected and analysed. The common theme with these designs is the lack of researcher imposed control and the reliance on the
subject to ‘tell their own story’ in their ‘own unique setting’. In this way analysis of data is ongoing and moves from description to explanation, to revealing meaning to theory generation (Depoy 1994).

Ultimately I believe that the qualitative aspect of my study was influenced by the phenomenological approach. This approach is one in which the investigator is interested in a subjects everyday experiences and the interpretation of the meaning of these experiences. The phenomenologist believes that meaning can be understood only by those who experience it and is anchored on the notion of the limits of methods to share and communicate that experience (Darroch 1982). The first step from this perspective for my study was to identify the phenomena of investigation and would seem to include perceived pain and function and the factors that influence the changes in these two constructs following a therapeutic intervention. The phenomenological approach required the focus on the experience of these constructs from the perspective of the individual rather than seeking to broaden that experience to understanding a group or cultural context and seemed an appropriate approach to adopt.

This method enabled me to focus on describing subject’s experiences as they interacted with the whole experience of attending an outpatient department for a therapeutic injection the data being collected through observation and interviews. Data collected then being subject to a thematic analysis in an attempt to identify important issues raised by the subjects and with subsequent description and validation being centred on grounding in the subject’s own words. It was hoped that this would enable the collection of rich, in-depth, and detailed descriptions of the subject’s experiences together with some meaning
of these experiences as relate to the subject (Beyea 1997). Typically in phenomenology a small sample size is chosen but the information collected is detailed and in depth. This was reflected in the smaller group of subjects who were interviewed in comparison to the larger group whose outcome was assessed.

Ultimately I feel that my design was both descriptive and exploratory in nature seeking to yield knowledge regarding specific population parameters and relationships in addition to exploring new avenues of inquiry in terms of factors which may have influence over outcome following injection. I attempted to achieve this with a fusion of methodologies based in both the quantitative and qualitative paradigms but recognized that I would be unable to infer any direct causation and would have to be content with a description of possible relationships uncovered.

The benefit of hindsight raises whether this was the most appropriate approach to take, I think that for the reasons outlined, consideration of my own research abilities, the constraints upon my time in terms of work and the needs of the various stake holders involved including my NHS Trust, patients and my profession that I chose the correct approach. Was this approach implemented as well as it could have been, was it a true fusion of methodologies? If I have been reflexive in terms of openness in the description of my own ontology and epistemology and have also been able to provide clarity in regards to both my chosen methods and in the reporting of my findings then this question needs to be answered by the reader.
7 Conclusion

In conclusion the findings of this study demonstrated that the use of injection therapy in the management of osteoarthritis of the knee has a role to play in the symptomatic relief of perceived levels of pain and increase in reported levels of function. In addition a correlation was demonstrated between the pre-injection levels of perceived anxiety and level of reported social interaction and outcome such that high levels of reported anxiety and low levels of social interaction correlated with poor outcome. Other factors such as degenerative change as identified by x-ray and age also correlated with poor outcome but only on limited constructs. Qualitative data obtained through the use of face to face interviews and thematic analysis identified 4 key themes which potentially impacted on outcome following injection. Although no direct cause and effect relationship can be established and no absolute significance attached to any individual theme it was postulated that subject experience and knowledge appeared to be at the heart of many of the subject’s dialogues. It was suggested that an appropriate knowledge of condition allowed for a greater subject autonomy leading to enhanced outcome.

The findings of this study are important in so much as an understanding of the ‘non-physical’ factors which may influence outcome has the potential to inform strategies which could increase patients’ and practitioners’ satisfaction with the care they give and receive. An appropriate knowledge of condition has the capacity to correct erroneous beliefs and inform choice in terms of treatment. Knowledge of a condition encourages empowerment with subsequent autonomy. This study would support the view that provision of patients with an appropriate level of information regarding their condition and possible treatment options is important if we are to secure the best possible outcome.
Information of this kind could be provided in a group setting prior to any formal intervention such as injection providing patients with suitable facts on which they could make more informed choices. It seems likely that the addition of such group work would offer a relatively low cost adjunct to the overall treatment package offered. This approach should perhaps also be extended to our professional training programmes both at the under and post graduate level ensuring physiotherapists are able to and willing to deliver appropriate education. Certainly clinicians should consider how they empower their patients in terms of knowledge given and the meaningfulness of the clinician / patient interaction in such a way so that patient are as fully engaged in the whole process as possible.
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## AIMS-2 SF
### ARTHRITIS IMPACT MEASUREMENT SCALES 2 Short Form

**INSTRUCTIONS:** Please answer the following questions about your health. Most questions ask about your health during the past 4 weeks. There are no right or wrong answers to the questions and most can be answered with a simple check (✓). Please answer every question.

<table>
<thead>
<tr>
<th>DURING THE PAST 4 WEEKS ...</th>
<th>All days</th>
<th>Most days</th>
<th>Some days</th>
<th>Few days</th>
<th>No days</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often were you physically able to drive a car or use public transportation?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>2. How often were you in a bed or chair for most or all of the days?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>3. Did you have trouble doing vigorous activities such as running, lifting heavy objects, or participating in strenuous sports?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>4. Did you have trouble either walking several blocks or climbing a few flights of stairs?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>5. Were you unable to walk unless assisted by another person or by a cane, crutches, or walker?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>6. Could you easily write with a pen or pencil?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>7. Could you easily button a shirt or blouse?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>8. Could you easily turn a key in a lock?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>9. Could you easily comb or brush your hair?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>10. Could you easily reach shelves that were above your head?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>11. Did you need help to get dressed?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>12. Did you need help to get in or out of bed?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☑</td>
</tr>
</tbody>
</table>

*Adapted from AIMS-2 - R. Meenan - Boston, Ma*
### During the Past 4 Weeks

<table>
<thead>
<tr>
<th>Question</th>
<th>All Days</th>
<th>Most Days</th>
<th>Some Days</th>
<th>Few Days</th>
<th>No Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. How often did you have severe pain from your arthritis?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. How often did your morning stiffness last more than one hour from the time you woke up?</td>
<td></td>
<td></td>
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<tr>
<td>15. How often did your pain make it difficult for you to sleep?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16. How often have you felt tense or high strung?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. How often have you been bothered by nervousness or your nerves?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. How often have you been in low or very low spirits?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>19. How often have you enjoyed the things you do?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>20. How often did you feel a burden to others?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>All Days</th>
<th>Most Days</th>
<th>Some Days</th>
<th>Almost Never</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>21. How often did you get together with friends or relatives?</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>22. How often were you on the telephone with close friends or relatives?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>23. How often did you go to a meeting of a church, club, team or other group?</td>
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</tr>
<tr>
<td>24. Did you feel that your family or friends were sensitive to your personal needs?</td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

**If you are unemployed, disabled or retired, END of questionnaire.**

<table>
<thead>
<tr>
<th>Question</th>
<th>All Days</th>
<th>Most Days</th>
<th>Some Days</th>
<th>Few Days</th>
<th>No Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. How often were you unable to do any paid work, house work or school work?</td>
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</tr>
<tr>
<td>26. On the days that you did work, how often did you have to work a shorter day?</td>
<td></td>
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</tr>
</tbody>
</table>
Appendix 2  McGill Pain Questionnaire

Please ✓ those words that describe your pain as mild, moderate or severe

<table>
<thead>
<tr>
<th>Throbbing</th>
<th>None</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shooting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stabbing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sharp</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cramping</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gnawing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hot - burning</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aching</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Tender</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Splitting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tiring - exhausting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sickening</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fearful</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Punishing - cruel</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Visual analogue scale

No --|------------------|---|---|---|---|
     | Pain | Pain | Pain | Pain | Pain |

Present Pain Intensity

0 - No pain
1 - Mild
2 - Discomforting
3 - Distressing
4 - Horrible
5 - Excruciating
Appendix. 3  Local Research and Ethics Committee Approval Letter

National Research Ethics Service

Camden & Islington Community Local Research Ethics Committee
Room 3/14
Third Floor, West Wing
St Pancras Hospital
4 St Pancras Way
London
NW1 0PE
Telephone: 020 7530 3799
Facsimile: 020 7530 3931

29 November 2007

Mr Peter Resteghini
Clinical Specialist Physiotherapy
Physiotherapy Department
Homerton University Hospital
Homerton Row
London
E9 6SR

Dear Mr Resteghini

Full title of study:  A prospective study examining the use of Injection Therapy in the management of osteoarthritis in a musculoskeletal outpatient clinic: can we predict outcomes?

REC reference number:  07/H0722/82

Thank you for your letter of 25 November 2007, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA) There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

This Research Ethics Committee is an advisory committee to London Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England
Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>Application</td>
<td></td>
<td>26 September 2007</td>
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<td>Investigator CV</td>
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<td>Protocol</td>
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<tr>
<td>Covering Letter</td>
<td></td>
<td>01 October 2007</td>
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<tr>
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<td></td>
<td>26 September 2007</td>
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<tr>
<td>Interview Schedules/Topic Guides</td>
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<td>Questionnaire: McGill Pain</td>
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<td>Participant Consent Form</td>
<td>Version 2</td>
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<tr>
<td>Response to Request for Further Information</td>
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<td>CV: Dr Mandy</td>
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R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.


Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

- Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk.

With the Committee’s best wishes for the success of this project.

Yours sincerely,

Ms Stephanie Ellis
Chair

Email: katherine.ouseley@camdenpct.nhs.uk

Enclosures:

Standard approval conditions

Copy to:

Sponsor and Research Governance contact:

Professor K L Costeloe
Clinical Governance Department
Homerton University Hospital
Homerton Row
London
E9 6SR
Appendix. 4  Letter to Referring Clinician

Dear Dr.

Re: Proposed Research Study

As part of the continued development of the Locomotor Service a planned research study is due to start which may involve patients that you have referred to the service. This study has been granted ethics clearance from the local ethics committee and has also been agreed by the Homerton University Hospital Clinical Governance Group.

Study Title

A prospective study examining the use of Injection Therapy in the management of osteoarthritis in a musculoskeletal outpatient clinic: can we predict outcomes?

Study Summary

Osteoarthritis affects more patients than any other musculoskeletal disorder and the number of patients suffering joint pain and stiffness as a result of this disease is set to increase in the next few decades. In addition only a small fraction of these patients require surgery.

One of the main treatment modalities used in the management of osteoarthritis is the injection of corticosteroid and hyaluronan. The aim of this study is to assess outcome following injection in the management of osteoarthritis within the Locomotor Service and to investigate possible factors that may influence this outcome with regard to reported levels of anxiety, social function and degree of degenerative change as reported on x-ray.

Study Plan

Subjects will be invited to take part in the study that from clinical assessment have a diagnosis of peripheral osteoarthritis and are deemed to have the potential to benefit from injection therapy.

Subjects giving their consent would at their initial appointment be asked to complete the two questionnaires.

After completion of the questionnaires subjects will be offered an appropriate injection. This would be carried out as standard clinic practice. Subjects will then be reviewed at 1-month and 3-month post injection and the two questionnaires again completed. In addition at the initial assessment and at 1-month follow up a 10% subset of subjects will be invited to interview to fully explore their perceptions of the treatment received.

The questionnaires that are completed will be anonymous and answers will not affect the treatment that is given. Subjects choosing not to complete the questionnaires will be offered treatment as normal clinic practice.
It should be clear that no ‘new’ treatment is being tested and that the purpose of this study is to assess how useful injections are in treating patients with osteoarthritis and whether outcomes can be predicted.

The results from the study will be sent to you. These results will be in such a way that they can be displayed within your practice to enable subjects to see the outcome of the study.

If for any reason you would not want your patients being included in this study please let me know and they will then be excluded. This would not affect your patient’s further treatment within the service.

If you require further details do not hesitate to contact me.

Yours Sincerely,

Peter Resteghini
Appendix 5 Participant Information Sheet

Participant Information Sheet for:

A prospective study examining the use of Injection Therapy in the management of peripheral osteoarthritis in a musculoskeletal clinic: can outcomes be predicted?

I would like to invite you to take part in the above research study which we think may be important. The information which follows tells you about this study. It is important that you understand this information. It says what will happen if you take part and what the risks might be.

Whether or not you do take part is entirely your choice.

Please ask any questions you want to about the research and we will try our best to answer them. Below are some answers to some of the questions you may have.

Study Summary

Osteoarthritis is when your joints wear down. Commonly it increases as you grow older. It affects more people than any other joint problem and the number of people suffering joint pain and stiffness as a result of this condition is set to increase in the next few decades. In addition only a small number of these patients require surgery.

Injections are one of the main treatments used to help osteoarthritis.

The aim of the study is to see if there are any factors which may affect the usefulness of an injection for osteoarthritis. The factors we will look at are anxiety, pain, social function and the amount of wearing on x-ray.

Study Plan

You are invited to take part in the study because from your first appointment you were given a diagnosis of osteoarthritis and it is thought that you may benefit from an injection.

If you give your consent you will at your initial appointment be asked to complete two questionnaires.

After completion of the questionnaires you will be offered an appropriate injection. This would be carried out as standard clinic practice. You will then be given another appointment at 1-month and 3-month after the injection and asked to complete the two questionnaires again. In addition at the pre-injection and 3-month follow up you may be selected to take part in a short interview. This interview will be taped.

It should be clear that no ‘new’ treatment is being tested and that the purpose of this study is to assess how useful injections are in treating patients with osteoarthritis at the Homerton University Hospital.
The questionnaires you will be asked to fill in are anonymous and your answers will not affect the treatment you receive. If you choose not to complete the questionnaire this will not affect the treatment you will then receive.

There are no more dangers to taking part in this research than having the standard clinic treatment for osteoarthritis. The treatment you will receive during the research is the same as you might receive if you were not involved in the research and will be explained before any procedure is started.

Your confidentiality will at all times be protected. The questionnaires you will be asked to fill in are anonymous and any notes taken during consultation will be treated in the same way that all other clinic notes are treated.

Your GP will be informed that you are taking part in the study and be kept informed of the outcome.

You are free to decide not to be in this study or to drop out at any time. If you decide not to be in the study, or drop out, this will not put at risk your ordinary medical care.

You will always be able to contact an investigator to discuss your concerns and/or to get help:

Mr. Peter Resteghini  
The Physiotherapy Dept. Homerton University Hospital, Homerton Row, E9 6SR  
020 8510 5751  
peter.resteghini@homerton.nhs.uk

Or

Ms. Carol Alexander  
The Physiotherapy Dept. Homerton University Hospital, Homerton Row, E9 6SR  
020 8510 7835  
carol.alexander@homerton.nhs.uk

What happens if something goes wrong?

We will take every care in the course of this trial. If through our negligence any harm to you results, you will be compensated. However, a claim may have to be pursued through legal action. Even if the harm is not our fault the Trust will consider any claim sympathetically. If you are not happy with any proposed compensation you may have to pursue your claim through legal action.
Appendix 6. Participants Consent Form

A prospective study examining the use of Injection Therapy in the management of osteoarthritis in a musculoskeletal outpatient clinic: can we predict outcomes?

- I agree to take part in this research which is to examine the use of Injection Therapy in the management of osteoarthritis in a musculoskeletal outpatient clinic to see if outcome can be predicted. □

- The researcher has explained to my satisfaction the purpose of the study and the possible risks involved. □

- I have had the principles and the procedure explained to me and I have also read the information sheet. I understand the principles and procedures fully. □

- I am aware that I will be required to answer questions in the form of a questionnaire and may receive an x-ray. □

- I understand that any confidential information will be seen only by the researchers and will not be revealed to anyone else. □

- I understand that I am free to withdraw from the study at any time, without giving a reason, and that this will not affect the treatment I receive. □

Name (please print)……………………………………………………………………………………………………………………………

Signed………………………………………………………………………………………………………………………………………….

Date………………………………………………………………………………………………………………………………………….
Appendix. 7  Assessment Form

A prospective study examining the use of Injection Therapy in the management of peripheral osteoarthritis in a musculoskeletal clinic: can outcomes be predicted?

Study Assessment Form

<table>
<thead>
<tr>
<th>Patient:</th>
<th>D.O.B:</th>
<th>TSS:</th>
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Clinician: Peter Resteghini

Date:

Consent Signed:

1. What is your problem today? Can you tell me how it started and how it affects you?

2. What are your expectations of your appointment today? What do you expect to happen?
Agg
Ease
24 Hour Pattern
Locking
Clicking/clunking
Giving way
Swelling

HPC:

Previous investigations/treatment

PMH:

Allergies:

DH:

Family Medical History:

Analgesia: None 1/week 1/day 2/day x/day

F/SH: Work

Sport

O/E: Muscle wasting: None mild moderate severe

Effusion: None mild moderate severe

Fixed Flexion Deformity: Quads lag:

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<td></td>
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<tr>
<td>Extension</td>
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</table>

Ligament/Meniscal Tests:

Palpation: X-ray grade:

Diagnosis: Plan:

Signature:
Appendix 8  Kellgren-Lawrence Grading System for OA

Grade 0: No features
Grade 1: Doubtful: minute osteophyte, doubtful significance
Grade 2: Minimal: definite osteophyte, unimpaired joint space
Grade 3: Moderate: moderate diminution of joint space
Grade 4: Severe: joint space greatly impaired, with sclerosis of subchondral bone

Grade 2 & 3

Left Image: Grade 2 with narrowing of the joint space (black arrowhead)

Right Image: Grade 3 with narrowing of the joint space and osteophytes (white arrowheads)

Grade 4
Appendix. 9  Interview Record

A prospective study examining the use of Injection Therapy in the management of osteoarthritis of the knee: can outcomes be predicted?

Interview Record

Patient No:  Date:

Pre-injection interview

1. What are your expectations with regard to today’s appointment? How do you think this injection will affect your knee?

2. What is your understanding of your arthritis?

3. What was the major reason for you seeking referral to Hospital?

4. Do you think exercise will help with your arthritis?

Post injection interview (3-month follow up)

From pre –injection interview: ownership/expectations/helplessness/interaction

1. How did your knee feel following the injection?

2. Do you still have to alleviate your symptoms? If yes how?

3. Does your knee feel the way you expected it to feel following the injection? (If yes probe and ask for a description. If no probe and find out why).

4. What are your experiences of previous treatments aimed at your osteoarthritis?

5. How satisfied are you with your treatment to date?

6. How would you describe yourself? As an active person? Do you regularly meet with other people and socialise?

7. Would like to say anything else with regard to your treatment? Are there any other types of service that you think would be appropriate to meet your needs?
### Appendix. 10 Triamcinolone PGD

Patient Group Direction for the Administration / Supply of Triamcinolone Acetonide in the Treatment of Peripheral Musculoskeletal Disorders.

This patient group direction (PGD) is for use within the Homerton University Hospital NHS Trust by those named in the document. The original signed copy should be held by the manager of the service the PGD is designed to support.

<table>
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<tr>
<th>Name of medicine to be supplied or administered</th>
<th>1. Triamcinolone Acetonide – Kenalog 40mg/ml.</th>
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<td>Legal classification</td>
<td>POM</td>
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<td>To be used outside terms of Summary of Product Characteristics (SPC)</td>
<td>Yes – Mixed with 0.5, 1, &amp; 2% Lidocaine for pain relief Injection for soft tissue conditions such as neuroma, plantar fasciitis, digital periostitis are not included in the SPC but are commonly treated with this therapy.</td>
</tr>
<tr>
<td>Clinical situations for which medicine is to be used</td>
<td>For the treatment of peripheral musculoskeletal disorders</td>
</tr>
<tr>
<td>Criteria for inclusion</td>
<td>Patients under the care of the Physiotherapy Department or Locomotor Service with peripheral soft tissue or joint pain</td>
</tr>
</tbody>
</table>
| Criteria for exclusion                         | • Known hypersensitivity to local anaesthetic or corticosteroid  
• Local infection at site of injection  
• Unstable joints  
• Children under 16  
• Peripheral vascular disease  
• Prosthetic joint  
• Psychogenic disorders |
| Reasons for seeking further advice from a doctor | 1. Where a systemic inflammatory disease process may be contributing to local symptoms and treatment of this disease process may be more appropriate.  
2. Unstable co-existing disease (e.g. Diabetes)  
3. Post injection infection  
4. Pregnancy and lactation if patient does not wish to delay injection |
| Dosage                                         | Range: 5-40mg  
• smaller joints 5-10mg  
• larger joints 10-40mg  
• soft tissue 10-20mg |
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<thead>
<tr>
<th><strong>Route of administration</strong></th>
<th>Intra-articular or periarticular</th>
</tr>
</thead>
</table>
| **Frequency of administration** | 1. Minimum of 4 weeks between injections, maximum of three injections at any one site  
2. Single injections into several sites for multiple joint involvement, up to a total of 80mg, have been given without undue reactions |
| **Period of administration** | Stat |
| **Warnings** | 1. Steroid flare  
2. Infection  
3. Tissue atrophy / discolouration  
4. Dizziness / flushing  
5. Arthropathy |
| **Follow up** | 1 month post injection |
| **Arrangements for referral** | Patients may be referred to a consultant for review if appropriate with regard to adverse reactions or ineffective treatment |
| **Details of records to be kept** | Details of necessary record keeping including any follow-up action and arrangements for medical referral, providing a full audit trail of medication administered using a PGD, to be kept with patient notes:  
- Patient documentation completed within CSP guidelines  
- Patient consent, warnings and advice  
- Drug name/s, dose/s, volume/s and batch number/s  
- Patient satisfaction survey and analysis of outcome measurements  
- All patients reviewed after four weeks post injection as a minimum  
- Randomised audit of notes, subject to peer review, undertaken after a three-month period  
- A written report of the procedure will be sent to the referring Clinician |
| **Staff permitted to supply/administer under this PGD** | State Registered Physiotherapists with ACPOM / SOM Diploma in Injection Therapy |
| **PGD comes into effect** |  |
| **PGD to be reviewed** |  |
### 11.1 Demographic Data

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Appendix. 12 Statistical Analysis Descriptive Data

12.1 Pre and 1 month post Analysis – All Data

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### Appendix 13 Initial and Reduced Themes from pre and post-interview.

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**Themes in bold italics are those identified by the second reader**
Appendix. 14 Example of pre and post-injection interview script: subject HA8

Interview Record

Patient No: HA8

Pre-injection interview

5. You have mentioned that your expectations with regard to today’s appointment are.........How do you think this injection will affect your knee?

Well well I’m not sure really I suppose I expect it to be a bit more easier like less pain when I’m walking and less pain easier like when I’m sleeping. The pain is the big problem you see it’s worse than ever now yes and feels like it is just getting more and more nothing seems to get rid of it sometimes.

If the injection helps and can take away the aching you know I think that’s it I hope it helps do you think it might help?

I think it would be great if the injection could help with the pain I have I really want the injection to help and take the pain away

It’s depressing isn’t it the pain all the time and you try and do stuff but can’t not like you used to do anyway.

6. What is your understanding of your arthritis?

Arthritis well the kind I have is the type that the joint wears away isn’t it the joint wears away and is worn down.

I did read a bit about it and the GP told me some things I think its where the bones the bones and joints wear they are worn down and jelly in the knee dries out so that the bones well the bones they rub together they rub on each other and that causes the pain. That’s what I think anyway.

7. What was the major reason for you seeking referral to Hospital?

Well like I said pain is the thing the pain is the reason I need help and something to take this away if you can the pain and tight feeling in the knee it felt like it was too tight too stiff and that meant I couldn’t bend the knee.
The worse thing though was sleep I couldn’t sleep at all with the pain that is new and that was what really made me think well I need something done if I can’t sleep that’s it.

Not sleeping made me feel sick and that made my mind up about trying to get some help.

The pain has made me feel very down really like it’s depressing me if I could sleep I think that would help and if I could do more exercise.

8. Do you think exercise will help with your arthritis?

Well I used to do alot walking the dog and even some swimming you know but I had to stop a while ago because the pain had increased and it just felt too much. After doing it the walking or swim the knee felt very stiff for a day or more. I’ve tried some exercise since but it’s really difficult.

I told the GP and she said I should try and continue but I was worried I might make it worse you know in the future and I wanted to see if you could help.

If the injection could help me with pain and that stiff feeling then I would be able to do more exercise and may be get back to swimming like I used to do before.

**Post Interview Record (3-month follow up)**

*From pre–injection interview: ownership/expectations/helplessness/interaction*

8. How did your knee feel following the injection?

9. Do you still have to alleviate your symptoms? If yes how?

10. Does your knee feel the way you expected it to feel following the injection? *(If yes probe and ask for a description. If no probe and find out why).*

11. What are your experiences of previous treatments aimed at your osteoarthritis?

12. How satisfied are you with your treatment to date?

13. How would you describe yourself? As an active person? Do you regularly meet with other people and socialise?

14. Would like to say anything else with regard to your treatment? Are there any other types of service that you think would be appropriate to meet your needs?
I was very happy with it you know the injection very happy I thought it might hurt more after the injection like you said it might do but no bit of an ache that’s all nothing too much really.

I did put some ice on like a pack a frozen pack for a few times that and then nothing no problem and I’m pleased to say it’s felt much better since I mean not completely gone but much better than it was that a lot easier in the morning it doesn’t feel so tight and stiff like it did well during the day I still get some pain but not as much really not like it used to be so yes I’m quite happy about that really I know it won’t last forever well I know that but well if it just helps with the pain a bit that would be good so yes good.

I did take painkillers a lot paracetamol mostly and some brufen ones the Dr gave me well I can’t say I don’t take any now but I definitely take less now than I did before you know less than I did I take a few now and then when I need to like at night before bed it can sometimes still be a bit achy but really not as often as I did which I’m pleased about really you know I don’t like to take too many tablets because well I worry about the side effects.

Well I have had exercise before when I went to the physiotherapist before I came to you I got given the exercise to do I know they should help but the pain well it kind of stopped me from doing any or I couldn’t do them very often yes I know they should help that’s why I tried to do them I really did but when the knee was too painful it was very difficult to do that and well to be honest that’s when I gave up a little I couldn’t be bothered too much well the GP the Dr he gave me the brufen tablets to take and I took the other tablets the paracetamol but that is all no I haven’t had any other tablets or treatments no no injection before this one I got here.

Yes yes of course I’m very happy with the treatment so far like I said it helped it’s not gone completely but it’s gone a lot from what it was before the injection and that’s something just to have that relief of things so it doesn’t hurt as much is great it’s a help.

Well like I said I know it won’t go for ever if the joint I worn then that’s against me isn’t it I’m not going to get younger am I? the pain won’t go completely even if it did a expect the knee would still be worn away you can’t turn back time if it’s worn it’s worn and that’s that I think the important thing well that is to keep going I don’t mean just the arthritis but well as you get older you can’t stop if you do that’s it isn’t it you would just fall apart.

Well no one is going to help are they at the end of the day it’s you it’s your body you know it’s my knee not yours so it’s me that has to do something about it I mean you’re the expert the injection helps that’s great but you can’t keep doing that so people should help themselves a bit.

I would say the main thing is the pain it really gets to you I don’t mind if it comes and goes but if it is there all the time well it just wears you down grinds away at you there’s no break from it I know the injection is not a permanent cure well you said that but well just to get even a couple of weeks rest from the pain would be good you
know stop you going mad yes I think that is important even if the pain only goes for a while it helps and that break well it really can make a difference kind of like a holiday yes like a holiday well I mean you would like to be on holiday all the time but even a week away is good for you it recharges things doesn’t it you feel better when you get back and can get on with work and things well if the treatment can help with that like a holiday then it’s worth it.

I would be happy if it were only a couple of weeks just for that break I would I think that’s important anything yes you said if the pain went that I should then get back to the exercise well I have and I can walk further and the pain doesn’t stop me quite so much that’s got to help you feel better and well may be I will get fitter I think I had started to put on a bit of weight really you know with not exercising I had put some pounds on and I think that’s difficult to lose when you are older although I want to you know I want to get fitter no reason why not?

I think another problem is that well people don’t always listen may be if you were younger and had knee pain or something people would take more notice and help or do something I think though if you are older and have wearing joints like my knee well I think people can just say what do you expect you wear down at your age take it easy well I don’t want to take it easy do I? I want to keep going if I stop I may as well give up and they can put me in a box now! No I think people should try and help well if your older and want to keep going they should not look at age I mean there are some people much younger aren’t there younger than me and they don’t seem to do anything do they they don’t do anything and that’s why there is so many problems like you hear about all the problems you know with people being too fat and obese well that can’t help can it? No I want to keep going for as long as I can just keep going.

Yes very active well the knee did slow me and still does a bit but no I try and do lots of things I’m always busy you know I still work and then the family and the dog well the dog keeps me busy I need to walk him over the marshes 2 times every day of the week it doesn’t matter on the weather I still take him out I have too so that’s good exercise I remember that you said walking was a good exercise for the knee sometimes I meet with a friend and we walk the dogs together she has a mongrel but that’s alright you know they are sometimes the best to have.

I still work although part time you know about 3 days per week that suites me really because I can look after the dog and do my shopping and things when I’m not working no I wouldn’t like to work full time to busy I’m pretty happy with the job as it is.

That’s why I needed to get this better I didn’t have time for the pain it slows you down and makes you feel your age too much it becomes your main thing does that make sense? Well like I am me and I am busy with things but if you have pain it becomes your main thing doesn’t it it becomes the centre like the rest of your life has to work around it yes you can only think of the pain that’s right I would wake up with it and then go to bed again with it like I said about the break to get some rest even only a bit is good so that the pain doesn’t become the biggest thing there is I suppose I was worried it had started to take over a bit I didn’t like that well you feel kind of out of control I suppose yes I suppose I’m someone who likes to be in control not the other way around
well no one likes to be pushed about do they not really I mean so well yes the pain had started to push me around it’s still there but I feel like well I feel like I am in a bit more control now it’s not pushing me around like it did.
Appendix 15  Details of Sponsorship

Given the financial constraints in the NHS during the duration of my doctorate little funding was available from my employer and a number of agencies were approached for funding in regard to this study. One such application was directed to the Arthritis Research Campaign (ARC).

Arthritis Research Campaign,

Copeman House,

St. Mary’s Gate,

Chesterfield,

Derbyshire, S4 7TD

During the course of the first year of my Doctorate a successful application to ARC was shortlisted. Following an interview at ARC’s offices this study was granted support in the form of full funding of all course fees due to the University of Brighton.

I do not believe that this represents any conflict of interest. The only stipulation put in place by ARC being a full update of work once completed. No other support or competing interests were involved.

Reflecting on my doctorate journey and considering this journey as an apprenticeship in research I think this successful application represented more than just financial support. The whole grant application process from the initial search for a possible sponsor to final interview has, I believe, been an essential part of this overall journey. My current role within the NHS needs to include an element of research to it and certainly my doctorate
has provided me with an excellent grounding in research methodologies. The process of grant application has also given me some understanding of what is required to gain support from appropriate external agencies to ensure that future research carried out in my department has a better chance of being successful. In addition the process of being interviewed relatively early in my research by a peer group who had experience within the area of my study but who were unconnected with either the University of Brighton or the Homerton University Hospital was invaluable in terms of helping to refine some of my thoughts and plans, and as it happened in offering some very positive feedback and encouragement.
Chapter VII Acknowledgements

1. Course Fee Sponsorship  Arthritis Research Campaign

2. Statistical Advice  Ms. Viv Bewick, Senior Lecturer Computing
Mathematical and Information Services, University of Brighton

3. Supervisors  Dr. A Mandy, Dr. P Mandy University of Brighton

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